

33,500,000 Shares

Common Stock

This is an initial public offering of shares of common stock of Parabilis Medicines, Inc. We are offering 33,500,000 shares of our common stock.

Following this offering, we will have two classes of common stock: the voting common stock offered hereby and non-voting common stock. For a description of the rights of the voting common stock and non-voting common stock, see the section titled “[Description of Capital Stock](#)” beginning on page 202 of this prospectus. We are offering voting common stock in this offering, and unless otherwise noted, all references in this prospectus to our “common stock,” “common shares” or “shares” refer to our voting common stock.

Prior to this offering, there has been no public market for our common stock. The initial public offering price per share is \$20.00. Our common stock has been approved for listing on The Nasdaq Global Select Market under the symbol “PBL5”.

We are an “emerging growth company” and “smaller reporting company” as defined under the U.S. federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements in this prospectus and future filings.

Investing in our common stock involves a high degree of risk. See the section titled “[Risk Factors](#)” beginning on page 15 to read about factors you should carefully consider before deciding to invest in shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	\$ 20.00	\$ 670,000,000
Underwriting discounts and commissions (1)	\$ 1.40	\$ 46,900,000
Proceeds, before expenses, to Parabilis Medicines, Inc.	\$ 18.60	\$ 623,100,000

(1) See the section titled “*Underwriting*” for additional information regarding compensation payable to the underwriters.

We have granted the underwriters the option to purchase up to an additional 5,025,000 shares of common stock from us, at the initial public offering price, less the underwriting discounts and commissions.

In connection with our strategic research collaboration, Regeneron Pharmaceuticals, Inc. (“Regeneron”) has agreed to purchase approximately \$75.0 million of shares of our common stock in a concurrent private placement exempt from the registration requirements of the Securities Act of 1933, as amended, at a per share price equal to 90% of the initial public offering price (or 4,166,666 shares). The private placement will close concurrently with, and is contingent and conditioned upon consummation of, this offering; however, this offering is not contingent on the consummation of the concurrent private placement. In connection with the concurrent private placement, we have entered into a stock purchase agreement with Regeneron. The underwriters of this offering will not receive any fee in connection with the concurrent private placement.

The underwriters expect to deliver the shares against payment on or about June 11, 2026.

Leerink Partners

BofA Securities

Evercore ISI

Guggenheim Securities

LifeSci Capital

Prospectus dated June 9, 2026

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Neither we nor the underwriters have authorized anyone to provide you any information or make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside of the United States.

Basis of Presentation

Except where the context otherwise requires or where otherwise indicated, the terms “Parabilis,” “we,” “us,” “our,” “our company,” “Company” and “our business” refer to Parabilis Medicines, Inc. and its wholly-owned subsidiaries, Parabilis Security Corporation and Parabilis Medicines (Shanghai) Ltd Co.

Our audited consolidated financial statements include the accounts of Parabilis Medicines, Inc. Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States (“GAAP”). Our fiscal year ends on December 31 of each year. References to 2024 and 2025 refer to the years ended December 31, 2024 and December 31, 2025, respectively.

Certain monetary amounts, percentages and other figures included in this prospectus have been subject to rounding adjustments. Percentage amounts included in this prospectus have not in all cases been calculated on the basis of such rounded figures, but on the basis of such amounts prior to rounding. For this reason, percentage amounts in this prospectus may vary from those obtained by performing the same calculations using the figures in our consolidated financial statements included elsewhere in this prospectus. Certain other amounts that appear in this prospectus may not sum due to rounding.

Trademarks and Trade Names

We own, have applied for or have rights to use one or more registered and common law trademarks, service marks and/or trade names in connection with our business in the United States, which may be used throughout this prospectus. This prospectus also includes trademarks, trade names, and service marks of third-parties which are the property of their respective owners. Our use or display of third parties' trademarks, service marks, trade names or products in this prospectus and our other public filings is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks, logos and trade names referred to in this prospectus and our other public filings may appear without the ®, TM or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable owner of or licensor to these trademarks, service marks and trade names.

Market, Industry and Other Data

The market data and certain other statistical information used throughout this prospectus are based on independent industry publications, governmental publications, reports by market research firms, or other independent sources that we believe to be reliable sources. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosures contained in this prospectus, and we believe that these sources are reliable; however, we have not independently verified the information contained in such publications. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section titled "*Risk Factors*" and elsewhere in this prospectus. Some data are also based on our good faith estimates.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including the sections of this prospectus titled “Risk Factors,” “Special Note Regarding Forward-Looking Statements,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus, before making an investment decision.

Company Overview

We are a clinical-stage biopharmaceutical company built to develop transformative medicines addressing some of the most consequential, yet historically undruggable, protein targets driving human disease. We leverage our proprietary platform to pioneer a novel therapeutic modality, Helicons, which are stabilized helical peptides engineered to bind and precisely modulate proteins that have long been beyond the reach of conventional medicines.

To our knowledge, our lead product candidate, zolucetide, is the first-ever drug to directly target the interaction between β -catenin and the T-cell factor (“TCF”) family of transcription factors. This is the central node in the Wnt/ β -catenin cell signaling pathway, which regulates cell proliferation and differentiation and whose hyperactivation is a driver of millions of cancer cases annually across many tumor types. Drugging this critical node eluded three decades of intensive efforts to do so across the pharmaceutical industry. Zolucetide has been evaluated in over 150 patients to date and has generated promising clinical data in a range of solid tumors driven by alterations in the Wnt/ β -catenin pathway. In our lead indication, desmoid tumors, we have observed tumor reductions in 100% of patients with a 74% objective response rate (“ORR”) in patients who have had at least two post-baseline scans.

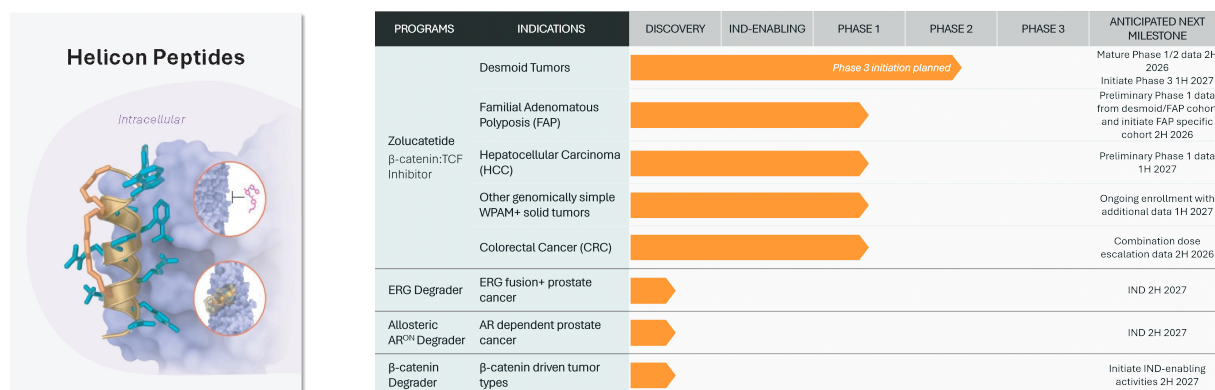
Objective responses have been observed across patients who have failed γ -secretase inhibitors (“GSIs”) and those who have never taken GSIs. Importantly, zolucetide has been able to generate this rate of response with a tolerability profile that we believe is more favorable than that of currently available drug therapy. We plan to initiate a global registrational Phase 3 trial for zolucetide in patients with desmoid tumors in the first half of 2027.

We believe zolucetide provides clinical validation of our first-in-industry Helicon approach and represents an expansive opportunity for medical and commercial impact. Our preclinical pipeline provides additional examples of the repeatability of our Helicon approach and includes programs targeting two key drivers of prostate cancer, the ETS-related gene (“ERG”) and the androgen receptor (“AR”) in its active state (“AR^{ON}”). Our current pipeline is focused on various cancers and tumor types; however, we believe Helicons could also have broad applicability against targets in many diseases with substantial unmet need outside oncology, and we plan to evaluate other therapeutic areas in the future.

An estimated 80% of biologically validated disease targets are considered undruggable, largely because the majority reside inside cells and present flat interaction surfaces. Small molecules can enter cells but cannot bind flat surfaces, and antibodies and other highly-selective biologics can selectively bind flat protein surfaces but cannot enter cells to access these targets. To our knowledge, Helicons are the only modality to date with the potential to consistently solve this problem as they are engineered for cell penetration and capable of binding to flat intracellular protein target surfaces with high specificity. Helicons combine the precision of antibodies and biologics with the intracellular access and tunability of small molecules in a single modality, enabling direct engagement of historically inaccessible protein targets. Our proprietary Helicon discovery platform allows us to integrate ligands and additional functionalities at multiple positions to precisely tune potency, selectivity, and pharmacologic properties. While our initial programs are focused on disrupting protein-protein interactions and inducing targeted protein degradation, we believe our platform can incorporate other advances in small molecule drug design and extend them to targets that are likely to remain out of reach for other modalities.

Our Helicon discovery platform integrates advanced artificial intelligence (“AI”)- and physics-based computational modeling with high-throughput peptide synthesis and experimental screening to discover and develop drug candidates. Since our founding, we have advanced computational models as well as custom design, synthesis, handling and manufacturing know-how to position us to produce Helicons reliably and at scale. A decade of applying these capabilities to Helicon drug discovery has generated vast proprietary datasets, comprising millions of data points for hundreds of thousands of Helicons across dozens of drug-like properties. These data power a continuous learning loop that refines our models from target selection through lead optimization, enhancing our speed, precision, and ability to generate high quality molecules against difficult targets. As a result, our platform produces unique complex synthetic molecules at scale and a compounding advantage that we believe is difficult to replicate.

We are advancing a wholly-owned pipeline of Helicon-based product candidates against high-value targets.



Our lead product candidate, zolucetide, is, to our knowledge, the first and only investigational therapy that inhibits the β-catenin:TCF interaction, the critical downstream node of the Wnt/β-catenin pathway. Activating mutations in this pathway, gain of function β-catenin mutations, or loss of function Adenomatous Polyposis Coli (“APC”) mutations, are present in over 10% of all cancers and span a broad range of tumor types.

We are evaluating zolucetide in ongoing clinical trials across multiple solid tumor indications, with more than 150 patients dosed to date. Zolucetide has been observed to be well tolerated across the therapeutic dose range. We believe the data generated to date, along with our understanding of the underlying Wnt/β-catenin pathway, support zolucetide’s potential to benefit patients across multiple tumor types driven by β-catenin or APC alterations and its advancement into a Phase 3 registrational trial. Our target indications include:

- Desmoid Tumors:** Our lead indication for zolucetide is desmoid tumors, which are rare, locally invasive soft tissue tumors driven by somatic or germline β-catenin pathway mutations. We estimate that approximately 11,000 desmoid tumor patients in the United States are actively managed under physician care. Desmoid tumors impose substantial and long-term morbidity, including pain, functional and mobility impairment, and the potential for life-threatening complications depending on tumor location. Given the chronic nature of the disease and onset in a predominantly young patient demographic with a near-normal life expectancy, prolonged or lifelong management is typically required. The only existing U.S. Food and Drug Administration (“FDA”) approved therapy for desmoid tumors, a GSI, does not address the underlying Wnt/β-catenin-driven disease biology. In our ongoing clinical trials, as of February 16, 2026, 38 desmoid patients have been enrolled and treated with zolucetide, of which 25 had sufficient follow up to be response-evaluable, and all 25 patients showed tumor reductions (disease control rate (“DCR”) of 100%). Of the 19 patients with at least two post-baseline scans, 74% (14/19) had an objective response per RECIST 1.1. We have observed responses in patients naive to GSI therapy, those who had progressed on GSI therapy, as well as patients that discontinued GSI therapy due to tolerability issues. To date, we have observed a tolerability profile that we believe compares favorably to the tolerability profile associated with GSIs and other off-label therapies, and supports continued development. We believe a medicine for the treatment of desmoid tumors with a superior efficacy and safety profile, compared to the existing systemic therapy, could significantly improve patient outcomes and expand the desmoid tumor commercial opportunity. We plan to initiate a registrational Phase 3 trial for zolucetide in patients with desmoid tumors in the first half of 2027.
- Familial Adenomatous Polyposis (“FAP”):** We are evaluating zolucetide’s potential in FAP, an orphan disease that impacts an estimated 34,000 people in the United States. FAP is characterized by extensive precancerous polyps in the gastrointestinal tract, with a near-inevitable risk of polyp progression to colorectal cancer in the absence of life-altering colon-removal surgery. There is currently no approved treatment for FAP. Desmoid tumors and FAP share common β-catenin biology, and approximately 10% of desmoid tumor patients also have underlying FAP. In the desmoid tumor cohort of our ongoing Phase 1/2 clinical trial, administration of zolucetide in two patients with FAP and an associated desmoid tumor demonstrated significant improvement in duodenal polyposis burden at 10 and 60 weeks, respectively, following initiation of treatment. As of February 16, 2026, we have enrolled six desmoid tumor patients with FAP in our ongoing clinical trial and are also planning to enroll a separate dedicated cohort of patients with FAP beginning in the second half of 2026.

- **Hepatocellular Carcinoma (“HCC”):** We are evaluating zolucetide’s potential in HCC, the most common type of primary liver cancer. HCC accounts for approximately 80-90% of liver cancer cases globally, with an estimated 38,000 new HCC cases annually in the United States and approximately 700,000–800,000 new cases worldwide. Approximately 30% of HCC tumors harbor β -catenin mutations and are otherwise relatively low in mutational burden. In a heavily pre-treated patient with CTNNB1-mutant HCC treated with zolucetide, we observed a confirmed partial response for nine months. Based on this observation, we began enrolling an HCC-specific cohort in our ongoing Phase 1/2 clinical trial.
- **Additional Rare Tumors:** There are over 70 different cancer types with documented APC or β -catenin mutations, equating to approximately 10% of all tumors and a prevalence in the United States of approximately 1.8 million patients. In pursuit of this significant opportunity, we are evaluating zolucetide in additional rare Wnt/ β -catenin-driven tumors that harbor APC loss or activating β -catenin mutations, including adamantinomatous craniopharyngioma (“ACP”), solid pseudopapillary neoplasm, salivary gland tumors, and ameloblastoma where we have observed partial responses to date. For these and potentially other rare tumor types, we are evaluating various regulatory strategies, including potentially accelerated development approaches based on a shared genomic signature of Wnt/ β -catenin pathway activation or, where appropriate, histologic characteristic clustering. Tumor-agnostic or molecularly defined approval pathways have been used selectively in oncology, and we believe targeting the root genetic cause of Wnt/ β -catenin pathway activation-driven disease may support a similar approach.
- **Colorectal Cancer (“CRC”):** We are also evaluating the potential for zolucetide in CRC, the third most commonly diagnosed cancer globally with approximately two million new cases annually. APC mutations, which drive aberrant β -catenin activation, occur in more than 80% of microsatellite stable CRC patients, representing the most prevalent mutations observed in this tumor type. In our ongoing clinical trials, we have observed disease stabilization and ctDNA reductions in a subset of CRC patients treated with zolucetide monotherapy, and we are currently evaluating multiple rational combination regimens, based on the results of paired tumor biopsies showing tumor differentiation and a dose responsive functional pathway inhibition. Our ongoing rational combination regimen includes anti-Vascular Endothelial Growth Factor (“VEGF”), DNA-damaging chemotherapy, and anti-programmed cell death protein 1 (“PD-1”) agents, as supported by preclinical and early translational data. We have also generated preclinical evidence for a rational combination with a RAS inhibitor.

Taken together, we believe the breadth of clinical activity and tolerability profile observed to date reinforce zolucetide’s potential as a pipeline-in-a-product with the ability to address significant unmet need across multiple tumor types. We expect to generate substantial additional clinical data as we advance zolucetide into registrational development in desmoid tumors and continue to expand our understanding of its therapeutic potential across additional indications.

Beyond zolucetide, we are advancing two preclinical stage Helicon programs in prostate cancer: an ERG degrader and an allosteric AR^{ON} degrader. Both programs seek to leverage the unique properties of Helicons to address areas of unmet need in prostate cancer treatment by targeting degradation of the historically undruggable ERG protein, an oncogenic driver present in approximately 40-50% of prostate cancer patients, and of AR via a novel AR binding site that seeks to overcome the primary drivers of resistance to AR targeted therapies.

- **ERG:** We have identified novel peptide binding sites on ERG and developed bifunctional degraders that have been observed to drive potent, selective ERG degradation in cells and *in vivo* tumor models. We have observed that patient-derived tumor models are dependent on ERG protein expression and activity for growth, which we believe supports the clinical therapeutic potential of our ERG degrader in ERG fusion-positive prostate cancer. We are now testing our lead Helicon in Investigational New Drug (“IND”)-enabling studies and continue to advance additional Helicons for optionality.
- **AR^{ON}:** Our AR^{ON} degrader is designed to overcome resistance driven by AR mutations and amplification, both of which limit the effectiveness of current AR-targeted therapies. In approximately 80% of patients, resistance to AR-targeted therapies is associated with amplification of the AR gene and point mutations at the drug binding site of AR. Approved AR antagonists and clinical-stage AR degraders of which we are aware target the same ligand binding pocket, making them non-combinable and vulnerable to the same resistance mechanisms. Our AR degrader binds to a historically undruggable allosteric co-activator protein binding site that is accessible only when androgen is bound to the receptor. As we are binding to this allosteric site and are not competitive with the binding site of all approved AR antagonists, we believe we will avoid the frequent mutations that occur within the ligand binding domain. By selectively targeting this active pool of AR, we believe our AR^{ON} degrader can more effectively address AR amplification, which we consider the most clinically significant driver of resistance in metastatic castration-resistant prostate cancer (“mCRPC”). Importantly, because it binds at the allosteric co-activator protein binding site, our AR^{ON} degrader is uniquely suited for combination with existing AR antagonists. These therapies all bind the androgen-binding pocket and are not currently combinable with one another. We believe that such a combination therapy approach could slow the development of resistance, improve efficacy, and meaningfully extend treatment duration. Our AR^{ON} degrader program is in late lead optimization and advancing toward IND-enabling studies.

In addition to pursuing additional targets, we are continuing to develop novel approaches to target β -catenin, building on the foundational biology established with zolucetide within Parabilis.

- **β -catenin Degradar:** Two avenues have emerged from our efforts to maximize the clinical potential of β -catenin targeting agents. First, we have identified multiple binding sites on β -catenin beyond the site leveraged by zolucetide and are exploring how β -catenin target engagement at these sites may impact different aspects of tumor biology. The downstream biology affected by Helicon binding to these sites is dependent on the multitude of intracellular protein complexes in which β -catenin resides within the tumor cell. Second, we have successfully applied our bifunctional degrader technology to develop β -catenin degraders using both zolucetide and the additional binding site Helicons as the anchor for this approach. The degrader functionality has the potential for improved potency via a catalytic mechanism of action and has the potential to drive unique biology by virtue of removing β -catenin protein rather than inhibiting protein-protein interactions.

We intend to advance multiple additional discovery-stage programs that target genetically validated, historically undruggable proteins where we believe Helicons may offer a meaningful advantage over existing modalities. We apply a rigorous framework to evaluate and prioritize programs that may result in substantial therapeutic and commercial opportunities before committing substantial resources toward those that we believe have the highest probability of clinical and commercial success. Given the versatility of the Helicon platform, we also believe there may be opportunities to selectively explore additional therapeutic approaches on our own and through strategic collaborations where a partner's complementary expertise could be leveraged. We recently entered into a collaboration with Regeneron with a focus on evaluating Antibody-Helicon Conjugates ("AHCs"), a potentially novel approach that combines antibody targeting capabilities with Helicon payloads designed to modulate intracellular proteins. We view this collaboration as an opportunity to explore the broader applicability of Helicons in a focused and capital-efficient manner alongside a leading partner.

Our Strategy

We intend to advance differentiated and potentially high value Helicon medicines that address genetically validated, yet historically undruggable, targets in areas of high unmet medical need. To pursue our vision, we are focused on the following key priorities:

- Complete clinical development of, and, if approved, commercialize zolucetide in desmoid tumors globally.
- Continue developing zolucetide in FAP through both our current Phase 1/2 enrollment of FAP-desmoid patients as well as a dedicated FAP cohort. Evaluate registrational path with regulatory agencies, and, if approved, commercialize zolucetide in FAP.
- Continue developing zolucetide in HCC and other β -catenin- and APC-driven diseases, including ACP and ameloblastoma.
- Maintain and expand our position as a leader in drugging the Wnt/ β -catenin pathway.
- Progress our ERG and allosteric AR^{ON} degraders, the next two programs in our pipeline of Helicon drug candidates, into IND-enabling toxicology studies.
- Continue to expand our pipeline of product candidates leveraging our proprietary Helicon discovery platform.
- Continuously improve our Helicon discovery platform to protect and extend our competitive advantage.
- Further develop integrated computational, translational, and clinical capabilities to efficiently, precisely, and effectively progress our product candidates through internal development.
- Explore and deliver on opportunities to extend the reach of our platform and capabilities through selective strategic partnerships.

Our Team

Our work requires a unique kind of organization. Tackling high-difficulty biology and building a new therapeutic modality demands a team with the judgment to identify the right problems, the technical depth to solve them, and the persistence to see them through. We apply a first principles approach to solve the complex issues that impact our business and are unafraid to challenge industry norms in our pursuit. At Parabilis, we have built a deeply integrated team of drug hunters, data scientists, and clinical and operational experts who are aligned around a shared goal of translating ambitious science into real medicines for patients.

Our team is led by Mathai Mammen, M.D., Ph.D., President, Chairman, and CEO of Parabilis. Previously, Dr. Mammen served as Global Head of R&D and a member of the Executive Committee at Johnson & Johnson. There, he led and evolved one of the world's largest pharmaceutical research and development organizations and spearheaded the strategic integration of data science and AI across the company's portfolio. During his tenure, his team secured global approvals for nine medicines, including Darzalex[™], Faspro[™], Balversa[™], Carvykti[™], Rybrevant[™], and Tecvayli[™] in oncology; Tremfya[™] and Ponvory[™] in immunology; and Spravato[™] and Invega Hafyera[™] in neuroscience. Before Johnson & Johnson, Dr. Mammen was a Senior Vice President at Merck, and contributed to the development of Keytruda[™] and the discovery of elenitide. Earlier in his career, he co-founded Theravance, Inc., where he led R&D toward five approved therapies. In total, he has led the discovery/development of 19 approved medicines.

Our leadership team includes additional members with deep domain expertise, such as our Chief Medical Officer, Fawzi Benzaghrou, M.D., who most recently served as Senior Vice President and Global Head of Oncology R&D at Ipsen, where he contributed to the development and approval of multiple oncology therapies, including Cabometyx[™] and Onivyde[™]. Our Scientific Co-founder and Executive Vice President of Platform Technology, John McGee, holds a Ph.D. in biochemistry from Harvard University, where he worked on both the *de novo* screening and multiplexing platforms that form the core of Parabilis' discovery engine. Our Chief Financial Officer, Tom Kotarakos, previously led two biotechnology companies through initial public offerings. Our Chief Business and Strategy Officer, Helen Ho, Ph.D., previously served as Chief Business Officer at Blueprint Medicines, where she, among other responsibilities, oversaw portfolio strategy and new product planning. Our Executive Vice President of Discovery Science, Markus Haerberlein, Ph.D., previously served as Head of Research at Alkermes. Our Executive Vice President of Discovery Biology, Jonathan Hurov, Ph.D., previously worked at Agios Pharmaceuticals and Cygnal Therapeutics, where he oversaw platform development and the company's early research.

Company History

We were founded in 2015 based on technology in-licensed from the laboratory of Greg Verdine, Ph.D., at Harvard University. This technology served as the foundation of our Helicon discovery platform, which we have subsequently advanced and expanded through continued internal development, as we advance our proprietary capabilities and pursue our mission to develop transformative medicines for patients in need. Since our founding, we have developed a substantial portfolio of wholly owned intellectual property, including patents and proprietary trade secrets. The current state and operation of the Helicon platform are not dependent on the continued use of the originally in-licensed technology or any other third party intellectual property.

Our platform was purpose-built over a decade to enable Helicon discovery. The first five years were devoted to developing and scaling high-throughput synthesis and data collection methods, generating proprietary datasets comprising millions of data points across hundreds of thousands of Helicons and dozens of drug-like properties. Over the subsequent five years, we leveraged these data to build a suite of custom AI- and physics-based computational models, and to rigorously test and refine them in the context of active discovery programs. These models are now deployed at every stage of discovery, from target selection through lead optimization. Each program we pursue feeds new data back into model training, creating a continuous learning loop. The result is a fully integrated discovery engine that has delivered repeated success against challenging targets and that we believe represents a durable competitive moat.

Since our inception, we have raised over \$800 million in financing from world class investors, including ARCH Venture Partners, Cormorant Asset Management, Fidelity Investments, GV, Milky Way Investments Group Limited, Nextech, RA Capital and venBio. Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and in certain cases received their shares in prior offerings at prices lower than the price offered to the public in this offering.

Summary of Risks Associated With Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks include, but are not limited to, the following:

- We are a clinical-stage biotechnology company with a limited operating history and no products approved by regulators for commercial sale, which may make it difficult to evaluate our current and future business prospects.
- Even if this offering and the concurrent private placement are completed, we will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate programs, product candidates (including clinical trials), investment in our Helicon discovery platform, or future commercialization efforts.
- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

- We are dependent on the success of our product candidates, including zolucetide, and our ongoing and anticipated trials may not be successful.
- Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, and utilize novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.
- Preclinical and clinical development is inherently lengthy and uncertain. Preclinical and clinical trials of our product candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which would have a material adverse impact on our Helicon discovery platform or our business.
- We expect that in the future we will conduct clinical trials for product candidates outside the United States, and Regulatory Authorities (as defined in the section titled “*Risk Factors*”) may not accept data from such trials.
- If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for, or commercialize our product candidates.
- Interim, initial, topline, and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Regulatory approval processes are lengthy, time-consuming and inherently unpredictable, and if we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we may develop, and our ability to generate revenue will be materially impaired.
- Our approach to the engineering and development of our programs is unproven, and we may not be successful in our efforts to identify and develop any programs and product candidates of commercial value by leveraging our Helicon discovery platform.
- We are substantially dependent on the successful application of our Helicon discovery platform to develop programs and product candidates that can be commercialized by us or our current or future collaboration partners.
- Issues relating to our use of AI in the identification of our programs and the engineering and development of our product candidates could adversely affect our business and operating results.
- We rely on third parties for the supply and manufacture of our product candidates for our research, preclinical and clinical activities, and may do the same for commercial supplies of our products, if approved.
- We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates.
- We rely on and expect to continue to rely on third parties to conduct aspects of our research, preclinical studies, clinical protocol development, and clinical trials for our programs and product candidates.
- Our success is largely based upon our intellectual property and proprietary technologies, and we may be unable to adequately protect and/or enforce our intellectual property.
- The biopharmaceutical market is intensely competitive. If we are unable to compete effectively with existing drugs, new treatment methods and new technologies, we may be unable to successfully commercialize any drugs that we develop.
- An active trading market for our common stock may not develop.
- The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

The summary risk factors described above should be read together with the text of the full risk factors in the section titled “*Risk Factors*” and the other information set forth in this prospectus, including our consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission (“SEC”). The risks summarized above or described in full elsewhere in this prospectus are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

Corporate Information

We were incorporated under the laws of the State of Delaware in July 2015 under the name FOG Pharmaceuticals, Inc. We changed our name to Parabilis Medicines, Inc. in October 2024. Our principal executive offices are located at 30 Acorn Park Drive, Cambridge, MA 02140, and our telephone number is (617) 945-9510. We have two subsidiaries, Parabilis Security Corporation, formed in December 2018 under the laws of the Commonwealth of Massachusetts, and Parabilis Medicines (Shanghai) Ltd Co, formed in March 2026 under the laws of Shanghai, China. Our website address is www.parabilismed.com. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Concurrent Private Placement

In connection with our strategic research collaboration, Regeneron Pharmaceuticals, Inc. (“Regeneron”) has agreed to purchase approximately \$75.0 million of shares of our common stock in a concurrent private placement exempt from the registration requirements of the Securities Act of 1933, as amended (the “Securities Act”), at a per share price equal to 90% of the initial public offering price (or 4,166,666 shares). The private placement will close concurrently with, and is contingent and conditioned upon consummation of, this offering; however, this offering is not contingent on the consummation of the concurrent private placement. In connection with the concurrent private placement, we have entered into a stock purchase agreement with Regeneron. The underwriters of this offering will not receive any fee in connection with the concurrent private placement.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an “emerging growth company” (“EGC”) as defined in the Jumpstart Our Business Startups Act of 2012, as amended (“JOBS Act”). As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this prospectus;
- reduced disclosure about our executive compensation arrangements;
- not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (“Sarbanes-Oxley Act”); and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on the financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Additionally, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we may not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result of this election, our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We have in the past chosen and may in the future choose to early adopt any new or revised accounting standards whenever such early adoption is permitted.

We are also a “smaller reporting company,” meaning that the market value of our shares held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700.0 million and our annual revenue was less than \$100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our voting and non-voting common stock held by non-affiliates is less than \$250.0 million or (ii) our annual revenue was less than \$100.0 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than \$700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

THE OFFERING

Common stock offered by us	33,500,000 shares
Overallotment option	We have granted the underwriters an option for a period of 30 days to purchase up to 5,025,000 additional shares of common stock from us at the initial public offering price, less underwriting discounts and commissions on the same terms as set forth in this prospectus.
Concurrent private placement	In connection with our strategic research collaboration, Regeneron has agreed to purchase approximately \$75.0 million in shares of our common stock in a concurrent private placement exempt from the registration requirements of the Securities Act, at a per share price equal to 90% of the initial public offering price (or 4,166,666 shares). The private placement will close concurrently with, and is contingent and conditioned upon consummation of, this offering; however, this offering is not contingent on the consummation of the concurrent private placement. In connection with the concurrent private placement, we have entered into a stock purchase agreement with Regeneron.
Common stock to be outstanding immediately after this offering and the concurrent private placement	116,564,570 shares (or 121,589,570 shares if the underwriters exercise their overallotment option in full).
Non-voting common stock to be outstanding immediately after this offering	1,581,210 shares.
Total common stock and non-voting common stock to be outstanding immediately after this offering and the concurrent private placement	118,145,780 shares (or 123,170,780 shares if the underwriters exercise their overallotment option in full).
Use of proceeds	We estimate that the net proceeds from the sale of our common stock in this offering will be approximately \$618.2 million (or approximately \$711.7 million if the underwriters exercise in full their overallotment option), based on the initial public offering price of \$20.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. In addition, we expect to receive an additional \$75.0 million in net proceeds from the sale of shares of our common stock in the concurrent private placement, after deducting estimated private placement expenses payable by us. We currently intend to use the net proceeds we receive from this offering, to continue the ongoing clinical development of zolucetide in desmoid tumors, to continue the ongoing clinical development of zolucetide across several additional indications, to advance our pipeline of additional programs, and the remainder for continued evolution of the Helicon platform and for general corporate purposes, including additional development efforts, working capital and operating expenses. Assuming completion of the concurrent private placement in accordance with Regeneron's contractual obligations, we expect to receive additional proceeds that would be available to fund any of the foregoing uses. See the section titled "<i>Use of Proceeds</i>" for additional information.
Risk factors	Investment in our common stock involves substantial risks. See the section titled " <i>Risk Factors</i> " for a discussion of factors you should carefully consider before deciding whether to invest in our common stock.
Nasdaq Global Select Market trading symbol	"PBLs"

Unless otherwise noted, the number of shares of our common stock and non-voting common stock that will be outstanding after this offering and the concurrent private placement is based on 80,479,114 shares of common stock outstanding as of March 31, 2026, after giving effect to (1) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 73,992,071 shares of common stock and 1,581,210 shares of non-voting common stock upon the closing of this offering and (2) the issuance of 2,777,777 shares of common stock issuable upon the conversion of a Simple Agreement for Future Equity (“SAFE”), in the aggregate amount of \$50.0 million, based on the initial public offering price of \$20.00 per share, and excludes:

- 8,823,077 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2026 under our 2016 Employee, Director and Consultant Equity Incentive Plan, as amended (“2016 Plan”), with a weighted average exercise price of \$2.67 per share;
- 5,986,341 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2026 under our 2026 Stock Option and Grant Plan (“January 2026 Plan”), with a weighted average exercise price of \$3.15 per share;
- 1,174,922 shares of common stock issuable upon exercise of outstanding stock options granted after March 31, 2026 pursuant to our January 2026 Plan, with a weighted average exercise price of \$4.09 per share;
- 3,069,339 shares of common stock reserved for future issuance as of March 31, 2026 under the January 2026 Plan, which ceased to be available for issuance at the time that our 2026 Stock Option and Incentive Plan (“2026 Plan”) became effective;
- 1,110,000 shares of common stock reserved for future issuance under our 2026 Employee Stock Purchase Plan (“ESPP”), which became effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP;
- 11,070,000 shares of our common stock that became available for future issuance under our 2026 Plan, which became effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any shares underlying outstanding stock awards granted under the January 2026 Plan and 2016 Plan that expire or are repurchased, forfeited, cancelled, or withheld; and
- 24,152 shares of our common stock issuable upon exercise of warrants outstanding as of March 31, 2026 at an exercise price of \$4.82 per share.

Unless otherwise indicated, the information in this prospectus reflects or assumes the following:

- a 1-for-1.5389 reverse stock split of our common stock, effected on June 3, 2026;
- the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 73,992,071 shares of common stock and 1,581,210 shares of non-voting common stock upon the closing of this offering;
- the issuance of 2,777,777 shares of common stock issuable upon the conversion of a SAFE, in the aggregate amount of \$50.0 million, based on the initial public offering price of \$20.00 per share;
- the issuance of 4,166,666 shares of our common stock in the concurrent private placement, which is to be completed concurrently with, and is contingent and conditioned upon consummation of, the closing of this offering;
- no exercise of the outstanding stock options or warrants described above after March 31, 2026;
- no exercise of the underwriters’ overallotment option to purchase up to 5,025,000 shares of common stock in this offering; and
- the filing and effectiveness of our seventh amended and restated certificate of incorporation immediately prior to the closing of this offering and the adoption of our amended and restated bylaws which became effective upon the effectiveness of the registration statement of which this prospectus forms a part.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated statements of operations for the years ended December 31, 2024 and 2025 and for the three months ended March 31, 2025 and 2026 and our summary consolidated balance sheet data as of March 31, 2026. We have derived the summary consolidated statements of operations data for the years ended December 31, 2024 and 2025 from our audited consolidated financial statements included elsewhere in this prospectus. We have derived the summary consolidated statements of operations data for the three months ended March 31, 2025 and 2026 and the summary consolidated balance sheet data as of March 31, 2026 from our unaudited condensed consolidated financial statements included elsewhere in this prospectus, which have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future and our results for the three months ended March 31, 2026 are not necessarily indicative of the results that may be expected for the year ending December 31, 2026. You should read the following summary financial data together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus. The summary consolidated financial data included in this section are not intended to replace the consolidated financial statements and are qualified in their entirety by our consolidated financial statements and the related notes included elsewhere in this prospectus.

(in thousands, except share and per share amounts)	Year Ended December 31,		Three Months Ended March 31,	
	2024	2025	2025	2026
Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 100,829	\$ 125,583	\$ 33,905	\$ 37,753
General and administrative	25,296	26,496	6,336	9,700
Total operating expenses	126,125	152,079	40,241	47,453
Loss from operations	(126,125)	(152,079)	(40,241)	(47,453)
Other income (expense):				
Interest income	6,408	3,386	1,257	2,429
Interest expense	(1,486)	(1,522)	(399)	(292)
Sublease income - related party	4,166	4,228	1,057	—
Change in fair value of preferred stock tranche right liability	(975)	—	—	—
Other income	98	98	—	—
Total other income, net	8,211	6,190	1,915	2,137
Net loss	\$ (117,914)	\$ (145,889)	\$ (38,326)	\$ (45,316)
Cumulative dividends on convertible preferred stock	(34,581)	(41,044)	(9,781)	(17,689)
Deemed dividend upon down round of convertible preferred stock	(8,986)	—	—	(7,875)
Net loss allocable to common stockholders ⁽¹⁾	\$ (161,481)	\$ (186,933)	\$ (48,107)	\$ (70,880)
Net loss per share allocable to common stockholders, basic and diluted ⁽¹⁾	\$ (83.48)	\$ (92.40)	\$ (23.84)	\$ (34.58)
Weighted average common shares outstanding, basic and diluted ⁽¹⁾	1,934,297	2,023,175	2,017,610	2,050,028
Pro forma net loss per share allocable to common stockholders, basic and diluted (unaudited) ⁽²⁾		\$ (1.82)		\$ (0.56)
Pro forma weighted average common shares outstanding, basic and diluted (unaudited) ⁽²⁾		80,374,210		80,401,059

- (1) See Notes 2 and 16 to our audited consolidated financial statements and Notes 2 and 14 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus for a description of the method used to calculate net loss per share allocable to common stockholders, basic and diluted.
- (2) Pro forma net loss per share allocable to common stockholders, basic and diluted for the year ended December 31, 2025 and three months ended March 31, 2026 was calculated using the weighted average number of shares of common stock and non-voting common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock and non-voting common stock, and the conversion of our outstanding SAFE

into shares of our common stock, as if such conversion had occurred as of January 1, 2025, based on the initial offering price of \$20.00 per share. Pro forma net loss per share allocable to common stockholders, basic and diluted does not include the effect of the shares expected to be sold in this offering and the concurrent private placement.

(in thousands)	As of March 31, 2026		
	Actual	Pro Forma ⁽¹⁾	Pro Forma, As Adjusted ⁽²⁾
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 329,039	\$ 329,039	\$ 1,022,239
Working capital ⁽³⁾	277,832	277,832	972,523
Total assets	384,173	384,173	1,075,882
Simple agreement for future equity	50,000	—	—
Convertible preferred stock	814,540	—	—
Accumulated deficit	(586,820)	(592,376)	(592,376)
Total stockholders' (deficit) equity	(570,320)	294,220	987,420

- (1) The pro forma consolidated balance sheet data give effect to (i) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 73,992,071 shares of our common stock and 1,581,210 shares of non-voting common stock upon the closing of this offering, (ii) the conversion of our outstanding SAFE into 2,777,777 shares of our common stock, including a change in the fair value of the SAFE liability of \$5.6 million after March 31, 2026 based on the initial offering price of \$20.00 per share, and (iii) the filing and effectiveness of our seventh amended and restated certificate of incorporation, which will occur immediately prior to the closing of this offering.
- (2) The pro forma as adjusted consolidated balance sheet data give effect to (i) the pro forma adjustments set forth in footnote (1) above, (ii) the issuance and sale of 33,500,000 shares of our common stock in this offering at the initial public offering price of \$20.00 per share after deducting underwriting discounts and commissions and estimated offering expenses payable by us and (iii) the issuance and sale of 4,166,666 shares of common stock in a concurrent private placement at a price per share equal to 90% of the initial public offering price per share of the shares offered in this offering, after deducting estimated private placement expenses payable by us.
- (3) We define working capital as current assets less current liabilities. See our consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all other information in this prospectus, including our consolidated financial statements and related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before investing in our common stock. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations. The market price of our common stock could decline if one or more of these risks or uncertainties actually occur, causing you to lose all or part of the money you paid to buy our common stock. Certain statements below are forward-looking statements. See the section titled “Special Note Regarding Forward-Looking Statements” appearing elsewhere in this prospectus.

Risks Related to Our Business, Financial Position, and Capital Needs

We are a clinical-stage biotechnology company with a limited operating history and no products approved by regulators for commercial sale, which may make it difficult to evaluate our current and future business prospects.

Since our inception in 2015, we have focused substantially all of our efforts and financial resources on developing our Helicon discovery platform and researching and developing programs and product candidates, including our lead product candidate, zolucetide. All of our programs and product candidates are still in the research, preclinical development or clinical development stages. We have not yet demonstrated our ability to successfully initiate or complete Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing, and distribution activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We have no products approved for commercial sale and we can provide no assurance that we will obtain regulatory approvals to market and sell any products in the future. We therefore have never generated any revenue from product sales, and we do not expect to generate any revenue from product sales for the foreseeable future. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. If we do not address these risks and difficulties successfully, our business will suffer.

Even if this offering and the concurrent private placement are completed, we will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate programs, product candidates (including clinical trials), investment in our Helicon discovery platform, or future commercialization efforts.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete. We expect to spend substantial amounts to (i) continue our research and development activities, perform preclinical studies, and conduct clinical trials of our current and future programs and product candidates, (ii) continue to develop our Helicon discovery platform, (iii) seek regulatory approvals for our product candidates, including zolucetide and (iv) launch and commercialize any product candidates for which we receive regulatory approval, including potentially building our own commercial sales, marketing, and distribution organization.

As of March 31, 2026, we had approximately \$329.0 million in cash and cash equivalents. In May 2026, we entered into a License and Collaboration Agreement with Regeneron (the “Regeneron Agreement”), and in connection therewith, we expect to receive a non-refundable upfront payment in the amount of \$50.0 million, which is due by June 17, 2026. In addition, Regeneron has agreed to purchase \$75.0 million of our common stock in the concurrent private placement. We estimate that the net proceeds from this offering will be approximately \$618.2 million, based on the initial public offering price of \$20.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. In addition, we expect to receive an additional \$75.0 million in net proceeds from the sale of shares of our common stock in the concurrent private placement, after deducting estimated private placement expenses payable by us. We believe, based on our current operating plan, that the net proceeds from this offering together with our existing cash and cash equivalents, and an upfront payment of \$50.0 million we expect to receive from Regeneron, will be sufficient to fund our operations into the second half of 2029. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, royalty financings, government or other third-party grants, asset sales, partnership, collaboration, or licensing arrangements, such as our collaboration with Regeneron, or a combination of these approaches. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our spending will vary based on new and ongoing research and development and corporate activities. Because the length of time and activities associated with research and development of our programs and product candidates

are highly uncertain, we are unable to estimate the actual funds we will require for research, development, marketing, and commercialization activities. Our future funding requirements, both near and long term, will depend on many factors, including, but not limited to the:

- number of programs that result in product candidates we choose to develop further;
- initiation, progress, timing, costs, and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- resources required to further develop our Helicon discovery platform;
- clinical development plans we establish for our product candidates;
- terms of any agreements with our current or future collaboration partners;
- outcome, timing, and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration (the “FDA”), the Medicines and Healthcare products Regulatory Agency (the “MHRA”), the European Medicines Agency (the “EMA”), the Pharmaceuticals and Medical Devices Agency, and other comparable foreign regulatory authorities (collectively, the “Regulatory Authorities”);
- cost of filing, prosecuting, maintaining, defending, and enforcing our patent claims and other intellectual property (“IP”) rights;
- effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;
- cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of our current and future product candidates; and
- cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive marketing approval and reimbursement in regions where we choose to commercialize our products on our own.

To date, we have financed our operations primarily with proceeds from sales of our convertible preferred stock, borrowings under a term loan and the issuance of a SAFE. In May 2026, we entered into the Regeneron Agreement with Regeneron, and in connection therewith, we expect to receive a non-refundable upfront payment in the amount of \$50.0 million. In addition, Regeneron has agreed to purchase \$75.0 million of our stock in the concurrent private placement.

We cannot be certain that additional funding will be available on favorable terms, or at all. Any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop our programs, develop and, if approved, commercialize our product candidates, or develop our Helicon discovery platform. In addition, we cannot guarantee that future financing will be available in sufficient amounts, at the right time, on favorable terms, or at all. Among other possibilities, negative clinical trial data or setbacks, or perceived setbacks, in our programs or product candidates, or with respect to our Helicon discovery platform, could impair our ability to raise additional financing or grants, or our ability to enter into partnership, collaboration, and licensing arrangements, in each case, on favorable terms, or at all. Moreover, the terms of any equity or debt financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, or the possibility of such issuance, may cause the market price of our shares to decline. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that may adversely affect our stockholders’ rights.

Further, to the extent that we raise additional capital through the sale of common stock or securities convertible into or exchangeable for common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital from third parties through public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration and licensing arrangements, or a combination of these approaches, we may have to relinquish certain valuable rights to our programs or product candidates, technologies, or future revenue streams. We also could be required to seek collaboration partners for one or more of our current or future programs and product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to programs and product candidates or intellectual property that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts, at the right time, on favorable terms, or at all, we may have to significantly delay, scale back, or discontinue the development of one or more of our programs, the development and commercialization of one or more of our product candidates, if approved, or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition, and results of operations, cause the price of our common stock to decline, and negatively impact our ability to fund operations.

We may decide to collaborate for the future development and potential commercialization of our product candidates, and such collaborations may include funding for which we are responsible. However, we cannot guarantee that either we or any collaboration partners will have the available funds to fund the research and development activities contemplated by such agreements. If we determine to fund development or commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our programs and product candidates or bring them to market and generate product revenue.

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We have no products approved for commercial sale and have not generated any revenue from product sales. We will continue to incur significant research and development and other expenses related to our programs, product candidates, Helicon discovery platform, and ongoing operations. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity (deficit) and working capital. We have incurred net losses in each year since our inception in 2015, including net losses of \$117.9 million and \$145.9 million for the years ended December 31, 2024 and 2025, respectively and \$38.3 million and \$45.3 million for the three months ended March 31, 2025 and 2026, respectively. As of March 31, 2026, we had an accumulated deficit of \$586.8 million.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities and the development of our Helicon discovery platform. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding, including through our licensing and collaboration arrangements. We have not initiated pivotal clinical trials for any of our product candidates, and it will be several years, if ever, before we or a collaboration partner have a product candidate ready for commercialization. Even if we or a collaboration partner obtain regulatory approval to market a product, our future revenues will depend upon the size of any markets in which such product have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share in those markets. We may never achieve profitability.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- expand the number of our research and development programs;
- continue or expand our scope of research or development of our current programs and product candidates in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical, clinical, or other studies or trials for our programs and product candidates, including pursuant to our licensing and collaboration arrangements;
- change or add additional manufacturers or suppliers, or create and scale internal manufacturing capabilities;
- add additional infrastructure to our quality control and quality assurance groups to support our operations as we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts;
- seek marketing approvals and reimbursement for our product candidates and products;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- acquire or in-license technologies;
- make payments under any in-license agreements;
- maintain, protect, and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

Biopharmaceutical product development entails substantial upfront capital expenditures and significant risk that any program or product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement, and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, you should carefully consider our prospects, factoring in the costs, uncertainties, delays, and difficulties frequently encountered by companies in clinical development, especially clinical-stage biotechnology companies such as ours. Any predictions about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays, and other known or unknown factors in achieving our business objectives.

Additionally, our expenses could increase beyond our expectations if we are required by any Regulatory Authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in the development of zolucetide and our other product candidates, such as delays in completing clinical trials.

We are dependent on the success of our product candidates, including zolucetide, and our ongoing and anticipated trials may not be successful.

Our future success is dependent on our ability to timely obtain marketing approval for, and then successfully commercialize, our product candidates, including zolucetide. We are investing a majority of our financial resources into the research and development of our product candidates, including our clinical trial for zolucetide for desmoid tumors and across additional indications. We may not be able to successfully develop or obtain regulatory approval for zolucetide in any of these indications.

Our product candidates will require additional clinical development, evaluation of clinical, preclinical, and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment, and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote product candidates before we receive marketing approval from the applicable Regulatory Authorities, and we may never receive such marketing approvals.

The success of our product candidates will depend on a variety of factors. We do not have control over many of these factors, including certain aspects of clinical development and the regulatory submission and review process, potential threats to our intellectual property rights, and our manufacturing, marketing, distribution, and sales efforts of those of any current or future collaborator. In addition, we do not have control over whether products that target the same indications as our product candidates are introduced, which could impact the competitiveness of our product candidates. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of these product candidates, even if approved. If we are not successful in commercializing zolucetide or any other product candidate, or are significantly delayed in doing so, our business will be materially harmed.

Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, and utilize novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.

Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, which may result in uncertainty regarding our current and future development efforts and ability to obtain regulatory approval for such candidates. We select programs for cancer driver targets based on what we believe are compelling biological rationales. We explore new programs based on extensive preclinical data analysis which sometimes cannot predict efficacy or safety in humans.

Some of our product candidates utilize novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent drug candidate development and approval, or discovery of unknown or unanticipated adverse effects. Even though there may be approved therapies to treat the conditions we are targeting, our product candidates are being developed to direct our therapies to a novel target, or to target a different binding site on a known target. We utilize structural biology in tight integration with our medicinal chemistry and biology capabilities to predict and design the compounds that we believe will achieve the most desirable characteristics, including potency, selectivity, bioavailability, and drug-like properties. A disruption in any of these capabilities may have significant adverse effects in our ability to expand our pipeline of product candidates, and we cannot predict whether we will continue to have access to these capabilities in the future to support our pipeline development. In addition, there can be no assurance that we will be able to identify, design and synthesize the necessary compounds or that these or other problems related to the development of product candidates will not arise in the future, which may cause significant delays or raise problems we may not be able to resolve.

Regulatory approval of novel product candidates such as ours can be more expensive, riskier, and take longer than for other, more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to our and Regulatory Authorities' lack of experience with them. The novelty of the mechanism of action of any of our product candidates may lengthen the

regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates, or lead to significant post-approval limitations or restrictions. The novel mechanism of action also means that fewer people are trained in or experienced with product candidates of this type, which may make it more difficult to find, hire and retain personnel for research, development, and manufacturing positions and to identify clinical trial investigators to use our product candidates in trials. Because our product candidates utilize a novel mechanism of action that has not been the subject of extensive study compared to more well-known product candidates, there is also an increased risk that we may discover previously unknown or unanticipated adverse effects during our preclinical studies and clinical trials. Because our product candidates are designed to target novel protein binding sites, we may be required to provide more preclinical and clinical data to demonstrate the potential of our product candidates. Any such events could adversely impact our business prospects, operating results, and financial condition.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our product candidates may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives, such as the expected timing of a potential Phase 3 registrational trial of zolucetide for the treatment of desmoid tumors or our submission of an Investigational New Drug (“IND”) application for any of our other product candidates. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, in some cases for reasons beyond our control, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs, and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our substantial reliance on third-party contract research organizations (“CROs”) for the performance of certain research activities, including synthesis, biology, drug metabolism and pharmacokinetics (“DMPK”), toxicology, and other research activities for the discovery and development of products;
- our substantial reliance on third-party CROs to engage, qualify, and prepare clinical trial sites, complete these trials successfully, in compliance with regulatory requirements, and on schedule;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by Regulatory Authorities and the timing thereof;
- other actions, decisions, or rules issued by regulators;
- our substantial reliance on third-party contract development and manufacturing organizations (“CDMOs”) to manufacture our product candidates;
- our CDMOs’ access to sufficient, reliable, and affordable supplies of materials used to manufacture our product candidates;
- the efforts of any collaboration partners with respect to the development, manufacturing and commercialization of our product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

Any inability to meet milestones as publicly announced, or at all, may delay the commercialization of our product candidates or result in commercialization never being achieved and, as a result, our stock price may decline. Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and potentially on less favorable terms and prior to achieving targeted development milestones, and may decrease the attractiveness of our product candidates relative to competitive products expected to be approved by the applicable Regulatory Authorities prior to our product candidates.

Our quarterly and annual operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline and negatively impact our financing or funding ability as well as negatively impact our ability to exist as a standalone company.

Our financial condition and operating results have varied in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this prospectus:

- inability to develop promising programs;
- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- the feasibility of developing, manufacturing, and commercializing our product candidates;
- our ability to manage our growth;
- the outcomes of research programs, clinical trials, or other product development or approval processes conducted by us and any collaboration partners;
- our ability to develop or successfully commercialize product candidates;
- the ability of our current or any future collaboration partners to develop and successfully commercialize product candidates;
- our relationships, and any associated exclusivity terms, with any current or future collaboration partners, including Regeneron;
- our contractual or other obligations to provide resources to fund our programs and product candidates;
- our operation in a net loss position for the foreseeable future;
- risks associated with the international aspects of our business, including the conduct of clinical trials in international locations and potential commercialization in such locations, including in China;
- our ability to accurately report our financial results in a timely manner;
- our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to obtain, protect, maintain, and enforce our IP rights;
- our ability to prevent the theft or misappropriation of our IP and know-how or proprietary technologies;
- potential advantages that our competitors and potential competitors may have in securing funding, obtaining and maintaining the rights to critical IP, or developing competing technologies or products;
- our ability to obtain additional capital that may be necessary to expand our business;
- our collaboration partners' ability to obtain additional capital that may be necessary to develop programs and develop and commercialize product candidates pursuant to our partnership, collaboration, and licensing arrangements;
- the effect of changes in government regulation;
- cybersecurity breaches and other business interruptions such as power outages, strikes, acts of terrorism, or natural disasters; and
- changes in tax policy and our ability to use our net operating loss ("NOL") carryforwards to offset future taxable income.

Our term loan contains restrictive covenants that may impair our ability to conduct business.

Our term loan with Silicon Valley Bank ("SVB") contains a number of customary affirmative and negative covenants that, among other things, limit or restrict our ability to: sell assets; change our line of business; enter into mergers or consolidations; incur certain additional indebtedness; incur liens; pay dividends and make other distributions or payments in respect of capital stock; make certain investments; engage in certain transactions with affiliates; or become an investment company. As a result of these covenants and restrictions, we are limited in how we conduct our business and we may be unable to raise additional debt or other financing to compete effectively or to take advantage of new business opportunities. The terms of any future indebtedness we may incur could include more restrictive covenants. Failure to comply with such restrictive covenants may lead to default and acceleration under our term loan and may impair our ability to conduct business. We may not be able to maintain compliance with these covenants in the future and, if we fail to do so, we may not be able to obtain a waiver from the lender or amend the covenants, which may adversely affect our financial condition.

Risks Related to the Research, Development, Regulatory Review, and Approval of Our Product Candidates

Preclinical and clinical development is inherently lengthy and uncertain. Preclinical and clinical trials of our product candidates may be delayed, and certain programs may never advance into or through the clinic or may be more costly to conduct than we anticipate, any of which would have a material adverse impact on our business.

Preclinical and clinical testing is expensive and complex and can take many years to complete, and its outcome is inherently uncertain. We or our collaboration partner may not be able to initiate, may experience delays in, or may have to discontinue preclinical studies and clinical trials for our product candidates.

Before we can initiate clinical trials for a product candidate, we must first complete extensive preclinical studies, including IND-enabling good laboratory practices (“GLP”) toxicology testing, which support our planned INDs in the United States, or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies. For example, while Regulatory Authorities like the FDA have signaled through draft guidance a movement away from animal testing for monoclonal antibodies, we have thus far depended on the availability of non-human primates (“NHPs”) to conduct certain preclinical studies that we are required to complete prior to submitting an IND or foreign equivalent prior to initiating clinical development, and prior to submitting a marketing application. During the past several years, there was a global shortage of NHPs available for drug development. If the shortages in NHPs or other laboratory animals occur in the future, this could significantly increase the costs of obtaining, or decrease the availability of, NHPs or other laboratory animals for our future preclinical studies if regulators continue to require NHP data, or we require other laboratory animals, to support our preclinical and clinical development programs. This could also result in delays in our development and approval timelines.

We must also complete extensive work on Chemistry, Manufacturing and Controls (“CMC”) activities (including yield, purity, and stability data) to be included in any IND filing. CMC activities require extensive manufacturing processes and analytical development, which is uncertain and lengthy. For instance, batch failures have occurred and may occur in the future as we scale up our manufacturing. In addition, we may have difficulty identifying appropriate buffers and storage conditions to enable sufficient shelf life of batches of our preclinical or clinical product candidates. If we are required to produce new batches of our product candidates due to insufficient shelf life, it may delay the commencement or completion of preclinical or clinical trials of such product candidates.

We cannot predict whether Regulatory Authorities will accept the results of our preclinical testing or our proposed clinical programs or whether the outcome of our preclinical testing, studies, and CMC activities will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in Regulatory Authorities allowing clinical trials to begin.

Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would significantly harm our business. Our development costs will also increase if we experience delays in testing or obtaining regulatory approvals, and we may be required to obtain additional funds to complete clinical trials. There can be no assurance that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. Regulatory Authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

We or our collaboration partner also may experience numerous unforeseen events during, or as a result of, any clinical trials that we conduct, which could delay or prevent us or our collaboration partner from successfully developing our product candidates, including:

- Regulatory Authorities, institutional review boards (“IRBs”) or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site for any number of reasons, including concerns regarding safety and aspects of the clinical trial design;
- we may experience delays in reaching, or fail to reach, agreement on favorable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience challenges in manufacturing sufficient quantities of our product candidates, or obtaining sufficient quantities of combination therapies for use in clinical trials;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;

- the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- the outcome of our preclinical studies and our early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results;
- we may have to amend clinical trial protocols submitted to Regulatory Authorities or conduct additional studies or add additional cohorts to reflect changes in regulatory requirements or guidance, which may be required to resubmit to an IRB, ethics committee and Regulatory Authorities for re-examination;
- clinical trials of any product candidates may fail to show safety or efficacy, or produce negative or inconclusive results, and we may decide, or Regulatory Authorities may require us, to conduct additional nonclinical studies or clinical trials, or we may decide to abandon development programs;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- differences in clinical trial design between early-stage clinical trials and later-stage clinical trials may make it difficult to extrapolate the results of earlier clinical trials to later clinical trials;
- preclinical and clinical data are often susceptible to varying interpretations and analyses, and many product candidates believed to have performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval;
- Regulatory Authorities or other reviewing bodies may find deficiencies with, fail to approve, or subsequently find fault with the manufacturing processes or facilities of our CDMOs, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate, or not available at an acceptable cost, or we may experience interruptions in supply;
- product candidates may have undesirable side effects or degradation products, any of which could lead to serious adverse events (“SAEs”) or other unexpected characteristics;
- occurrence of SAEs in trials of the same class of product candidates conducted by other companies that could be considered similar to our product candidates; and
- the potential for approval policies or regulations of Regulatory Authorities to significantly change in a manner rendering our clinical data insufficient for approval.

For example, we are developing a new formulation of zolucetide in a self-administered injectable formulation (the “Injectable Formulation”) for ease of use. All patients in our current Phase 1/2 trial are dosed using an intravenous (“IV”) infusion presentation. We intend ultimately to transition to an Injectable Formulation that will be delivered through an autoinjector, a pre-filled syringe or an on-body device for ease of patient dosing and for what we believe will be a greater commercial opportunity. In March 2026, in our healthy volunteers trial to bridge IV to injectable formulations, we observed several injection site reactions (“ISRs”), all at low levels (Grade 1 and Grade 2) with a first generation formulation. Although we plan to continue working toward an Injectable Formulation, we intend to conduct a pivotal Phase 3 trial of zolucetide in desmoid tumors initially using only the IV infusion presentation. We expect Regulatory Authorities will require us to conduct, among other things, pharmacokinetic (“PK”) compatibility studies to bridge the IV infusion presentation to these new planned injection presentations, human factors testing to support self-administration of zolucetide, and potentially a separate Phase 2 trial to validate the equivalence of the current IV formulation to the Injectable Formulation. Any of these additional steps could delay marketing approval of zolucetide in one or more formulations and jeopardize our ability to commence product sales and generate revenue from zolucetide, if approved. There is no assurance that we will be successful in developing an Injectable Formulation or demonstrating the equivalence of any of these delivery methods in clinical trials, any other studies, or at all, and any failure would impede our development and commercialization strategy for zolucetide.

We could also encounter delays if a clinical trial is suspended or terminated by us or any Regulatory Authority, ethics committee or the IRBs of the institutions in which such trials are being conducted, or if such trial is recommended for suspension or termination by the Data Safety Monitoring Board (“DSMB”) for such trial. We may experience delays in gaining clearance from Regulatory Authorities to initiate clinical trials through the imposition of a clinical hold in order to address comments from such Regulatory Authorities on our clinical trial design or other elements of our clinical trials. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by a Regulatory Authority, unforeseen safety issues or adverse side

effects, failure to demonstrate a benefit or adequate benefit risk ratio from using a product candidate, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Further, conducting clinical trials in foreign countries, as we intend to do for zolucetide and as we may in the future for our other product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries.

In addition, our ability to access and use clinical trial data for ongoing trials and any new trials conducted in China will be highly dependent on acceptance and approvals from Human Genetic Resources Administration of China (“HGRAC”). There is no guarantee that the HGRAC will not impede our ability to obtain and use clinical trial data for trials conducted in China in a timely manner or in a way that facilitates our use of such data. We intend to rely on our sites in China to provide us with significant data and other information related to our product candidates, including preclinical and clinical data. We may not be able to independently verify or audit all of such data (including possibly material portions thereof). As a result, such data may be inaccurate, misleading, or incomplete.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to Regulatory Authorities. A Regulatory Authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The Regulatory Authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the applicable Regulatory Authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize zolucetide or any other product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business, financial condition, results of operations, and growth prospects. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates. Any delays in the development of our product candidates may harm our business, financial condition, and prospects significantly.

We expect that in the future we will conduct clinical trials for product candidates outside the United States, and Regulatory Authorities may not accept data from such trials.

We expect to conduct future clinical trials and arms of our clinical trials for our product candidates internationally in the future. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by Regulatory Authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, regardless of whether such trials were conducted under an IND, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the U.S. population and U.S. medical practice, the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice (“GCP”) regulations, and the FDA can validate the data through on-site inspections or other appropriate means. Many foreign regulatory authorities have similar approval requirements, including in relation to the use of data from clinical trials conducted in foreign jurisdictions. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that Regulatory Authorities will accept data from trials conducted outside of the United States or the applicable jurisdiction. If Regulatory Authorities do not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in any product candidates that we develop being delayed or not receiving approval for commercialization in the applicable jurisdiction. Additionally, recent policy proposals in the United States may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly.

If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for, or commercialize our product candidates.

The results observed from preclinical studies or early-stage clinical trials of zolucetide or any other product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. For example, results seen in our Phase 1/2 clinical trial for zolucetide in patients with desmoid tumors may not translate to similar results in our planned

registrational Phase 3 trial or in other future clinical trials in patients with such tumors and may not be predictive of outcomes for zolucetide in other indications. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as those observed in earlier studies and trials, and we may not have generated sufficient safety data to support a marketing application by the time of our targeted submission as other third-party products or product candidates that we believe may have similar profiles. In addition, in our planned future clinical trials, we may utilize clinical trial designs or dosing regimens or methods of delivery that have not been tested in prior clinical trials.

There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of zolucetide or any other product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, adverse safety or efficacy observations made in clinical trials.

Additionally, we intend to utilize an “open-label” clinical trial design for certain of our clinical trials, and are currently using such design in our Phase 1/2 clinical trial of zolucetide for the treatment of advanced solid tumors. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results of a product candidate when studied in a controlled environment with a placebo or active control.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain approval from Regulatory Authorities.

Interim, initial, topline, and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular preclinical study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to evaluate all data fully and carefully. As a result, the topline or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Therefore, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participants’ enrollment continues and more participants’ data become available or as participants from our clinical trials continue other treatments for their disease. Similarly, we may disclose data from a small initial number of patients, or a single patient, in a particular indication as we continue to accrue data, and while initial data may be positive, the final data in a larger number of participants may not ultimately support further development in that indication. For example, we disclose elsewhere in this prospectus that, in our Phase 1/2 clinical trial studying desmoid tumor effect, administration with zolucetide in two patients who also had Familial Adenomatous Polyposis (“FAP”) associated with desmoid tumor led to a significant improvement in duodenal polyp burden in these FAP patients including substantial reduction in polyp number and size. There can be no guarantee that these two patients will continue to show improvement or that we will see similar results in a well-controlled, multi-patient clinical trial designed to study zolucetide for the treatment of FAP. Adverse differences between interim data and final data, and between limited data and more expanded data as it becomes available, could result in abandonment of a program or a product candidate and/or otherwise significantly harm our business prospects.

Further, others, including Regulatory Authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions, study population size, safety database size, or interpretations of data or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular product candidate or the approvability or commercialization of the particular product candidate and could adversely affect the success of our business. In addition, the information we choose to publicly

disclose regarding a particular study or trial is based on what is typically extensive information, and investors may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline or preliminary data that we report differ from actual results, or if others, including Regulatory Authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and growth prospects. Further, disclosure of interim, topline, or preliminary data by us or by our competitors could result in volatility in the price of our common stock.

If we encounter difficulties identifying and enrolling participants in our clinical trials, including participants with the required or desired characteristics to achieve diversity in a trial, our clinical development activities could be delayed or otherwise adversely affected.

We depend on enrollment of participants in our clinical trials for our product candidates. We may find it difficult to enroll trial participants in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Delays or difficulties in enrollment may result in increased costs or otherwise affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates, or result in termination of the clinical trials altogether. For example, in order to enroll a sufficient number of patients in our ongoing Phase 1/2 clinical trial for zolucetide in patients with advanced solid tumors and our planned Phase 3 clinical trial in desmoid tumors, we plan to contract with one or more sites in Australia and China.

Identifying and qualifying trial participants to participate in clinical trials of our product candidates is critical to our success. Patient and subject enrollment is affected by factors including: severity of the disease under investigation; complexity and design of the trial protocol; size of the targeted patient population; eligibility criteria for the trial in question; proximity and availability of clinical trial for the disease or condition under investigation; available sites for prospective trial participants; availability of competing therapies and clinical trials, including between our own clinical trials; efforts to facilitate timely enrollment in clinical trials; patient referral practices of physicians; ability to monitor trial participants adequately during and after treatment; ability to recruit clinical trial investigators with the appropriate competencies and experience; clinicians' and trial participants' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating; our ability to obtain and maintain participant informed consent; and the risk that trial participants enrolled in clinical trials will not complete a clinical trial.

The timing of our clinical trials depends on the speed at which we can recruit trial participants to participate in testing our product candidates. If trial participants are unwilling to participate in our studies because of negative publicity from adverse events in our trials or other trials of similar products, or those related to specific therapeutic area, or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting trial participants, conducting studies, and obtaining regulatory approval of potential products may be delayed, which could also have significant commercial competitive impacts in the future.

In particular, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition may reduce the number and types of trial participants available to us, because some trial participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a third party. Potential participants may elect to enroll in other clinical trials offering oral medications out of convenience, rather than participate in our clinical trials which provide for IV delivery of drug product. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which may reduce the number of trial participants who are available for our clinical trials at such clinical trial sites. Additionally, if new product candidates show encouraging results, potential trial participants and their doctors may be inclined to enroll trial participants in clinical trials using those product candidates. If such new product candidates show discouraging results or other adverse safety indications, potential trial participants and their doctors may be less inclined to enroll trial participants in our clinical trials.

Due to the significant resources required for drug development and depending on our ability to access capital, we intend to prioritize the development of zolucetide for desmoid tumors and other rare tumors. As a result, we may not focus on other indications or potential product candidates that may have been more profitable.

Due to the significant resources required for drug development, we must decide which indications to pursue and advance and the amount of resources to allocate to each product candidate. Our decisions concerning the allocation of research, development, collaboration, management, and financial resources toward particular indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. For example, our current strategy is to pursue regulatory approval of zolucetide for the treatment of desmoid tumors and to evaluate a potential label expansion into other types of rare tumors and other conditions. If we make incorrect determinations regarding the viability or market potential of zolucetide, or misread trends in the biotechnology industry, our business, financial condition, results of operations, and growth prospects could be

materially and adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to our product candidates through collaboration, licensing, or royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

Regulatory approval processes are lengthy, time-consuming, and inherently unpredictable, and if we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we may develop, and our ability to generate revenue will be materially impaired.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming, and uncertain, and may prevent us from obtaining approvals for the commercialization of any product candidates we may develop. Any product candidate we may develop and the activities associated with its development and commercialization, including design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by Regulatory Authorities. To obtain the requisite regulatory approvals to commercialize any of our product candidates, we and any collaboration partners must demonstrate through extensive preclinical studies and clinical trials that our products are safe, pure and effective in humans, including the target population. Successful completion of clinical trials is a prerequisite to submitting a New Drug Application (“NDA”) to the FDA, a Marketing Authorization Application (“MAA”) to the EMA, and similar marketing applications to other Regulatory Authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates.

Clinical evaluation of investigational drugs is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. Generally, two adequate and well-controlled Phase 3 clinical trials of a product candidate in the relevant patient population have been required by the FDA and other major Regulatory Authorities for approval of an NDA, although there are known exceptions, including in rare diseases and oncology. In February 2026, the FDA Commissioner publicly indicated that a single adequate and well-controlled pivotal clinical trial supported by confirmatory evidence will be the FDA’s default standard moving forward for novel products, rather than two such trials. This statement was not a formal agency action and the scope, implementation, and durability of this policy position remain uncertain. The FDA retains broad discretion to require additional clinical data for any product candidate, including a second adequate and well-controlled clinical trial. Regulatory Authorities may disagree with us about whether a clinical trial is adequate and well-controlled or may request that we conduct additional clinical trials prior to regulatory approval. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. In addition, there is no assurance that the doses, endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from Regulatory Authorities or those that have been used for the approval of similar drugs, will be acceptable for future approvals. The clinical development of our product candidates is also susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate purity, potency, or efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements, and determination by Regulatory Authorities that a product candidate may not continue development or is not approvable. It is possible that even if our product candidates have a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events or other adverse events, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

Our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- Regulatory Authorities may disagree with the dosing regimen, clinical trial design, or conduct of our clinical trials;
- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- we may be unable to demonstrate to the satisfaction of Regulatory Authorities that a product candidate is safe and effective for any of its proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by Regulatory Authorities for approval;
- Regulatory Authorities may disagree with our interpretation of data from clinical trials or preclinical studies;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union (the “EU”), or elsewhere;
- we may be unable to demonstrate that a new formulation of a product candidate is equivalent to the formulation of an existing product candidate;
- Regulatory Authorities may not file or accept our NDA or marketing application for substantive review;
- Regulatory Authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of our CDMOs;
- staffing changes and backlogs at Regulatory Authorities may create unexpected delays in the review and approval of any applications we may submit;
- the approval policies or regulations of Regulatory Authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- product labeling or product insert requirements or requirements to conduct post-marketing studies.

Failure to obtain marketing approval for a product candidate in a jurisdiction will prevent us from commercializing the product candidate in that jurisdiction. We have not received approval to market any product candidates from Regulatory Authorities in any jurisdiction, and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval in any market. We have no experience as an organization in filing and supporting the applications necessary to gain marketing approvals and will need to rely on CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate’s safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant Regulatory Authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory Authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and may require additional preclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Additional delays or non-approval may result if an FDA Advisory Committee or other Regulatory Authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials, and the review process. Any such delays may decrease the attractiveness of our product candidates relative to competitive products that are expected to be approved by the applicable Regulatory Authorities prior to our product candidates, and adversely affect our business.

In addition, if our product candidates receive marketing approval, we will be subject to significant regulatory obligations to submit safety and other post-marketing information and reports, to register manufacturing facilities, and to comply (or ensure that our third-party providers comply) with current Good Manufacturing Practices (“cGMPs”) and Good Clinical Practices (“GCPs”) for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a Regulatory Authority, or a third party might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-approval could lead to civil or criminal investigations and sanctions, and could adversely affect our business, financial condition, results of operations, and growth prospects.

Regulatory Authorities also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of potentially costly post-marketing studies, may not approve the price we intend to charge for our product candidates, or may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Regulatory Authorities review the CMC section of regulatory filings. Any aspects found unsatisfactory by Regulatory Authorities may result in delays in clinical trials and commercialization. In addition, Regulatory Authorities conduct pre-approval inspections of clinical sites and manufacturing sites at the time of an NDA. Any findings by Regulatory Authorities and failure to comply with requirements may lead to delay in approval and failure to commercialize the product candidate.

If we fail to expand our development of zolucetide into additional indications, or fail to develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

Although we are initially focused on developing and commercializing zolucetide for the treatment of desmoid tumors, we also plan to evaluate developing zolucetide for the treatment of FAP, HCC and other rare solid tumors and related conditions. Expansion into new indications will require additional, time-consuming development efforts and significant additional expense prior to commercial sale, including preclinical studies, clinical trials and approval by Regulatory Authorities. All product candidates are prone to the risks of failure that are inherent in biopharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, there can be no assurance that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, other Regulatory Authorities must also approve the manufacturing and marketing of the product candidate in non-U.S. jurisdictions. In order to eventually market any of our product candidates in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding safety and efficacy. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve product testing and validation and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

Our current and future clinical trials may reveal significant adverse events or undesirable side effects not seen in our preclinical studies and may result in a safety profile that could halt clinical development, inhibit regulatory approval, limit commercial potential, or market acceptance of any of our product candidates.

There is typically an extremely high rate of attrition for product candidates across categories of medicines proceeding through clinical trials. These product candidates may fail to show the desired safety and efficacy or safety, purity and potency profile in later stages of clinical trials despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates.

Undesirable side effects caused by our product candidates, whether used alone or in combination with other therapies, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by Regulatory Authorities. We may observe unexpected and undesirable safety or tolerability issues with our product candidates in ongoing or future clinical trials. For example, in March 2026, in our healthy volunteers trial to bridge IV to injectable formulations, we paused dosing of participants with the initial Injectable Formulation due to several ISRs, all at low levels (Grade 1 and Grade 2).

If significant adverse events or unacceptable side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting trial participants to any of our clinical trials, trial participants may withdraw from trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, Regulatory Authorities, or an IRB, may impose a clinical hold, suspend, or terminate clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of any of our product candidates could result in harm to patients that are administered any of our product candidates. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, unfavorable benefit risk ratio may inhibit market acceptance of the approved product due to its tolerability versus other therapies. In addition, an extended half-life could prolong the duration of undesirable side effects, which could also inhibit market acceptance. Any of these developments could materially harm our business, financial condition and prospects.

Moreover, clinical trials are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

In addition, even if we successfully advance our product candidates or any future product candidates through clinical trials, such trials will only include a limited number of patients and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate after approval. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of using our product candidates over a multi-year period.

If any of the foregoing events occur or if one or more of our product candidates prove to be unsafe, our entire pipeline or our Helicon discovery platform could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if we obtain regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Even if our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval. For example, the holder of an approved NDA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may: issue a warning letter asserting that we are in violation of the law and potentially restricting our ability to sell, manufacture, import or export our products; seek an injunction or impose civil or criminal penalties or monetary fines; suspend or withdraw regulatory approval or revoke a license; suspend any ongoing clinical trials; refuse to approve a pending NDA or supplements to a NDA submitted by us; seize product; or refuse to allow us to enter into supply contracts, including government contracts. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any approved products and generate revenues.

If we are successful in gaining approval for any of our product candidates, we and our CDMOs, which manufacture our products under contract, will continue to face significant regulatory oversight of the manufacturing and distribution of our products. Product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by Regulatory Authorities for compliance with cGMP and adherence to commitments made in the NDA. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a Risk Evaluation and Mitigation Strategy (“REMS”) as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Comparable requirements may apply in foreign countries. In addition, if Regulatory Authorities approve any of our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information, reports and registration.

Regulatory Authorities may impose consent decrees or withdraw or vary approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our CDMOs or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program or a comparable foreign program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by Regulatory Authorities to approve pending applications or supplements to approved applications filed by us or suspension, variation or withdrawal of approvals;
- product seizure, detention or refusal to permit the import or export of our product candidates;
- total or partial suspension of production, distribution, manufacturing or clinical trials;
- operating restrictions;
- suspension of licenses; and
- injunctions, fines or the imposition of civil or criminal penalties.

Additionally, Regulatory Authorities strictly regulate marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label.

The policies of Regulatory Authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. In addition, the U.S. Supreme Court’s July 2024 decision to overturn established case law giving deference to Regulatory Authorities’ interpretations of ambiguous statutory language has introduced ongoing uncertainty regarding the extent to which the FDA’s regulations, policies and decisions may become subject to increasing legal challenges, delays and/or changes. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For more information, see the section titled “*Business—Government Regulation.*”

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We may develop certain of our product candidates in combination with other therapies or as add-ons to the standard of care. Developing combination treatments increases complexity and risk, including risks of drug-drug interactions, unforeseen side effects or failures in our clinical trials that could delay or prevent their regulatory approval or limit the commercial profile of an approved label.

We are currently evaluating zolucetide in patients receiving standard-of-care chemotherapy and other agents, including in combination with FOLFOX plus bevacizumab, trifluridine/tipiracil plus bevacizumab, and nivolumab, for the treatment of CRC, and in combination with nivolumab for the treatment of solid tumors, to assess zolucetide’s potential as part of combination regimens for the treatment of and reduction in tumors in CRC and other solid tumors. The use of our product candidates in combination with each other and/or in patients already receiving other companies’ treatments may subject us to risks that we would not face if our product candidates were to be administered as monotherapies.

For example, either the combination of our product candidates with each other, or when used in patients already receiving other companies' products or product candidates, may result in unexpected adverse side effects or toxicities that the product candidates or other therapy do not produce when used alone. In addition, the product candidates may interact with each other, or with other companies' products or product candidates that patients receiving our product candidates may also be receiving, in undesirable ways that could negatively impact the potency or efficacy and safety of our product candidates, or of the other companies' products or product candidates. Testing product candidates in patients already receiving other treatments may increase the risk of significant adverse effects or failed clinical trials. The timing, outcome and cost of the potential adverse effects of developing products to be used in patients already receiving other therapies is difficult to predict and dependent on a number of factors that are outside our reasonable control. If serious adverse or unexpected side effects are identified during development and are determined to be attributed to our product candidates, or the result of drug-drug interactions between our product candidate and any of the concomitant therapies given to the trial subjects, we, the Regulatory Authorities, or IRBs and other reviewing entities, could interrupt, delay, or halt clinical trials and could result in a more restrictive label or particularly narrow product indication (substantially limiting the product's commercial opportunities), a REMS or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities.

In addition, to the extent we choose to develop and commercialize a product candidate for use in patients receiving an already approved therapy, as is the case, in part, with zolucetide, any safety, efficacy, regulatory, manufacturing or supply issues that could arise with respect to the approved therapy could have an adverse impact on us. Prescribing information for the approved therapy, such as risk information like a boxed warning, or limitations of use, could negatively impact our ability to develop and commercialize a product as an add-on or as further supportive care to the approved therapy. If the approved therapy is replaced as the standard of care, Regulatory Authorities may require us to conduct additional clinical trials, or we may not be able to obtain adequate reimbursement from third-party payors. Further, Regulatory Authorities could revoke approval of the therapy patients in our clinical trials are receiving. The occurrence of any of these risks could result in an add-on product candidate being developed as further supportive care, if successfully developed and approved, being removed from the market or being less successful commercially. If Regulatory Authorities revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with respect to, therapies we choose to evaluate in conjunction with or as background or standard of care therapy for any of our product candidates, we may be unable to obtain regulatory approval of or to commercialize such product candidates in combination with these therapies. If we experience safety, tolerability or toxicity issues in any of our ongoing or planned clinical trials that allow patients to remain on other therapies, or if the efficacy data from these trials of our candidates administered to patients on other therapies are not favorable, our clinical development plans could be materially negatively affected or delayed, or we may not receive regulatory approval for our product candidates, which would materially harm our business and likely cause the market price of our common stock to decline.

In addition, because zolucetide is expected to be administered in combination with other therapies for certain indications, payors may assess the overall cost of the treatment regimen, not solely the cost or value proposition of our licensed product. Combination regimens are subject to heightened reimbursement risk, as payors may:

- decline to cover the full regimen based on the aggregated cost of the component therapies;
- require step-through use of lower-cost or single-agent treatments before approving the combination;
- assign the combination to a more restrictive formulary tier, resulting in higher patient cost-sharing or reduced utilization;
- impose prior authorization, clinical criteria or other restrictions that limit prescribing; or
- negotiate price concessions with us based on the cost structure or formulary status of the companion therapy.

Even if our product candidate demonstrates clinical benefit as part of a combination regimen, payors may determine that the incremental value is insufficient to justify the overall cost and may refuse to reimburse at levels that are acceptable to us or that support commercial viability. In addition, we do not control the pricing, contracting strategy or reimbursement profile of the companion therapy, which may change over time and adversely impact the attractiveness or economics of the combination. If coverage for the companion therapy is reduced, withdrawn, or made more restrictive, the value proposition for our product candidate could be materially weakened.

We have received Fast Track Designation for zolucetide in desmoid tumors, and we may in the future seek additional designations for our product candidates with Regulatory Authorities that are intended to confer benefits such as a faster development process, a streamlined review or regulatory exclusivity. There can be no assurance that we will successfully obtain additional designations, and even where our product candidates have been or are granted such designations, we may not be able to realize the intended benefits of such designations.

Regulatory Authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address serious conditions. These designations may confer benefits such as additional interaction with Regulatory Authorities, streamlined development pathways and expedited review procedures. However, there can be no assurance that we will successfully obtain such designations for our product candidates, and if we do successfully

obtain such designations, that a Regulatory Authority will not revoke such designation. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for our product candidates, there can be no assurance that we will realize their intended benefits.

For example, if a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation from the FDA. Fast Track Designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. An NDA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. In November 2025, we obtained Fast Track Designation for zolucetide in desmoid tumors, and we may seek additional designation for our current and future product candidates. Even where we have received and may in the future receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Additionally, the FDA may rescind any Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development activities.

Even in the absence of obtaining certain designations, a sponsor can seek priority review at the time of submitting a marketing application. The FDA may designate an application for priority review if the product is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for acting on a marketing application from ten months to six months. Priority review designation may be rescinded if a product no longer meets the qualifying criteria, and a priority review designation does not guarantee that FDA will in fact act more quickly on the application than if it were a standard review application.

Where appropriate, we may secure approval from Regulatory Authorities through the use of expedited approval pathways, such as accelerated approval from the FDA or comparable foreign abbreviated pathways. Even if we receive accelerated approval from the FDA or approval following comparable foreign abbreviated pathways by foreign Regulatory Authorities, if our confirmatory trials do not confirm clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or such Regulatory Authorities may seek to withdraw the accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our potential future product candidates from Regulatory Authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act ("FDCA"), and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also gives the FDA increased authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send status updates on such studies to the FDA every 180 days to be publicly posted by the agency, or if such post-approval studies fail to verify the drug's predicted clinical benefit. The FDA is empowered to act, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress.

Prior to seeking accelerated approval, or approval following comparable foreign abbreviated pathways, we would seek feedback from Regulatory Authorities and would otherwise evaluate our ability to seek and receive such accelerated approval or approval following comparable foreign abbreviated pathways. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from Regulatory Authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to apply for accelerated approval, or comparable foreign abbreviated pathways, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all. Regulatory Authorities could also require us to conduct further studies prior to considering our application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway, or comparable foreign abbreviated pathway, and subsequently converted by Regulatory Authorities to full approval. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We have been granted Orphan Drug Designation for zolucetide for the treatment of desmoid tumors and we may seek Orphan Drug Designation for other indications or for our other product candidates, but we may be unsuccessful in obtaining or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

As part of our business strategy, we have sought and may in the future seek Orphan Drug Designation for the product candidates we develop, and we may be unsuccessful in obtaining or maintain such designations. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In January 2026, the FDA granted Orphan Drug Designation to zolucetide for the treatment of desmoid tumors.

Similarly, in Europe, the European Commission grants Orphan Drug Designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an Orphan Drug Designation application. Orphan Drug Designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug Designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA, or the FDA from approving another marketing application for the same drug and for the same indication during the period of exclusivity, except in limited circumstances. The applicable period is seven years in the United States and 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

Even though we have obtained Orphan Drug Designation for zolucetide for the treatment of desmoid tumors, that exclusivity may not effectively protect such product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we have received Orphan Drug Designation for zolucetide for the treatment of desmoid tumors and may seek Orphan Drug Designation for applicable indications for our current and any future product candidates, we may be unable to maintain or obtain such designations. Even where we have and may in the future receive such designations, there is no guarantee that we will enjoy the benefits of such designations.

Disruptions at the FDA and other government agencies caused by, funding shortages, staffing limitations, or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent new or modified products from being developed, review, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and Regulatory Authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign Regulatory Authorities' ability to perform routine functions. Average review times at the FDA and foreign Regulatory Authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain Regulatory Authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, or if renewed global health concerns, funding shortages or staffing limitations hinder or prevent the FDA or other Regulatory Authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Our Helicon Discovery Platform and Our Use of Artificial Intelligence

Our approach to the engineering and development of our programs is unproven, and we may not be successful in our efforts to identify and develop any programs and product candidates of commercial value by leveraging our Helicon discovery platform.

The Helicon discovery platform and our approach to drug engineering and development utilizes, among other things, our proprietary AI and machine learning solutions to create a pipeline of product candidates. Because our approach is both proprietary and pioneering, the cost and time needed to develop our programs and product candidates can be difficult to predict, and our efforts may not result in the engineering and development of commercially viable human therapeutics.

Any drug engineering and development that we are conducting with our Helicon discovery platform may not be successful in identifying programs and product candidates that have commercial value or therapeutic utility. The Helicon discovery platform may initially show promise in identifying potential programs and product candidates, yet fail to yield viable programs and product candidates for clinical development or potential commercialization for a number of reasons, including:

- research programs to identify new programs and product candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new programs and product candidates. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop programs and product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price;
- programs and product candidates engineered with our Helicon discovery platform may not demonstrate efficacy, safety or tolerability, including because they may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies, or otherwise may interact with human biological systems in unforeseen, ineffective or possibly harmful ways;
- programs and product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance;
- competitors may develop alternative therapies that render our programs and product candidates non-competitive or less attractive; or
- a potential product candidate may not be capable of being produced at an acceptable cost.

In addition, we may in the future seek to identify and develop programs and engineer and develop product candidates that are based on novel targets and technologies that are unproven. If our activities fail to identify novel targets or technologies for drug engineering and development, or such targets prove to be unsuitable for treating human disease, we may not be able to develop viable additional programs and product candidates. We may never receive approval to market and commercialize any product candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. If the product candidates resulting from our programs prove to be ineffective, unsafe or commercially unviable, our programs and product candidates would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are substantially dependent on the successful application of our Helicon discovery platform to develop programs and product candidates that can be commercialized by us or our current or future collaboration partners.

Since our formation, we have focused on investing in our Helicon discovery platform to unlock a new way of developing programs and product candidates for development and, if approved, potential commercialization by us and our collaboration partners. The biotechnology industry is capital intensive, and our success depends significantly on our ability to apply our Helicon discovery platform to develop programs and engineer and develop product candidates that can be further developed by us or our current or future collaboration partners. Our ability to engineer and develop product candidates and increase revenue depends in large part on our ability to continue to enhance and improve our Helicon discovery platform. We have invested, and expect to continue to invest, in research and development efforts, acquisitions and licensing agreements that further enhance our Helicon discovery platform. These investments may involve significant time, risks and uncertainties, including the risks that any new software or hardware enhancement or the integration of software or hardware from a third-party licensor may not be introduced in a timely or cost-effective manner; may interfere with our intellectual property; may not keep pace with technological developments; may not achieve the functionality necessary to generate significant revenues; or other risks inherent to the use of AI to develop software. The success of any enhancement to our Helicon discovery platform depends on several factors, including (i) the development of more advanced AI models and algorithms; (ii) the generation of additional high quality and relevant data; (iii) innovation and investment in other experimental, computational and/or infrastructure technologies, including automation technologies; and (iv) increased computational storage and processing capacity.

The Helicon discovery platform depends upon the continuous, effective and reliable operation of our laboratory systems and AI solutions, including software, hardware, databases and related tools and functions, as well as the integrity of our data. We have from time to time found defects, vulnerabilities or other errors in such tools, functions and data, and new errors may be detected in the future. The risk of errors is particularly significant when new software code or hardware is first introduced or when new versions or enhancements of existing software code or hardware are implemented. Errors may also result from the interface of our proprietary software and hardware tools with our data or with third-party systems and data.

Further, the price of new equipment and hardware, including graphics processing units (“GPUs”) and random access memory (“RAM”), is subject to market fluctuations. Such fluctuations are influenced by factors, including supply and demand for such equipment. In the case of GPUs and RAM for AI services, current demand for certain types of GPUs, RAM and networking equipment far exceeds supply, impacting the price and availability of such hardware. As a result, the cost of new equipment has been and may in the future be unpredictable, and may also be significantly higher than our historical costs.

If we are unable to successfully enhance our Helicon discovery platform, or if there are any defects or disruptions in our Helicon discovery platform that are not timely resolved, our ability to develop new innovations and ultimately gain market acceptance of our products and our Helicon discovery platform, could be materially and adversely impacted, and our reputation, business, operating results and prospects could be materially harmed.

We have limited clinical data on product candidates that were computationally engineered with our Helicon discovery platform demonstrating whether they are safe or effective for long-term treatment in humans. The long-term safety and efficacy of product candidates computationally engineered with our Helicon discovery platform is unknown. Our approach may not result in time savings, higher success rates or reduced costs as we expect it to, and if not, we may not attract collaborators or develop new product candidates as quickly or cost effectively as expected and we therefore may not be able to execute on our strategic approach as originally expected.

Product candidates engineered with our Helicon discovery platform require substantial technical, financial and human resources to develop and potentially commercialize. We may not be able to maintain sufficient resources and expertise to discover additional programs and product candidates. If we are unable to identify successful programs and product candidates for preclinical and clinical development and regulatory approval in a timely matter or at all, we could experience significant delays or an inability to successfully pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our product candidates, which could harm our business.

Issues relating to our use of AI in the identification of our programs and the engineering and development of our product candidates could adversely affect our business and operating results.

We incorporate AI solutions, among other technologies and capabilities, into our Helicon discovery platform. There are risks involved in utilizing AI, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of AI or other emerging technologies increases regulatory, cybersecurity and other significant risks. If our AI systems fail to achieve their intended purposes – such as identifying binding sites on proteins, identifying viable therapeutic candidates or targets, predicting biological outcomes, producing reproducible

results, and other similar or related purposes – our product development efforts may be delayed or unsuccessful. If we are unable to successfully integrate and manage AI within our business, or if AI fails to deliver the expected benefits, our ability to develop our programs and product candidates could be materially adversely affected.

Issues relating to the use of new and evolving technologies such as AI may cause us to experience brand or reputational harm, competitive harm, legal liability and new or enhanced governmental or regulatory scrutiny, and we may incur additional costs to resolve such issues. Known risks of AI generally include inaccuracy, hallucinations, bias, intellectual property infringement or misappropriation, data privacy and cybersecurity issues and data provenance disputes. Perceived or actual technical, legal, compliance, privacy, security, ethical or other issues relating to the use of AI in biopharmaceutical development may cause public confidence in AI to be undermined, which could slow market acceptance of product candidates discovered and developed using AI. In addition, litigation or government regulation related to the use of AI may also adversely impact our ability to identify programs and engineer and develop product candidates using AI, as well as increase the cost and complexity of doing so. For example, regulators may limit our ability to develop or implement our proprietary AI models and algorithms and/or may eliminate or restrict the confidentiality of our proprietary technology, or may limit our ability to secure intellectual property rights to technologies created with the assistance of our proprietary AI models and algorithms, which could have an adverse effect on our business, results of operations and financial condition.

We also face increased competition from other companies that claim to use AI and related methods for drug engineering and development, some of which have more resources than we do and may have developed more effective methods than we and any third-party collaborators have, which may reduce our and any third-party collaborators' effectiveness in identifying potential product candidates and attracting additional collaborators to work with us. In particular, biotechnology companies based in China present both known and emerging competitive threats to our business. Many of these companies operate within innovation ecosystems characterized by substantial government investment, access to large and rapidly expanding biological and clinical datasets, and accelerated regulatory or funding pathways. These factors may allow Chinese biotechnology companies to develop, train and deploy advanced computational models, drug discovery platforms or design technologies more rapidly or at lower cost than we can. If our competitors are able to utilize new technologies more effectively (including but not limited to those that may involve AI or be created using AI) to discover, develop and commercialize products that compete with any of our programs and product candidates, such technologies could adversely impact our ability to compete.

Further, AI may have or produce errors or inadequacies that are not easily detectable. The quality of AI outputs depends heavily on the quality and quantity of input data. If the data used to train AI or the content, analyses or recommendations that AI applications assist in producing are or are alleged to be deficient, inaccurate, incomplete, hallucinatory, overbroad or biased, our business, financial condition and results of operations may be adversely affected. Developing, testing and deploying AI systems may also increase the cost profile of our product offerings due to the nature of the computing costs involved in such systems, which could impact our project margin and adversely affect our business and operating results.

The legal landscape and subsequent legal protection for the use of AI remains uncertain, and the increasing use of AI in drug discovery and development introduces new and evolving risks related to ownership, inventorship and protection of intellectual property generated by or with the assistance of AI technologies. For example, generative AI may be used improperly or inappropriately, which could lead to the tainting of our proprietary information and render us unable to qualify for certain patent or trade secret protection. Moreover, if our vendors, employees, suppliers or contractors with access to our proprietary and confidential information and know-how were to disclose such information as inputs to third-party AI tools this could lead to loss of trade secret protection and otherwise impact our ability to realize the benefit of our intellectual property. If we do not have sufficient rights to collect or use the data on which our AI relies or to the outputs produced by our Helicon discovery platform, we may incur liability through the alleged violation of certain laws, third-party privacy rights, online terms of service or other contracts to which we or our data providers are a party. In addition, we rely on third-party software and hardware for our Helicon discovery platform. If the relevant software or hardware, or updates to such software or hardware, were to become unavailable to us in the future on reasonable commercial terms, or if they became the subject of allegations of intellectual property infringement, our ability to continue to use our Helicon discovery platform could be affected. We also rely on public sources of data, such as the Protein Data Bank, Uniprot and DepMap, among others, which, if they became unavailable to us on reasonable terms, could affect our Helicon discovery platform. Regulatory and legal frameworks governing inventions created with or using AI are still developing and may create uncertainty regarding our ability to secure and enforce rights in such inventions.

AI presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of AI, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business operations. As with many technological innovations, AI presents risks and challenges that could impact our business. In addition to our Helicon discovery platform, we have adopted and integrated, and in the

future may adopt and integrate additional generative AI tools into our systems for specific use cases reviewed by our legal department and information technology department. Our vendors may incorporate generative AI tools into their offerings without disclosing this use to us, and the providers of these generative AI tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative AI, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Our use of AI may also lead to novel and urgent cybersecurity and privacy risks, which may adversely affect our operations and reputation, as well as the operations of any third-party collaborators. Emerging ethical issues surround the use of AI, and we may be subject to reputational and legal risk if our deployment or use of AI becomes controversial. Our use of AI may also, in the future, result in cybersecurity incidents that implicate personal data of customers or patients. Any such cybersecurity incidents related to our use of AI could adversely affect our reputation and results of operations.

A growing number of federal, state, and international legislators, agencies and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of AI, and use of such technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of AI and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. For example, the EU's Artificial Intelligence Act entered into force on August 1, 2024, with most provisions becoming effective on August 2, 2026. This legislation imposes significant obligations on providers and deployers of AI systems and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. The recently enacted United States Department of Justice Data Security Program (also known as the Bulk Data Transfer Rules), effective April 8, 2025, imposes complex additional restrictions on international data transfers, which may affect our ability to do business in manufacturing and clinical research in foreign countries. Likewise, in the United States, several states, including Colorado and California, passed laws to regulate various AI uses, including on deployment of AI in healthcare settings. At the federal level, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The FDA, for example, issued draft guidance on the use of AI in regulatory decision-making for drug products that centers on the context of use while establishing a credibility assessment framework for establishing and evaluating AI model outputs intended to support regulatory decision-making. If we develop or use AI systems governed by these laws or regulations, including as informed by regulatory guidance, we would need to meet higher standards of data quality, transparency, monitoring and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non-compliance. We expect other jurisdictions will adopt similar laws. Uncertainty in the legal regulatory regime may require significant resources to modify and maintain business practices to comply with U.S. and non-U.S. laws, the nature of which cannot be determined at this time. The scope of requirements depends on legal and risk determinations that rely on novel legal provisions that have not yet been interpreted by courts or regulators, and non-compliance can lead to significant fines or significant restrictions on our ability to conduct our business activities.

We utilize third-party open-source software ("OSS"), which presents risks that could adversely affect our business and subject us to possible litigation.

We utilize software that is licensed from third parties under open-source licenses, and we expect to continue to use such OSS in the future. Use of OSS may entail greater risks than use of third-party commercial software because open-source licensors generally do not provide support, updates or warranties or other contractual protections regarding infringement claims or the quality of the code. OSS may also be more susceptible to security vulnerabilities. The availability of OSS could be adversely affected by service outages, data loss, privacy breaches, cyber-attacks and other events relating to the availability of these applications and services they provide, which could diminish the utility of these services and harm our business. We also could be subject to lawsuits by third parties alleging that what we believe to be licensed OSS infringes such parties' intellectual property rights, which could be costly for us to defend and require us to devote additional research and development resources to change our solutions. Some OSS licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of OSS we use. If we combine our proprietary software with OSS in a certain manner, we could, under certain of the OSS licenses, be required to release the source code of our proprietary software to the public. This could allow our competitors to create similar products with lower development effort and time, and ultimately could result in a loss of product sales for us. Although we monitor our use of OSS, the

terms of many OSS licenses have not been interpreted by U.S. courts, and there is a risk that those licenses could be construed in a manner that could impose unanticipated conditions or restrictions on our ability to commercialize our product candidates. We could be required to seek licenses from third parties in order to continue using our software, to re-engineer our software or to discontinue use of our software in the event re-engineering cannot be accomplished on a timely basis, any of which could materially and adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Manufacturing of Our Product Candidates and Our Future Pipeline

We rely on third parties for the supply and manufacture of our product candidates for our research, preclinical and clinical activities, and may do the same for commercial supplies of our products, if approved. As our pipeline increases and matures, the increased demand for supplies from our manufacturers may increase the risk that we will not have sufficient supply when needed or at an acceptable cost.

We currently utilize, and expect to continue to utilize, CDMOs to, among other things, supply and manufacture raw materials, components, parts and consumables, and to perform quality testing for our preclinical and clinical supply for all of our product candidates. For example, we are party to agreements with WuXi AppTec Co. Ltd. (“WuXi”) and Bachem Americas, Inc. for our active pharmaceutical ingredient (“API”), and Alcam Corporation (“Alcami”) for our drug product manufacturing. We intend to continue to rely on these manufacturers, and other manufacturers to manufacture zolucetide. In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our CDMOs will be required to increase their production and optimize their manufacturing processes while maintaining the quality of our product candidates, as applicable. The transition to larger scale production could prove difficult. If our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the same quality, then we may not be able to meet the demands of clinical trials or market demands, which could adversely impact our ability to timely conduct our clinical trials or commercialize our product candidates, if approved, and have a material adverse impact on our business and results of operations. Furthermore, with the increase of companies developing complex synthetic therapeutics, there may be increased competition for the supply of the raw materials that are necessary to manufacture our product candidates, which could severely impact the manufacturing of our product candidates.

Even if we are able to maintain arrangements with our CDMOs, reliance on CDMOs entails additional risks, including:

- the failure of the CDMO to comply with applicable regulatory requirements and reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our CDMOs give greater priority to the supply of other products over our product candidates or otherwise do not perform satisfactorily according to the terms of the agreement between us;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- the possible breach of manufacturing agreements by our CDMOs because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by our CDMOs, at a time that is costly or inconvenient to us; and
- the possible misappropriation of our proprietary technology and IP, including our know-how.

If we are unable to maintain our key manufacturing relationships, we may fail to find replacement CDMOs, which could delay or impair our ability to obtain regulatory approval for our product candidates. If we do find replacement CDMOs, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the Regulatory Authorities.

We do not currently have long-term supply contracts with all of our suppliers and they are not obligated to supply materials to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant purchase orders. As a result, our suppliers could stop selling to us at commercially reasonable prices, or at all. While we intend to enter into long-term master supply agreements with certain of our suppliers and manufacturers in the future as we advance our clinical trials or commercialization plans, we may not be successful in negotiating such agreements on favorable terms or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. If we do enter into such long-term master supply agreements, or enter into such agreements on less favorable terms than we currently have with such manufacturers, we could be subject to binding long-term purchase obligations that may be harmful to our business, including in the event that we do not conduct our trials on planned timelines or utilize the materials that we are required to purchase.

Additionally, if a CDMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CDMO. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidates according to the specifications previously submitted to the Regulatory Authorities. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. The delays associated with the verification of a new CDMO could negatively affect our ability to develop or commercialize our product candidates in a timely manner or within budget. Furthermore, a CDMO may possess technology related to the manufacture of our product candidates that such third party owns independently. This would increase our reliance on such CDMO or require us to obtain a license from such CDMO in order to have another third party manufacture our product candidates.

If any of our product candidates are approved by any Regulatory Authority, we will likely utilize arrangements with CDMOs for the commercial production of such product. This process is difficult and time-consuming and we may face competition for access to manufacturing facilities as there are a limited number of CDMOs operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with CDMOs on satisfactory terms, which could delay our commercialization.

The operations of our suppliers and CDMOs, some of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects. As a result of our global suppliers, we are subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and CDMOs' compliance with cGMPs or status acceptable to Regulatory Authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries;
- disruptions in operations due to global, regional or local public health crises or other emergencies or natural disasters;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our CDMOs or suppliers are located.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs. It is possible further tariffs may be imposed that could affect imports of active pharmaceutical ingredients used in our product candidates, or our business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to such raw materials used in our product candidates. Given the unpredictable regulatory environment in China and the United States and uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements and policies, further governmental action related to tariffs, additional taxes, contracting matters, regulatory changes or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business, financial condition, results of operations and growth prospects. These and other factors beyond our control could interrupt our suppliers and CDMOs' production, influence their ability to export and manufacture our clinical supplies, cost-effectively or at all, and inhibit their ability to procure certain materials, any of which could harm our business, financial condition, results of operations and prospects.

We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. If we are unable to source these supplies on a timely basis, or establish longer-term contracts with our suppliers, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.

We depend on sole source and limited source suppliers for certain raw materials, APIs, drug products, drug substances and other materials used in our product candidates. For example, we are party to an agreement with Alcamis, which is currently our sole supplier for drug product. Any change in our relationships with such suppliers or changes to contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations and prospects. Moreover, there may be difficulties in scaling up the clinical or commercial quantities of our product candidates despite such agreements, and the costs of manufacturing could become prohibitive.

Furthermore, any of the sole source and limited source suppliers upon whom we rely could stop producing our supplies, cease operations or be acquired by, or enter into exclusive arrangements with, our competitors. In addition, geopolitical tensions may impact our suppliers. For example, the U.S. BIOSECURE Act, which was enacted in December 2025, prohibits federal agencies from procuring or using any biotechnology equipment or services provided or produced by “biotechnology companies of concern,” or entering, extending, or renewing any contracts with entities that use such biotechnology equipment or services from “biotechnology companies of concern” To perform on those contracts. The Office of Management and Budget (“OMB”) will issue a list of “biotechnology companies of concern” in the near term, which will include companies that are named in the Department of Defense’s 1260H List of Chinese military companies and companies that OMB designates as a “biotechnology company of concern,” which are entities under the control of a foreign adversary (like China) and that pose a risk to national security based on its research with foreign government militaries or multiomic data collection (e.g., collection of genomic information) without consent. While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts, and has carveouts that protect drugs paid under Medicaid, subject to the Secretary of Veteran Affairs’ discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain. This and similar laws could have the potential to restrict the ability of companies to work with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government. It is possible some of our contractual counterparties, including WuXi, could be impacted by such future legislation or government policies. If any of the other third-parties that we engage to supply any materials or manufacture products for our preclinical studies and clinical trials should cease to continue to do so, or if we are prevented or restricted from using their services for any reason, we could experience delays in advancing these studies and trials while we identify and qualify replacement suppliers.

Establishing additional or replacement suppliers, and obtaining regulatory clearance or approvals that may result from adding or replacing suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business, financial condition, results of operations and prospects. Any such interruption or delay may force us to seek similar supplies from alternative sources, which may not be available at reasonable prices, or at all. Any interruption in the supply of sole source or limited source components for our product candidates would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on limited or sole source suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

The product candidates we develop may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of our CDMOs encounter such difficulties, our ability to supply material for clinical trials or any approved product could be delayed or stopped.

The manufacturing processes for our product candidates are complex and, if not developed and manufactured under well-controlled conditions, can adversely impact pharmacological activity. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage and supply chain management or shipping. These difficulties could be due to any number of reasons, including, but not limited to, complexities of producing batches at larger scale, equipment failure, choice and quality of raw materials and excipients, analytical testing technology and product instability. Moreover, we are currently conducting, and will in the future conduct, our clinical trials internationally. For example, we plan to enroll patients in our ongoing Phase 1/2 clinical trial for zolucetide in patients with advanced solid tumors in Australia and China, and we plan to conduct our registrational Phase 3 clinical trial for zolucetide in patients with desmoid tumors in these countries. Logistical issues associated with shipping our product candidates and other materials globally from manufacturing sites to clinical sites, such as errors or improper handling by third-party carriers, transportation restrictions, or interruptions caused by natural disasters or force majeure events, could result in loss or destruction of, or damage to, our clinical supply, which may in turn cause delays in initiating or completing clinical trials.

As our product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Our rate of innovation is high, which has caused, and will continue to cause, a high degree of technological change. As we scale the manufacturing output for particular product candidates, we plan to continuously improve yield, purity and the pharmaceutical properties of our product candidates from IND-enabling studies through commercial launch, including shelf-life stability, and solubility properties of product and drug substance. Because of continuous improvement in manufacturing processes, we may switch processes for a particular product candidate during development. However, after a change in process, additional time is required for pharmaceutical property testing, such as 6- or 12-month stability testing. Such testing may require resupplying clinical material, or making additional cGMP batches to keep up with clinical trial demand before such pharmaceutical property testing is completed.

Such technological changes can negatively impact product comparability during and after clinical development. Furthermore, technological changes may drive the need for changes in, modification to or the sourcing of new manufacturing infrastructure or may adversely affect third-party relationships. Such technological changes also carry the risk that they will not achieve these intended objectives. Any of these technological changes could cause our product candidates to perform differently and affect the results of planned or future clinical trials conducted with the materials manufactured using altered processes, such as impacting the specification and stability of the product. Such changes may also require additional testing, notification or approval by Regulatory Authorities. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue. Changes in our manufacturing processes may lead to failure of lots and this could lead to a substantial delay in our clinical trials. Our product candidates may also prove to have a stability profile that leads to a lower than desired shelf life of the final approved product. This poses risk in supply requirements, wasted stock and higher cost of goods.

We have established a number of analytical assays, and may have to establish several more, to assess the quality of our product candidates. We may subsequently identify gaps in our analytical testing strategy that might prevent release of product or could require product withdrawal or recall. For example, we may discover new impurities that have an impact on product safety, efficacy or stability. This may lead to an inability to release product candidates until the manufacturing or testing process is rectified.

Moreover, there are risks inherent in biopharmaceutical manufacturing operations that could affect our ability and the ability of the CDMOs or contract manufacturing organizations to meet our delivery requirements or provide adequate amounts of material. The convergence of process and analytical technology, raw materials, consumables, equipment, physical infrastructure, including a clean room environment, and air handling and other utilities, results in complex procedures and systems that must work effectively to manufacture our product candidates. Failure or process defects in any of the interrelated systems at either our manufacturing facilities or those of our third-party providers could adversely impact our ability to manufacture and supply our product candidates.

Certain of our product candidates require specific shipping, storage, handling and administration, which in some cases, may require cold-chain logistics and subject our product candidates to risk of loss or damage if failures occur.

Certain of our product candidates are sensitive to temperature, storage and handling conditions. They must be stored at very low temperatures in specialized freezers or specialized shipping containers until immediately prior to use. The handling and administration of our product candidates may need to be performed according to specific instructions and in some steps within specific time periods. Failure to correctly handle our product candidates could negatively impact the efficacy and/or safety of our product candidates, or cause a loss of product candidates. In addition, because it is necessary to ship our product candidates and other materials globally from manufacturing sites to clinical sites, our product candidates will need to be frozen using specialized equipment and maintained following specific procedures in order to be shipped and stored without damage in a cost-efficient manner and without degradation. For administration, the cryopreserved product container must be carefully removed from storage, and rapidly thawed under controlled temperature conditions in an area proximal to the patient's bedside and administered into the patient. The handling, thawing and administration of the cryopreserved therapy product must be performed according to specific instructions, typically using specific disposables, specific bags and in some steps within specific time periods. Failure to correctly handle our product candidates, including the potential breakage of the cryopreservation bags or to follow the instructions for thawing and administration and or failure to administer our product candidates within the specified period post-thaw could negatively impact the efficacy and/or safety of our product candidates, or cause a loss of our clinical supply.

If any of our product candidates are approved, we will need to scale-up a cost-effective and reliable cold-chain distribution and logistics network, which we may be unable to accomplish. Failure to effectively scale-up our cold-chain supply logistics, by us or third parties, could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for our commercial supply, if approved. For these and other reasons, we may not be able to manufacture our current or future product candidates at commercial scale or in a cost-effective manner. Even if we or our CDMOs are able to manufacture and distribute the products, if our products require specific procedures to maintain and use them, we may be limited in commercial opportunity.

We are subject to significant regulatory oversight with respect to manufacturing our product candidates. The manufacturing facilities of our CDMOs or suppliers may not meet regulatory requirements. Failure to meet cGMP requirements set forth in regulations promulgated by Regulatory Authorities could result in significant delays in and costs of our products.

The manufacturing of therapeutics for clinical trials or commercial sale is subject to extensive regulation. Components of a finished product approved for commercial use or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including recordkeeping, and the implementation and operation of quality systems to control and assure the quality of products and materials used in clinical trials. Poor control of the cGMP production processes can lead to product quality failures that can impact our ability to supply product, resulting in cost overruns and delays to clinical timelines, which could be extensive.

Such production process issues include, but are not limited to: critical deviations in the manufacturing process; facility and equipment failures; contamination of the product due to an ineffective quality control strategy; facility contamination as assessed by the facility and utility environmental monitoring program; ineffective process, equipment or analytical change management, resulting in failed lot release criteria; raw material failures due to ineffective supplier qualification or regulatory compliance issues at critical suppliers; ineffective product stability; failed lot release or facility and utility quality control testing; ineffective corrective actions or preventative actions taken to correct or avoid critical deviations due to our developing understanding of the manufacturing process as we scale; and failed or defective components or consumables.

We must supply all necessary documentation in support of an NDA or other marketing authorization application on a timely basis and must adhere to the cGMP requirements of the Regulatory Authorities which are enforced, in the case of the FDA, in part through its facilities inspection program.

Regulatory Authorities typically require representative manufacturing site inspections to assess adequate compliance with cGMPs and manufacturing controls as described in the filing. If either we or one of our third-party manufacturing sites fails to provide sufficient quality assurance or control, the product approval to commercialize may not be granted. Inspections by Regulatory Authorities may occur at any time during the development or commercialization phase of products. The inspections may be product specific or facility specific for broader cGMP inspections or as a follow up to market or development issues that the regulatory agency may identify. Deficient inspection outcomes may influence the ability of our CDMOs or suppliers to fulfill their supply obligations, impacting or delaying supply or delaying product candidates.

The manufacturing process for any products that we may develop is subject to the approval process of the Regulatory Authorities, and we will need to contract with CDMOs who we believe can meet such requirements on an ongoing basis. If we or our CDMOs are unable to reliably produce product candidates to specifications acceptable to Regulatory Authorities, we or our collaboration partners may not obtain or maintain the approvals we or they need to commercialize such products. Even if we or our collaboration partners obtain regulatory approval for any of our product candidates, there is no assurance that either we or our contract manufacturing organizations will be able to manufacture the approved product to specifications acceptable to the Regulatory Authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts or increase our cost of goods. The occurrence of any of the foregoing could have an adverse effect on our business, financial condition, results of operations and growth prospects.

We have limited control over the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMPs. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of Regulatory Authorities, we may not be able to secure and/or maintain regulatory approval for our product candidates manufactured at these facilities. In addition, we have limited control over the ability of our CDMOs to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our CDMOs are engaged with other companies to supply or manufacture materials or products for such companies, which exposes our CDMOs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory status of our CDMOs' facility. Our failure, or the failure of our CDMOs, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates (including those of our collaboration partners) and our overall business operations. Our dependence upon others for the manufacture of our product candidates and raw materials may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

Regulatory Authorities may require us to submit product samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the Regulatory Authorities may require that we do not distribute a lot or lots until the relevant agency authorizes such release. Deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls with respect to products produced by either our own facilities or those of our CDMOs could cause us and our collaboration partners to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes and operations, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. While we will train and qualify all personnel around the appropriate handling of our products and materials, we may not be able to control or ultimately detect intentional sabotage or negligence by any employee or contractor.

Risks Related to Our Reliance on Third Parties

We rely on and expect to continue to rely on third parties to conduct aspects of our research, preclinical studies, clinical protocol development and clinical trials for our programs and product candidates. If these third parties do not perform satisfactorily, comply with regulatory requirements or meet expected deadlines, we may not be able to develop product candidates in a timely or cost-effective manner, or obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We currently rely and expect to continue to rely on third parties, such as CROs to perform early stage research work such as synthesis and biology, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials, including our ongoing Phase 1/2 clinical trial for zolucetide in patients with advanced solid tumors. We currently rely and expect to continue to rely on third parties to conduct certain research and preclinical testing activities. In some cases, these third parties may terminate their engagements with us. If we need to enter into alternative arrangements, it could delay our product development activities or increase our costs.

Our reliance on these third-parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory or contractual responsibilities. We will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs will be required to comply with regulations, including GCPs, for conducting, monitoring, recording and reporting the results of preclinical studies and clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial participants are adequately informed, among other things, of the potential risks of participating in clinical trials. We are also responsible for ensuring that the rights of our clinical trial participants are protected. These regulations are enforced by Regulatory Authorities for any product candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and Regulatory Authorities may require us to perform additional clinical trials before approving our marketing applications. There is no assurance that the FDA or other Regulatory Authorities, upon inspection, will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements in cGMP regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.

Although we intend to design the clinical trials for certain of our product candidates, our collaboration partners may design the clinical trials that they are managing (in some cases, with our input) and in the case of clinical trials controlled by us, we expect that CROs will perform many of the activities required to conduct clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will, in many respects, be outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials will also result in less direct control over the management of data developed

through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also potentially lead to mistakes as well as difficulties in coordinating activities. Outside parties may: have staffing difficulties; fail to comply with contractual obligations; experience regulatory compliance issues; undergo changes in priorities or become financially distressed; form relationships with other entities, some of which may be our competitors; have human errors or be subject to cyber-attacks.

These factors may materially adversely affect the willingness or ability of third parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs do not perform preclinical studies and clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CROs, we could be required to repeat, extend the duration of or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

We also expect to rely on other third parties to transport, store and distribute the required materials for our clinical trials. In the past, certain of our third-party vendors have mishandled our materials, resulting in loss of full or partial lots of material. Any further performance failure on the part of these third-parties could result in damaged products and could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue, causing us to default on our contractual commitments, result in losses that are not covered by insurance, and damage our reputation and overall perception of our products in the marketplace.

Any of the third-party organizations we utilize may terminate their engagements with us under certain circumstances. The replacement of an existing CRO or other third party may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates. For example, although we believe there are a number of other CROs we could engage, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, while we believe there may be suitable replacements for one or more of these service providers, there is a natural transition period when a new service provider begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition, results of operations and growth prospects.

We have in the past entered into, and in the future may enter into, partnership, collaboration, and licensing arrangements with third parties to support development and potential commercialization of programs and product candidates. If these partnership, collaboration, and licensing arrangements are not successful, our business could be adversely affected.

We have entered into and may in the future seek to enter into partnership, collaboration, and licensing arrangements with third parties, which we refer to generally as our “collaboration partners” for strategic purposes, including for purposes of collaborating with collaboration partners with distinctive capabilities or experience with different modalities, working with collaboration partners capable of advancing the development and commercialization of our product candidates, and providing access to additional capital.

For example, we are party to a collaboration arrangement with Regeneron, pursuant to which we collaborate on research and preclinical development programs directed toward certain targets. We may enter into additional partnership, collaboration, and licensing arrangements to take advantage of our Helicon discovery platform, including for purposes of accessing additional capabilities, expertise and funding in the future. Our existing partnership, collaboration, and licensing arrangements, and any future partnership, collaboration, and licensing arrangements we may enter into, could pose a number of risks, including the following:

- collaboration partners may not perform their obligations as expected;
- the clinical trials conducted as part of such partnership, collaboration, and licensing arrangement may not be successful;
- collaboration partners may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization of programs based on clinical trial results, changes in the strategic collaborators’ focus or available funding, or external factors, such as an acquisition, which divert resources or create competing priorities;
- collaboration partners may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaboration partners could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the strategic collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product candidates developed in partnership, collaboration, and licensing arrangements with us may be viewed by our collaboration partners as competitive with their own candidates or products, which may cause collaboration partners to cease to devote resources to the development of our programs or the development or commercialization of our product candidates;
- a collaboration partner with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product;
- a collaboration partner may exercise its right to terminate under a collaboration agreement which may require us to pay certain cancellations fees or reimburse such partner for certain expenses;
- disagreements with collaboration partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaboration partners may not properly maintain or defend our IP rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the interpretation of key terms regarding control, economic rights, or the ownership of intellectual property developed pursuant to our partnership, collaboration, and licensing arrangements;
- collaboration partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- partnership, collaboration, and licensing arrangements may, in certain instances, be terminated for the convenience of the collaboration partner and, if terminated, the development of our programs and product candidates may be delayed, or we may lose rights to IP or expertise related to such programs and products candidates, and we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates;
- future relationships may require us to incur non-recurring and other charges, assume indebtedness or contingent liabilities, increase our near- and long-term expenditures, acquire intangible assets, issue securities that dilute our existing stockholders, disrupt our management and business, or otherwise impact our ability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs;
- we could face significant competition in seeking appropriate collaboration partners and the negotiation process and diligence process is time-consuming and complex; and
- our international operations, through any future partnerships, collaborations, acquisitions or joint ventures, may expose us to certain operating, legal, and other risks not encountered in the United States.

Whether we reach a definitive agreement for a partnership, collaboration, or licensing arrangement will depend, among other things, on our assessment of the collaboration partner's resources and expertise, the terms and conditions of the proposed partnership, collaboration, or licensing arrangement, and the potential collaboration partner's evaluation of a number of factors. Those factors may include, among others: (i) our technologies and capabilities, including our Helicon discovery platform; (ii) our intellectual property position with respect to the subject program or product candidate; (iii) the design or results of clinical trials; (iv) the likelihood of approval by Regulatory Authorities; (v) the potential market for the subject product candidate; (vi) potential competing products; and (vii) industry and market conditions generally. In addition, the significant number of business combinations among large pharmaceutical and biotechnology companies has reduced the number of potential future collaboration partners with whom we can partner.

Partnership, collaborations, and licensing arrangements are complex and time-consuming to negotiate and document. We may have to relinquish valuable rights to our programs and product candidates, intellectual property or future revenue streams, or grant licenses on terms that are not favorable to us or in instances where it would have been more advantageous for us to retain sole development and commercialization rights. For some programs and product candidates, we depend on collaboration partners to design and conduct the clinical trials. As a result, we may not control the manner or time schedule in which these clinical trials are conducted, which may negatively impact our business operations. In addition, if any of our collaboration partners withdraws support for one or more of our programs or product candidates or otherwise impairs their development, our business could be negatively affected. In addition, management of our relationships with collaboration partners requires (i) significant time and effort from our management team; (ii) coordination of our marketing and research and development programs with the marketing and research and development priorities of our collaborators; and (iii) effective allocation of our resources across multiple projects.

Partnerships, collaborations, and licensing arrangements may never result in the successful development of programs or development and commercialization of product candidates or the generation of sales revenue. The success of these arrangements will depend heavily on the efforts and activities of our collaboration partners. Collaboration partners generally have significant discretion in determining the efforts and resources that they will apply to the development of programs and the development and commercialization of product candidates, and they may not pursue or prioritize the development and commercialization of such programs and product candidates in a manner that is in our best interests. Product revenues arising from partnership, collaboration, and licensing arrangements are likely to be lower than if we directly marketed and sold products. Disagreements with collaboration partners regarding clinical development or commercialization matters can lead to delays in the development process or commercialization of the applicable product candidate and, in some cases, the termination of the partnership, collaboration, or licensing arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Partnership, collaboration, and licensing arrangements are often terminable by the collaboration partner, and any such termination or expiration would adversely affect us financially and could harm our business reputation. If we were to become involved in arbitration or litigation with any of our collaboration partners, it would consume time and divert management resources away from operations, damage our reputation, impact our ability to enter into future partnership, collaboration, and licensing arrangements and may further result in substantial payments from us to our collaboration partners to settle those disputes.

We may not be able to establish additional partnership, collaboration, and licensing arrangements on a timely basis, on acceptable terms, or at all, and to maintain and successfully conclude them. Such arrangements with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return. If we are unable to establish or maintain partnership, collaboration, and licensing arrangements on terms favorable to us and realize the intended benefits of those arrangements, our research and development efforts and potential to generate revenue may be limited and our business and operating results could be materially and adversely impacted.

As part of these collaborations, we may not fully control the progression, clinical development, regulatory strategy or eventual commercialization, if approved, of our jointly-developed product candidates. As a result, our future success and the potential to receive revenues under these partnership, collaboration, and licensing arrangements are significantly dependent on our collaboration partners' efforts, over which we have little control. If our partnership, collaboration, and licensing arrangements do not result in the successful development and commercialization of product candidates, a collaboration partner determines not to proceed with the future development of a program or product candidate initially engineered or developed utilizing our Helicon discovery platform, a collaboration partner implements a clinical or regulatory strategy that ultimately does not enable the further development, approval or commercialization of the product candidate, or a collaboration partner terminates its arrangement with us, we may not receive any future research funding or milestone, earnout, royalty or other contingent payments under such arrangement, which may have a material and adverse effect on our business and revenues. In addition, our ability to monitor the achievement of clinical, regulatory and commercial milestones by our collaboration partners and enforce the payment of any corresponding fees is limited. If we do not receive the funding we expect under these agreements, the development of our and our other collaboration partners' product candidates could be delayed and we may need additional resources to develop such product candidates.

In addition, our collaboration partners have, and future collaboration partners may have, the right to terminate their agreements with us for convenience. If one of our collaboration partners terminates its arrangement with us, we may be required to pay certain fees, may find it more difficult to attract new partnership, collaboration, and licensing arrangements and the perception of us in the business and financial communities could be adversely affected. We cannot assure investors that we will be able to maintain or expand our existing collaboration partners or that our Helicon discovery platform will achieve adequate market acceptance among new collaboration partners. Any failure to increase penetration in our existing markets or new markets would adversely affect our ability to improve our operating results from our collaboration, partnership and licensing strategy.

All of the risks relating to product development, regulatory approval and commercialization described in this prospectus apply to the activities of our current and future collaboration partners. If we or our collaboration partners do not achieve regulatory approval for a sufficient number of product candidates, we may not be able to sustain our business model.

Risks Related to Our Intellectual Property

Our success is largely based upon our intellectual property related to our proprietary technologies, and we may be unable to adequately obtain, maintain, protect, defend and/or enforce our intellectual property.

Our success depends, in large part, on our ability to obtain, maintain, protect, defend and/or enforce patent, trademark, and other intellectual property, including trade secret and know-how, protection of our product candidates, Helicon discovery platform and other proprietary technologies, as well as our ability to operate, develop, manufacture and commercialize our product candidates without infringing, misappropriating or otherwise violating the intellectual property or other proprietary rights of our competitors or any other third parties, including any non-practicing entities or patent assertion entities. If we (or our licensees or licensors who may have the

right to prosecute, obtain, maintain, defend and/or enforce certain patents within our portfolio) fail to appropriately prosecute or are unable to obtain, maintain, defend and/or enforce patents for our product candidates (or aspects thereof), our ability to develop, manufacture, license and/or commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using, offering to sell, selling or importing competing products. Our failure or inability to properly and adequately protect the intellectual property rights relating to our product candidates could have a material adverse effect on our business, financial condition, results of operations and/or growth prospects.

We generally seek to protect our intellectual property position by filing and/or licensing patent applications in the United States and, in various patent families certain but not all foreign jurisdictions, related to our Helicon discovery platform, product candidates and other proprietary technologies that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent that the issued claims cover third parties' activities in the jurisdictions in which they are performed. We cannot be certain that the claims in any of our patent applications will be considered patentable by the United States Patent and Trademark Office ("USPTO"), courts in the United States or the patent offices and courts in other jurisdictions, including Europe, nor can we be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged. Accordingly, there can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will adequately cover our product candidates or otherwise afford sufficient protection against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated or held unenforceable. Furthermore, we may not be able to apply for patents on certain aspects of our current or future Helicon discovery platform, product candidates, or other proprietary technologies in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent protection we obtain may not be sufficient to prevent substantial competition.

The use of AI to design, develop and engineer proteins is a relatively new scientific field, the continued development and potential use of which has resulted in many different patents and patent applications from organizations and individuals seeking to obtain intellectual property protection in the field. In general, patents are reserved for human inventors and significant and novel legal questions remain in flux about the contributory roles of AI versus the human inventors in securing intellectual property rights. We may not be able to obtain, maintain, protect, defend, and/or enforce patent protection for our AI technologies including their uses in the development of Helicons including those utilized in our product candidates. Our current programs, in addition to AI technologies, include many other non-AI technologies and involve significant and critical input, direction, design optimization and/or decision-making from humans. Despite the significant and critical involvement of humans in the development of our current Helicon discovery platform and product candidates, our intellectual property rights including patents related thereto may be challenged, and we may not be able to adequately defend and/or enforce such intellectual property rights. Many aspects of our AI technologies are protected as trade secrets or otherwise as confidential information. We may not be able to preserve the confidentiality of our trade secrets and other confidential information; if confidentiality is lost, third parties including our competitors may be able to use such trade secrets and other confidential information.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining, maintaining, enforcing and defending patents. Patent applications are processed by various national patent offices around the world. There is uncertainty about which patents will issue, and, if they do, as to when, to whom, and with what claims. These risks and uncertainties include the following:

- the USPTO and various foreign government patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application or a finding that a patent is unenforceable, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patent being issued;
- patents that may be issued may not include claims that cover a broad enough scope to prevent competitor activities including alternative solutions by competitors;
- patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide adequate barriers to entry or any competitive advantage;
- because of the extensive time required for development, testing and regulatory review of a product candidate, it is possible that before a potential product can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization thereby reducing, or eliminating any advantage of the patent;

- our competitors, many of which have substantially greater resources than we or our partners do, and many of which have made significant investments in competing technologies, may seek, or may already have sought or obtained, patents that will limit, interfere with or eliminate our ability to make, use, offer to sell, sell, import or otherwise exploit our product candidates or other technologies;
- other parties may design or may have designed around our patent claims, or may develop or may have developed technologies that may be related or competitive to our product candidates or other technologies, may file and may have filed or may file patent applications and may receive or may have received patents that overlap or conflict with our patent filings, either by claiming the same or overlapping methods, products, reagents or devices or by claiming subject matter that could dominate one or more of our patent claims;
- any successful opposition to any patents owned by or in-licensed to us could deprive us of rights necessary for the development and exploitation of our product candidates and other technologies or the successful commercialization of any product candidates and other technologies that we may develop;
- because patent applications in the United States and most other jurisdictions are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates or other proprietary technologies;
- a court or patent office proceeding, such as a derivative action or interference, can be provoked or instituted by a third party or a patent office, and might determine that one or more of the inventions described in our patent filings, or in those we licensed, was first invented by someone else, so that we may lose rights to such invention(s);
- a court or other patent proceeding, such as an inter partes review, post grant review or opposition, can be instituted by a third party to challenge the inventorship, scope, validity and/or enforceability of our patent claims and might result in invalidation or revision of one or more of our patent claims, or in a determination that such claims are unenforceable;
- there may be significant pressure on the U.S. government and other governmental bodies to limit the scope of patent protection or impose compulsory licensing of patent rights for disease treatments that prove successful as a matter of public policy; such a limit of the scope of our patent protection or compulsory licenses may render ineffective any patent protection we might obtain for our products and product candidates and/or could lead us to earning no or an inadequate return on our investments;
- countries other than the United States may have patent laws less robust and/or less favorable to patentees than those of the United States, allowing competitors the ability to exploit these laws to create, develop, and market competing products using our technologies; and
- we may be involved in lawsuits and/or proceedings before government agencies, such as patent offices, to defend or enforce our patents or the patents we have rights to enforce, which could be expensive, time-consuming, distracting and/or unsuccessful.

The patent position of biotechnology and biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. The standards that the USPTO and its counterparts use to grant patents are not always applied predictably or uniformly and can change. Similarly, the ultimate degree of protection that will be afforded to biotechnology inventions, including ours, in the United States and other countries, remains uncertain and is dependent upon the scope of the protection decided upon by patent offices, courts and lawmakers. Moreover, there are periodic changes in patent law, as well as discussions in the U.S. Congress and in foreign jurisdictions about modifying various aspects of patent law. There is no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. In certain countries, for example, methods for the medical treatment of humans are not patentable. More generally, the laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for granting, maintaining, protecting, defending and enforcing our intellectual property rights.

Furthermore, the patent prosecution process is also expensive and time-consuming, and we may not be able to file, prosecute, maintain, protect, defend, enforce or license all necessary or desirable patents or patent applications, as applicable, at a reasonable cost or in a timely manner. It is possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. We also rely to a certain extent on trade secrets, know-how, and other technologies, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technologies not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

The issuance of a patent is not conclusive as to its inventorship, priority date, scope, term, validity or enforceability so that any patents that may issue or that we may license may be challenged in the courts or patent offices in the United States, Europe and other jurisdictions. Once granted, patents may remain open to a variety of challenges, including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings, and furthermore, may be challenged as a defense in any enforcement action that we might bring. Such challenges may result in loss of exclusivity or in patent claims being narrowed, terminated, disclaimed, invalidated, assigned to others or held unenforceable, any or all of which could limit our ability to stop others from using or commercializing similar or identical products, or limit the scope and/or term of patent protection of our products and product candidates and/or eliminate it altogether, thus hindering or removing our ability to limit third parties from making, using or selling products or technologies that are similar or identical to ours, and/or reduce or eliminate royalty payments to us from our licensees. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our ability to enforce our owned and in-licensed patent and other intellectual property rights depends on our ability to detect infringement, misappropriation and other violation of such patents and other intellectual property. It may be difficult to detect infringers, misappropriators and other violators who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement, misappropriation or other violation in a competitor's or potential competitor's product or service, and in some cases we may not be able to introduce obtained evidence into a proceeding or otherwise utilize it to successfully demonstrate infringement. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our owned or in-licensed patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. If any of our owned or in-licensed patents covering our product candidates or other technologies are narrowed, invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our product candidates or other technologies, our competitive position could be harmed or we could be required to incur significant expenses to protect, enforce or defend our rights. If we initiate lawsuits to protect, defend or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel, even if the eventual outcome is favorable to us. The degree of future protection for our intellectual property and other proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates and other technologies;
- any of our pending patent applications or those of our licensors may issue as patents;
- others will not or may not be able to make, use, offer to sell or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we were the first to make the inventions covered by each of the patents and pending patent applications that we own or license;
- we, our co-owners or our licensors were the first to file patent applications for the inventions;
- others will not develop similar or alternative products or technologies that do not infringe the patents we own or license;
- any of the patents we own or license will be found to ultimately be valid and enforceable;
- any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates and other technologies or will provide us with any competitive advantages;
- a third party may not challenge the patents we own or license and, if challenged, a court would hold that such patents are valid, enforceable and infringed;

- we may develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our business;
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights to prevent such activities and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our development and commercialization activities, including our manufacturing processes, or products will not infringe upon the patents of our competitors or any other third parties, including any non-practicing entities or patent assertion entities.

In addition to patents, we also rely on confidential proprietary source codes, trade secrets and know-how. Although we have taken steps to protect the confidentiality of such proprietary source codes, trade secrets and know-how, including maintaining data security protocols and capabilities and entering into confidentiality agreements with third parties, and confidential information and assignment agreements with employees, consultants and advisors, there exists the potential that third parties may still somehow obtain this information or arrive at the same or similar information independently, which could reduce or eliminate our competitive advantages. Moreover, we may become subject to allegations that we directly or indirectly (through our employees, consultants, advisors or independent contractors that we may engage to assist us in developing our product candidates) have wrongfully or inadvertently disclosed, acquired or used trade secrets or other proprietary information of third parties.

We have or may have in the future collaborations to develop collaboration product candidates. Such collaboration product candidates are subject to at least the same risks as product candidates developed by ourselves, and they may be subject to additional risks associated with our collaborators' technologies. We may not fully control the development, manufacturing, or commercialization of our collaboration product candidates or our collaborators' activities. We and our collaborators may be unable to adequately obtain, maintain, protect, defend and/or enforce relevant intellectual property rights to protect the collaboration product candidates, and the development, manufacturing, or commercialization of our collaboration product candidates, by us or our collaborators or jointly, may infringe or otherwise violate intellectual property rights of third parties. We may be held responsible for part or all damages and costs in connection with the development, manufacture, or commercialization of such collaboration product candidates, and/or may be required to partially or fully defend or indemnify our collaborators in connection with the development, manufacture, or commercialization of our collaboration product candidates.

We may be forced to litigate to enforce or defend our intellectual property rights.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement by competitors, and to protect our trade secrets and know-how against unauthorized use, but we may not be able to detect or prevent, alone or with our licensors and/or licensees, infringement, misappropriation or other violation of our intellectual property rights. In so doing, we may place our intellectual property at risk of being invalidated, held unenforceable or rendered limited or narrowed in scope such that we may not be able to adequately prevent the manufacture, sale or import of competitive products. In an infringement proceeding, a court may decide that a patent we own or license, or a patent we license in the future is invalid, unenforceable or not infringed, or may refuse to stop the other party from using the claimed invention at issue. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Further, an adverse result in any litigation or other proceedings before government agencies such as the USPTO, may place pending applications at risk of non-issuance or burden them with material limitations in scope. Further, derivation proceedings, *ex parte* reexamination, inter partes review, post grant review and opposition proceedings initiated by third parties or brought by the USPTO or any foreign patent authority may be used to challenge the inventorship, ownership, claim scope or validity of our patents. Additionally, because of the substantial amount of discovery typically required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information, trade secrets or know-how could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the value of the company. Such litigation or proceedings could substantially increase our operating losses, reduce the resources available for development activities or any future sales, marketing or distribution activities and distract our personnel from their normal responsibilities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and/or more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Intellectual property rights of third parties could adversely affect our ability to develop or commercialize our product candidates, and we might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates.

Our commercial success depends in part on our ability and the ability of any of our current or future partners to develop, manufacture, market, offer to sell, sell, import or otherwise exploit our product candidates and our technologies without infringing the intellectual proprietary rights of third parties. There is a substantial amount of litigation and patent office proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology, biopharmaceutical, pharmaceutical and high-tech industries, including patent infringement lawsuits, oppositions, *ex parte* reexaminations, post-grant review, inter partes review and interference proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing product candidates.

Third parties may assert that we are employing or have employed their proprietary technology without authorization. There may be third-party patents or patent applications that claim compositions, formulations, methods of manufacture or methods for use that cover or relate to our product candidates, their manufacture or uses. Because patent applications in most countries remain confidential for a period of time after they are filed (commonly, 18 months from their earliest priority date), it is possible that there are unpublished patent applications that may later issue with claims that our product candidates, or their manufacturing or uses, may be alleged to infringe. Because patent applications can take many years to issue, there may be pending patent applications which do not currently seem relevant, but may later result in issued patents that our product candidates, or their manufacturing or uses, may be alleged to infringe. In addition, third parties may file and obtain patents in the future and then allege that our technologies infringe these patents. Additionally, under U.S. patent law, a patent owner may seek a reissue within two years of issuance of a patent to broaden the scope of that patent's claims if certain legal requirements are met. As a result, patents that, at the time of issuance, do not appear relevant to our activities may later be broadened in a manner that could impact our business. There may be analogous processes for broadening the scope of patents in other jurisdictions as well. Further, patent owners may seek to amend claims in granted or issued patents or otherwise initiate proceedings at the USPTO, foreign patent agencies or courts to fix errors, deficiencies, etc. in their patents or during the prosecution, maintenance or defense of their patents so that claims that are unenforceable and/or not valid become enforceable and not invalid. We cannot guarantee that any of our or our licensors' or licensees' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are or will be correct, complete or thorough, nor can we be certain that we or our licensors or our licensees have identified or will identify each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the development, manufacture, and commercialization of our current and future products and product candidates in any jurisdiction. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We or our licensors or our licensees may incorrectly determine that our products or product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we or our licensors or our licensees may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop, manufacture and market our products and product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. As the number of competitors in the market grows and the number of patents issued in this area increases, the probability of patent infringement claims increases. Defense of infringement and other claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Because our product candidates are still in developmental stages, and one or more features of the product candidates or related technologies such as their structures, manufacture, formulations or uses, may still change, we cannot be confident that we are aware of all third-party intellectual property that might be relevant to products that we eventually hope to commercialize. Various third-party competitors practice in relevant spaces, and may have issued patents, or patent applications that will issue as patents in the future, that will impede or preclude our ability to commercialize products. Furthermore, while U.S. patent laws provide a "safe harbor" to our clinical product candidates under 35 U.S.C. § 271(e)(1), which exempts from patent infringement activities related to pursuing FDA approval for a drug product, that exemption expires upon or around an NDA submission. Given the uncertainty of clinical trials, we cannot be certain of the timing of their completion and it is possible that we might want to submit an NDA at a time when one or more relevant third-party patents is in force. Thus, it is possible that at the time that we commercialize our product candidates, one or more third parties may have issued or later issue patent claims that cover our products or critical features of their production or uses. We may not be able to commercialize our products if patents issued to third parties or other third-party intellectual property rights cover, or may be alleged to cover, our products or elements thereof, or their methods of manufacture or uses at the time that we seek to commercialize them. In such cases, we may not be in a position to develop or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, successfully design around their claims, or enter into a license agreement with the intellectual property right holder(s). Such litigation or licenses could be costly or not available on commercially reasonable terms or timing or at all, and design-around could be prohibitively expensive or impossible.

If a third party alleges that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property allegations, which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention and financial resources from our core business;
- substantial damages for infringement or other violation of third-party rights, which we may have to pay if a court decides that the product candidate or technology at issue infringes or otherwise violates the third-party's rights, and, if the court finds that the infringement or other violation was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees (and, in certain jurisdictions outside of the United States, we could be ordered to pay the patent owner's attorneys' fees even without such a finding);
- a court enjoining us from developing, manufacturing, importing, marketing or selling our product candidates, or from using our proprietary technologies, unless the relevant third party grants us an adequate license, which it is not required to do;
- even if a license is available from a third party, we may have to pay substantial royalties, upfront fees, milestones and other amounts and/or grant cross-licenses to intellectual property rights at terms that are not favorable to us, and a license may not be timely obtained; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our ability to commercialize our product candidates in the United States and abroad may be adversely affected if we cannot successfully defend against infringement allegations or obtain a license on commercially reasonable terms to relevant third-party patents that cover our product candidates. Even if we have a strong defense and/or believe that third-party intellectual property allegations are without merit, there can be no assurance that a court would find in our favor on questions of infringement, validity, enforceability and/or priority. A court of competent jurisdiction could hold that these third-party patents are valid and enforceable and have been infringed, which could materially and adversely affect our ability to commercialize our product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is high, which requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claims, there is no assurance that a court of competent jurisdiction would invalidate the asserted claims of any such U.S. patent. Further, there is no assurance that courts or other administrative or judicial tribunals outside the United States would invalidate the claims of non-U.S. patents that may be asserted against our products and technology.

If we are found to infringe a third party's patent rights, and we are unsuccessful in demonstrating that any such patents are invalid or unenforceable, we could be required to pay damages and to obtain a license (which can involve royalty payments) from such third party to continue developing, manufacturing, marketing or selling our product candidates and our technologies. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to it, and it could require us to pay substantial licensing fees and/or make royalty, milestone and/or other payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. We also could be temporarily or permanently forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a U.S. patent or other intellectual property right, and may not have to pay such damages outside the United States even if any infringement by our products or technology was not willful.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have acquired patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We may be forced to pay exorbitant settlement fees to settle such litigation and/or may face the negative consequences of infringement lawsuits by such patentees, such as injunctions against the commercialization of our products and technology and/or the distraction of our personnel from properly running our business due to the need to attend to such lawsuits.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motion, and other interim proceedings or developments in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, approved products, programs, or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, or discourage potential partners from entering into collaborations or business relationships with us, all of which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Some of our in-licensed intellectual property rights have been developed through programs funded by the U.S. government and/or government agencies and we may in-license additional intellectual property rights that are developed through programs funded by the U.S. government and/or government agencies, and we may ourselves enter into arrangements involving government funding of certain programs and we make inventions as a result of such funding. Our intellectual property rights to inventions from programs utilizing government funding may be subject to the applicable provisions of the Bayh-Dole Act of 1980 (the “Bayh-Dole Act”).

To the extent any of our current and future owned or in-licensed intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. The U.S. government and/or government agencies have provided funding or other assistance in connection with the development of certain intellectual property rights licensed to us. In the future, we may license additional intellectual property rights in inventions supported by the U.S. government and/or government agencies. We may also enter into future arrangements involving government funding. If we make or first reduce to practice inventions as a result of such funding, our intellectual property rights to such inventions may be subject to the applicable provisions of the Bayh-Dole Act. Any exercise by the government of certain rights could harm our competitive position, business, financial condition, results of operations and growth prospects.

U.S. government rights in certain inventions supported by the U.S. government and/or government agencies include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for governmental purposes. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if the government determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations, which are collectively referred to as march-in rights. The U.S. government will also have the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government, elect title and file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources.

In addition, the U.S. government requires that any products embodying an invention supported by the U.S. government funding or produced through the use of a subject invention supported by the U.S. government funding be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States. or that under the circumstances domestic manufacture is not commercially feasible. We may not be able to obtain a waiver of this preference for U.S. industry, and this preference may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our owned or in-licensed future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Certain government agencies may impose stricter or additional requirements beyond the Bayh-Dole Act in their funding agreements including more stringent requirements of manufacturing in the United States. If we are unable to comply with these manufacturing requirements, we may experience a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may not be successful in obtaining or maintaining adequate intellectual property rights to product components and manufacturing processes for our development pipeline and to commercialize our product candidates.

At present, we have rights to certain intellectual property, through licenses from third parties and under patent filings that we own to develop our product candidates. Because our pipeline may involve additional product candidates that could require the use of proprietary rights held by third parties, the growth of our business could depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific pharmaceutical formulations to work effectively and efficiently, and these rights may be held by others. We may be unable to acquire or in-license intellectual property rights that may be necessary to permit us to implement our platform technologies or develop, manufacture or use our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also

pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us in obtaining access to the relevant third-party rights due to their size, cash resources and greater clinical development and commercialization capabilities. Further, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the third party may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our product candidate and enabling our competitors to compete with our product candidate.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

We cannot ensure that pending claims in our and our licensors' pending patent applications will issue or that patents based on our or our licensors' patent applications will not be challenged and rendered invalid and/or unenforceable.

We have pending patent applications in the United States and/or foreign jurisdictions in our portfolio (owned or in-licensed) relating to our research programs and product candidates. However, we cannot predict:

- the scope of protection of any patent issuing based on our or our licensors' patent applications;
- whether the claims of any patent issuing based on our or our licensors' patent applications will provide adequate protection against competitors;
- whether or not third parties will find ways to challenge, narrow, invalidate or circumvent our or our licensors' patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our or our licensors' patents, if issued, and patent applications;
- whether we or our licensors will need to initiate litigation or administrative proceedings to obtain, defend and/or enforce our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or their manufacturing or uses.

We cannot be certain that the claims in our current or future patent applications directed to our product candidates, as well as technologies relating to our research programs, will be considered patentable by the USPTO or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of ordinary skill in the relevant art prior to the priority date of the claimed invention. The biotechnology and pharmaceutical industries are intense, fast-moving and highly competitive. There may be prior art of which we are not aware that may affect the patentability of our patent claims or affect the validity or enforceability of an issued patent claim relevant to our business. There is no assurance that there is no prior art of which we are aware, but which we do not believe is relevant to our patent claims or business, which may, nonetheless, ultimately be found to limit our ability to obtain, maintain, defend and/or enforce patent rights, including those that protect us against third parties to make, use, sell, offer for sale or import our products that may be approved in the future, or to otherwise impair our competitive position. In some cases, prior art may prevent us from obtaining, maintaining, defending and/or enforcing patent rights that are necessary to protect our product candidates.

Even if the patents do issue based on our owned or in-licensed patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, revoked, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our platform or product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our owned or in-licensed current or future issued patents will be found not invalid and enforceable by courts or other tribunals in the United States or foreign countries. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our product candidates are, and in the future, may be subject to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, or these agreements are terminated, or we otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

Certain aspects of some of our platform technologies and/or some of our product candidates utilize third-party technologies to which we have access through license or other agreements, and we may also enter into additional agreements with third parties in the future. Our current agreements with third parties impose, and may in the future impose additional, diligence, development and commercialization timelines, milestone payments, royalties, indemnification, insurance, non-competes or other obligations on us. If we fail to comply with our obligations to our licensors, collaborators or other third parties, our counterparties may have the right to terminate or take other actions under these agreements that are unfavorable to us. Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology that are necessary for our business. In particular, we have a license agreement with the President and Fellows of Harvard College (“Harvard”), pursuant to which we have obtained access to certain polypeptide technologies that can be useful for the development of one or more of our programs (the “Harvard License”). The intellectual property rights we in-licensed pursuant to the Harvard License include issued and/or pending patent filings that include claims that may generically cover the composition of matter, manufacturing and/or use of one or more of our current or future product candidates, including zolucetide. As described elsewhere in this prospectus, Harvard may terminate the Harvard License under certain circumstances. For more information, see the section titled “*Business—License Agreement.*”

Our success will depend in part on the ability of our licensors to obtain, maintain, defend and enforce our licensed intellectual property rights including patent protection for our licensed intellectual property. To the extent that the licensors’ inventions are made using the U.S. government support, such intellectual property rights are subject to provisions in the relevant agreements with the government and the Bayh-Dole Act. Further, certain patent filings relating to our product candidates may now or in the future be subject to step-in rights of certain of our licensors. We have limited or no control over our licensors’ preparation, filing, obtaining, maintaining, defending or enforcing the licensed intellectual property rights, or their compliance with the provisions in their agreements with the U.S. government or other third parties. We have limited or no control over certain of our licensors’, and may in the future have limited or no control of our other licensors’, prosecution activities or use or licensing of any other intellectual property that may be related to our in-licensed intellectual property. Our licensors may not successfully prosecute the patent applications we license. Even if patents issue from these patent applications, our licensors may fail to obtain sufficient breadth of scope to protect our products and technologies, may fail to maintain these patents, may determine not to defend these patents when challenged, and may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. If any of our licensors or licensees having rights to file, prosecute, maintain and defend our patent rights fail to conduct these activities for patents or patent applications protecting any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors or other third parties from making, using or selling competing products. In addition, we may sublicense certain of our rights under various third-party licenses to our collaboration partners. Any impairment of these sublicensed rights could result in reduced revenues under our partnership, collaboration or licensing arrangement or result in termination of an agreement by one or more of our collaboration partners. In addition, intellectual property rights that we may in-license in the future may be sublicensed under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

We cannot be certain that activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with our licensors, such licensors may have the right to control enforcement of our licensed patents or defense of any allegations asserting the invalidity or unenforceability of such patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors or, in some cases, other necessary parties, such as any co-owners of patents or other intellectual property from which we have not yet obtained a license or for which we obtained a license requiring consent or cooperation of the owner for purposes of enforcement. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such allegations to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of allegations asserting the invalidity or unenforceability of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after assuming control.

Our current or future license agreements may not provide exclusive or sufficient rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates in the future. Some licenses granted to us may be subject to certain preexisting rights held by the licensors or certain third parties. As a result, we may not be able to prevent third parties from developing and commercializing competitive products in certain territories or fields.

In the event that our third-party licensors or other counterparties determine that, in spite of our efforts, we have breached a license agreement or have failed to meet certain obligations thereunder, it may elect to terminate the applicable agreement or, in some cases, one or more licenses under such agreement or otherwise restrict our rights under the agreement. Such termination or restriction of rights could result in us losing the ability to develop and commercialize product candidates and technology covered by the licensed intellectual property. In the event of such termination, or if the underlying patent rights under a third-party in-license or other agreement fail to provide the intended exclusivity, third parties may be able to seek regulatory approval of, and to market, products identical or substantially similar to ours and we may be required to cease the development and commercialization of our product candidates. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to allegations, regardless of their merit, that we are infringing or otherwise violating a licensor's rights. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, the agreements under which we license or otherwise acquire intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant patents, know-how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes may also arise between us and our licensors or other counterparties regarding intellectual property subject to a license agreement, including: the scope of rights granted under the agreement and other interpretation-related issues; whether and the extent to which our technology and processes are covered by intellectual property of the licensor that is not subject to the agreement; our right to sublicense patent and other rights to third parties under collaborative development relationships; our diligence obligations with respect to the use of the licensed or otherwise acquired technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and the inventorship and/or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaboration partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on favorable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, for example, those described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

If we are unable to protect the confidentiality of our proprietary trade secrets or know-how, our business and competitive position would be harmed.

In addition to patent protection, we also seek to rely upon trade secret protection, data security protocols and capabilities, and non-disclosure agreements with our employees, consultants and third parties, to maintain our competitive position and to protect our confidential and proprietary source code, know-how and other information that is not patentable or processes for which patents are difficult to enforce, and any other elements of our product candidates and their discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, confidential information including trade secrets and know-how may be difficult to protect.

It is our policy to require our employees, corporate collaborators, outside scientific collaborators, CROs, CDMOs, consultants, advisors and other third parties to execute confidentiality agreements upon the commencement of employment, consulting or business relationships with us. However, we cannot guarantee that we have entered into agreements with each party that may have or have had access to our trade secret or proprietary technologies and processes. Despite our efforts, any of these parties may breach the agreements and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We may not be able to obtain adequate remedies for any such breaches.

In addition to contractual measures, we try to protect the confidential nature of our trade secret and proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect despite these precautions. Such measures may not, for example, in the case of misappropriation of trade secrets or know-how by an employee, former employee, or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee, former employee, or consultant from misappropriating our trade secrets or know-how and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully.

Enforcing a claim that a party wrongfully or illegally disclosed or misappropriated trade secrets or know-how can be difficult, expensive and time-consuming, and the outcome is unpredictable. Some courts inside and outside the United States are less willing or unwilling to protect trade secrets and know-how. In addition, trade secrets and know-how may be lawfully obtained or independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets or know-how, were to be disclosed or misappropriated, or if any such information were independently developed by a competitor, our competitive position could be harmed.

Certain former employees have obtained employment with companies or academic institutions that could be considered competitive with us and are operating their business in areas that are similar to ours, including in their business model, product design efforts, product development or formulation technology. This competition may be limited by contractual provisions; however, these contractual provisions may not be enforceable by us in the Commonwealth of Massachusetts or other jurisdictions. In addition, we may not be aware of such competitive employment arrangements until after our trade secrets or know-how has been disclosed to potentially competitive companies.

If we choose to go to court to enjoin a third party from using any of our trade secrets or know-how, we may incur substantial costs and/or we may ultimately not be successful. In addition, courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets or know-how. Even if we are successful, these types of lawsuits may consume, in addition to substantial costs, significant amounts of our time and other resources. We may also need to share our trade secret or proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may be subject to allegations that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties including alleged trade secrets of their former employers.

As is common in the biotechnology industry, we employ individuals, including certain of our key employees, and engage consultants and independent contractors. Many of our employees, consultants or independent contractors are or were previously employed at academic institutions or other biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to allegations that we, or our employees, consultants or independent contractors, have inadvertently or otherwise used or disclosed intellectual property, including trade secrets, know-how or other proprietary information, of any of their former employers or other third parties. Litigation may be necessary to defend against these allegations. If we fail in defending against, or successfully defending against, any such allegations, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such allegations, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to allegations challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to allegations that current or former employees, consultants, independent contractors, collaborators or other third parties have an ownership or other interest in our patents or other intellectual property. Ownership disputes may arise, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates and technology. Litigation may be necessary to defend against these and other allegations challenging inventorship or ownership. If we fail in defending against any such allegations, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse impact on our business. Even if we are successful in defending against such allegations, litigation could result in substantial costs and be a distraction to management and other employees.

In addition, while it is our policy to require our employees, consultants, and independent contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the inventorship and/or the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the USPTO and various non-U.S. patent agencies in several stages over the lifetime of the patents or applications. We rely on our outside counsel or vendor to pay these fees due; however, we cannot guarantee that we will successfully pay these fees. The USPTO and various non-U.S. government patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property, and we cannot guarantee that they will do so. In an event of abandonment or lapse of a patent or patent application, our competitors might be able to enter the market and this circumstance would have a material adverse impact on our business. We cannot be sure that we or our licensors will be able to fully comply with these requirements, and we or our licensors may lose material patent protection as a result.

In addition, public health pandemics, geopolitical instability, natural disasters, or similar events may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for our product candidates. There could also be delays at the USPTO caused by staffing cuts and other U.S. government actions as a result of the U.S. Department of Government Efficiency or other executive actions to reduce the size of the U.S. government.

The USPTO and various non-U.S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the United States, China, India and some European countries, a foreign filing license is required before certain patent applications are filed in other jurisdictions. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (e.g., items related to national security or national defense). In some cases, for example in China and India, a foreign filing license cannot be obtained retroactively in accordance with the applicable rules. There are situations in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent and/or rendering an issued patent unenforceable, resulting in the loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We may also be dependent on our licensors to take the necessary actions to comply with these requirements with respect to our licensed intellectual property. We cannot ensure that our licensors will take such action, or timely take such action, in a manner sufficient to protect our rights.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate or technology is invalid and/or unenforceable. In patent litigation in the United States and other jurisdictions, counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including patent subject matter eligibility, novelty, non-obviousness, written description and/or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third-parties may also raise similar allegations before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include post- or pre-grant administrative proceedings, such as *ex parte* reexamination, inter partes review, post grant review, interference proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability of patent rights covering a product candidate or technology, we would lose at least part, and perhaps all, of the patent protection on our product candidate or technology. Such a loss of patent protection could have a material adverse impact on our business. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls within the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1) or analogous laws outside the United States.

If we do not obtain sufficient patent term for our product candidates, our business may be materially harmed.

Patents have a limited term. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from the earliest non-provisional filing date, subject to patent term adjustments, extensions and disclaimers. Many foreign jurisdictions provide a similar 20-year nominal patent term, though many require payment of regular, often annual, annuities to maintain pendency of an application or viability of an issued patent. However, the actual protection afforded by a patent varies from country to country, and also depends upon many factors, including the type of patent, the scope of coverage, the availability of regulatory related extensions, the availability of extensions for patent office delays during the examination process, the availability of legal remedies in a particular country and the validity and enforceability of the patent, and whether a portion of the patent term has been terminally disclaimed based on other patents. These factors may emerge and change over the course of time, and accordingly, a patent's expiration date might change over time in unpredictable ways. Various extensions including patent term extension based on regulatory review and approval may be available, but the durations of such extensions, and the protections they afford, are limited in the United States and other countries and regions. Additional patent terms may be available through a patent term adjustment process in the United States, for delays caused by the USPTO during prosecution, which may be reduced by applicants' delays. Although various extensions or adjustments may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may face substantially increased competition from generics or biosimilars.

Depending upon the timing, duration and specifics of FDA regulatory approval of our product candidates, one or more patents issued from U.S. patent applications that we or a future licensor file may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") through patent term extension. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during the FDA regulatory review process based on the first regulatory approval for a particular drug. A maximum of one patent may be extended per FDA-approved drug as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, and only those claims covering such approved drug product, an approved method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates.

Despite the possibility of an extension, we may not be granted an extension in the United States or another jurisdiction because of, for example, failure to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time or the scope of patent protection that is granted through the extension may be less than we requested or expected and may not be sufficient to protect all uses of our products.

If we are unable to obtain patent term extension, or the foreign equivalent, or the term of any such extension is less than we requested or expected or the scope is not sufficient, our competitors or other third-parties may obtain approval of competing drugs following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors or other third-parties may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their drug earlier than might otherwise have been the case. Any of the foregoing could materially harm our business, financial condition, results of operations and growth prospects.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting, maintaining and defending patents covering our platform and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some or all countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in the United States. Competitors may use our technologies and innovations in jurisdictions where we have not obtained patent protection to develop their own products and technologies and, further, may export otherwise infringing products or technologies to territories where we have patent protection, but where enforcement is not as strong as in the United States or Europe. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon patent applications before they are granted. The examination of each patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even not issue in other jurisdictions. Furthermore, the requirements for patentability differ in certain jurisdictions and countries. For example, some countries do not grant claims directed to methods of treatment or have additional restrictions on the scope of method of treatment claims compared to the United States. Accordingly, depending on the country, the scope of patent protection may vary for the same product candidate or technology. For costs or other reasons, we may choose not to file, prosecute, maintain, defend and/or enforce certain patent filings, including abandoning pending patent applications or issued patents.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain protection efforts, and achieve successful protection, in all such markets. Additionally, the prosecution of patent applications can be a long process and patents may not be timely granted if ever granted, potentially delaying our ability to assert such patents against competitors. Accordingly, our efforts to protect our intellectual property rights in the United States and foreign countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business, the value of these rights may be diminished, and we may face additional competition.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States and Europe, and many companies have encountered significant difficulties in obtaining, defending or enforcing such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor obtaining, defending, or enforcing patents, trade secrets and other intellectual property rights, which could make it difficult for us to stop the infringement of any patents we obtain, prevent misappropriation of our intellectual property or prevent the marketing of competing products by third parties in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we obtain at risk of being invalidated or interpreted narrowly, and put our patent applications at risk of not issuing as patents, and could result in the assertion by third parties of claims or rights against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant, or any, commercial advantage from the intellectual property that we develop or license.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be materially impaired.

In Europe, a new unitary patent system took effect on June 1, 2023, which may significantly impact European patents, including those granted before the introduction of the new system. Under the new system, applicants can, upon grant of a European patent, opt for that patent to become a unitary patent which will be subject to the jurisdiction of a new unitary patent court (“UPC”). During the first seven years of the UPC’s existence, certain European patents granted before the implementation of the new system can be opted out of UPC jurisdiction, and validated as national patents in any one or more of the UPC countries. We may decide during this transition period to opt out future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. Patents that are under the jurisdiction of the UPC may be challenged in a single UPC-based revocation proceeding that, if successful, could invalidate the patent in all countries who are signatories to the UPC. The UPC may provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunction. Further, because the UPC is a new court system and there is no precedent for the court’s laws, there is increased uncertainty regarding the outcome of any patent litigation. We are unable to predict what impact the new patent regime may have on our ability to exclude competitors in the European market.

If we are unable to obtain and enforce patents as needed in particular markets, our ability to exclude competitors in those markets may be reduced.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, maintaining, defending and enforcing patents in the biotechnology industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and in other major jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions and to obtain, maintain, enforce and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our current or future owned and licensed patents.

The patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent rulings from the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have narrowed the scope of patent protection available in specified circumstances and weakened the rights of patent owners in specified situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with

respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents and to maintain, defend and/or enforce our existing or future patents. The U.S. Supreme Court has ruled on several patent cases in recent years, narrowing the scope of patent protection available in certain circumstances or otherwise weakening the rights of patent owners. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of issued or future patents. Depending on future actions by the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents in such countries and to maintain, defend and/or enforce our existing or further patents in such countries. We cannot predict how future decisions by the federal courts, the U.S. Congress, the USPTO and/or analogous courts and bodies outside the United States may impact the value of our patents. Changes in the patent laws of the United States and other jurisdictions might also adversely affect our business, financial condition, results of operations and prospects.

The USPTO has issued subject matter eligibility guidance instructing USPTO examiners on the ramifications of the Supreme Court rulings in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Association for Molecular Pathology v. Myriad Genetics, Inc.*, and applied the *Myriad* ruling to natural products and principles including all naturally occurring molecules. In addition, the USPTO continues to provide updates to its guidance that may make it impossible for us to obtain similar patent claims in future patent applications. Currently, our patent portfolio contains claims of various types and scopes, including methods of medical treatment. The presence of varying types of claims in our patent portfolio may not eliminate our exposure to potential validity challenges alleging a lack of subject matter eligibility. Furthermore, U.S. Court of Appeals for the Federal Circuit has held that an inventor on a U.S. patent must be a natural person and not a machine or AI. As a result, AI systems, regardless of their sophistication, cannot be named as inventors or joint inventors on a patent application as they are not natural persons. The USPTO has recently issued inventorship guidance for AI-assisted inventions. Given that we use AI in certain aspects of our Helicon discovery platform, certain AI-assisted inventions may be deemed ineligible for patent protection if it is determined that there is not a sufficient level of human inventive contribution.

In the United States, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law on September 16, 2011. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These included provisions that affect the way patent applications are prosecuted, redefine prior art and provide potentially more efficient and cost-effective avenues for competitors to challenge the validity of patents. The USPTO has promulgated regulations and developed procedures to govern administration of the Leahy-Smith Act. Many substantive changes to patent law associated with the Leahy-Smith Act has come into effect since March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

An important change introduced by the Leahy-Smith Act is that, as of March 16, 2013, the United States transitioned to a "first-inventor-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. This requires us to be cognizant of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either: (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the Leahy-Smith Act are changes that limit where a patentee may file a patent infringement suit and new procedures providing opportunities for third parties to challenge any issued patent in the USPTO. These new post grant challenges include post grant review and inter partes review proceedings before the Patent Trial and Appeal Board at the USPTO. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim unpatentable even though the same evidence would be insufficient to invalidate the claim if presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate patent claims that would not have been invalidated if challenged by the third party as a defendant in a district court action. The USPTO has made many changes and may make future changes to the rules of practice for implementing post-grant proceedings. These USPTO rules and changes thereto can impact the ability of third parties, and our ability, to challenge or defend U.S. patents before the USPTO.

Similarly, changes in patent law and regulations in other jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain, maintain, defend or enforce current and future patents in our portfolio.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. For example, the United States and foreign government actions related to Russia's invasion of Ukraine resulted in Russia issuing Decree No. 299 that effectively nullifies the enforcement of Russian patents owned by entities and individuals in "unfriendly" countries, including the United States.

Any trademarks we have obtained or may obtain may be infringed or otherwise violated or successfully challenged. If our trademarks and trade names are not adequately protected, or if we are unable to obtain desired trademarks or trade names, then we may not be able to build brand name recognition in our markets of interest and our business may be adversely affected.

We expect to utilize trademark protection for our products, product candidates and/or platform. Once we select new trademarks and apply to register them, our trademark applications may not be approved. During trademark registration proceedings in the United States and foreign jurisdictions, we may receive rejections. We are given an opportunity to respond to those rejections, but we may not be able to overcome such rejections and obtain sufficient, or any, trademark protection.

We have also not yet registered trademarks for any of our product candidates in any jurisdiction. Any trademark applications we file may be rejected and registered trademarks may not be obtained, maintained or enforced. If we do not successfully register our trademarks, we may encounter difficulty in enforcing, or be unable to enforce, our trademark rights against third parties, which could adversely affect our business and our ability to effectively compete in the marketplace.

In addition, any proprietary name we propose to use with any of our product candidate in the United States will need to be approved by the FDA, regardless of whether we have registered, or applied to register, the proposed proprietary name as a trademark. The FDA conducts a review of proposed proprietary names, including an evaluation of potential for confusion with other products' proprietary names, as part of the NDA review process. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

In addition, our unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic, or determined to be infringing on, misappropriating or violating other marks. In the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademark registrations may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product candidates, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion.

Our competitors may also infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. We may not be able to protect our rights to our trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. Any of the foregoing events may have a material adverse effect on our business.

Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement allegation asserted by the owner of a senior trademark. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain names or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- our product candidates, if approved, may eventually become commercially available in generic or biosimilar product forms;
- others may be able to make similar molecules to our product candidates that are not covered by the claims of the patents that we license or own now or in the future;

- we, or current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own;
- we, or current or future licensors or collaborators, may fail to meet our obligations to the U.S. government regarding any patents and patent applications funded by U.S. government grants;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing on our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own or license in the future will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents;
- it is possible that there are patent applications that may later issue with claims covering our product candidates or technology similar to ours;
- it is possible that our patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable or result in a change in ownership;
- issued patents that we own or in-license may be held invalid, unenforceable or narrowed in scope, including as a result of legal challenges;
- the claims of our issued patents or patent applications, if and when issued, may not cover our product candidates or narrowly cover them in such a way that competitors may be able to design around to avoid infringement allegations;
- the laws of foreign countries may not protect our proprietary rights or the proprietary rights of our current or future licensors or collaborators to the same extent as the laws of the United States;
- the inventors of our patents or patent applications may become involved with competitors, develop products or processes that are similar to or alternative to those claimed in our patent filings or become hostile to our patents or patent applications on which they are named as inventors, and might take action detrimental to our patent and other intellectual property rights;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and we intend to continue to do so in the future, and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- the product candidates and technology we develop may be covered by third-party patents or other intellectual property rights;
- the patents of others may prohibit or otherwise harm our ability to conduct our business; or
- we may choose not to apply for a patent in order to maintain certain trade secrets, know-how, or other technology confidential, and a third party may subsequently commercialize such technology and/or apply for and obtain a patent covering such technology.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to the Potential Commercialization of Our Pipeline

We have no sales, distribution or marketing experience, and may invest significant financial and management resources to establish these capabilities. If we are unable to establish such capabilities or enter into agreements with third parties to market and sell our future products, if approved, we may be unable to generate any revenues.

Given our stage of development as a company, we have no sales, distribution or marketing experience. To successfully commercialize any products that may result from our programs, we will need to develop sales and marketing capabilities in the United States, Europe and other regions, either on our own or with others. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of these product candidates. Any failure or delay in the development of our or third parties' internal sales, marketing, and distribution capabilities would adversely impact the commercialization of our product candidates.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- inadequate funding;
- our inability to recruit and retain an adequate number of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade an adequate number of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage compared to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We may enter into partnership, collaboration, and licensing arrangements with third parties to utilize their mature marketing and distribution capabilities, but we may be unable to enter into marketing agreements on favorable terms, if at all. If these third parties do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we may be unable to generate sufficient product revenue to sustain our business. We may be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without a significant internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

The biopharmaceutical market is intensely competitive. If we are unable to compete effectively with existing drugs, new treatment methods and new technologies, we may be unable to successfully commercialize any drugs that we develop.

The biopharmaceutical market is intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations, known and unknown, are pursuing the development of novel drugs for the same diseases that we are targeting or expect to target. Many of our competitors have:

- greater financial, technical and human resources than we have at every stage of the engineering, development, manufacture and commercialization of products;
- more extensive experience in preclinical testing, conducting clinical trials, obtaining regulatory approvals and in manufacturing, marketing and selling products;
- product candidates that are based on previously tested or accepted technologies;
- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

Accordingly, our competitors may be more successful than us in obtaining patent protection, regulatory exclusivities or FDA approval and commercialize products or achieve widespread market acceptance more rapidly than we do, which may impact future approvals or sales of our product candidates that receive regulatory approval. If the FDA approves the commercial sale of our product candidates, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect competition

among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product candidates receives regulatory approval but cannot compete effectively in the marketplace.

In addition, our competitors may develop partnership, collaboration, and licensing arrangements with or receive funding from larger pharmaceutical or biotechnology companies, providing them with an advantage over us. Our competitors may also succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than our product candidates, which could render our product candidates obsolete and noncompetitive. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business. Competitive products may make any products we develop obsolete or noncompetitive before we can recover the expenses of developing and commercializing our products, if approved.

We expect to face intense competition from drugs that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop products. We also expect to face competition from new drugs that enter the market. There are a number of drugs currently under development, which may become commercially available in the future, for the treatment of the conditions for which we are trying, or may in the future try, to develop products. These drugs may be more effective, safer, less expensive or marketed and sold more effectively, than any products we develop. In most cases, we do not currently plan to run head-to-head clinical trials evaluating our product candidates against the current standards of care, which may make it more challenging for our product candidates to compete against the current standards of care due to the lack of head-to-head clinical trial data.

If we successfully develop any product candidates, and obtain approval for them, we expect to face competition based on many different factors, including: the safety and effectiveness of our products relative to alternative therapies, if any; the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration; the timing and scope of regulatory approvals for these product candidates; the availability and cost of manufacturing, marketing and sales capabilities; the price of any approved product; reimbursement coverage; and patent position. See the section titled “*Business—Competition*” included elsewhere in this prospectus for examples of the competition that we face.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our product candidates.

The commercial success of any current or future product candidate, if approved, will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals, the commercial success of our products will depend in part on the medical community, patients and third-party or governmental payors, and our products in particular, as medically useful, cost-effective and safe. Furthermore, the method of administration of any of our products, if approved, could have an impact on commercial acceptance of any such products and ultimately the commercial success of such products. Furthermore, ethical, social and legal concerns about the application of AI to research and development of products could result in additional regulations restricting access to or otherwise limit demand for our products. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including: the potential efficacy and potential advantages over alternative treatments; the ability to offer our products, if approved, at competitive prices; the prevalence and severity of any side effects, including any limitations or warnings contained in a product’s approved labeling; the prevalence and severity of any side effects resulting from checkpoint inhibitors or other drugs or therapies with which our products are administered; relative convenience and ease of administration; any restrictions on the use of our products, if approved, together with other medications; the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; the strength of marketing and distribution support and timing of market introduction of competitive products; publicity concerning our products or competing products and treatments; and sufficient third-party insurance coverage or reimbursement, and patients’ willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the products may require significant resources and may never be successful. Our efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors due to the complexity and uniqueness of our product candidates.

Even if we are successful in getting marketing approval for any product, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and entry into managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for any of our products once approved, whether due to healthcare reform legislation or otherwise, market acceptance and commercial success would be reduced.

In addition, if any of our products are approved for marketing, we or a collaboration partner will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports for such product, and will need to continue to comply (or ensure that our third-party providers comply) with current cGMP and GCPs for any clinical trials that we or a collaboration partner conduct post-approval. In addition, there is always the risk that we or a collaboration partner or Regulatory Authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any such failure to comply or other issues with our product candidates identified post-approval could have a material adverse impact on our business, financial condition and results of operations.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. Recent and ongoing changes in the United States trade policy with foreign countries, including the continued uncertainty surrounding U.S. tariffs and potential retaliatory measures by foreign governments may disrupt the global supply chain for biopharmaceutical products. For example, in April 2025, the United States imposed “reciprocal” tariffs, which were broad tariffs on imports from virtually all countries, with particularly high tariffs on imports from China. The U.S. Supreme Court invalidated the reciprocal tariffs on February 20, 2026; however, President Trump has stated that he intends to use other authorities to maintain historically elevated tariffs. In response to higher U.S. tariffs, some countries have implemented retaliatory tariffs on U.S. goods, while others have negotiated agreements regarding U.S.-imposed tariffs. Historically, increased tariffs have led to more trade and political tensions and the status of these agreements between the United States and the various countries, in light of the U.S. Supreme Court’s February 20, 2026 decision, is not yet clear. Moreover, the United States has threatened to impose special tariffs on certain imported pharmaceutical products, which could take effect with minimal public notice. In any case, it is not yet clear whether these tariffs would apply to the importation of APIs and possibly bulk drug products that are intended for use in clinical trials and not for commercial sale, which could increase the costs of materials for our clinical trials. Any direct tariffs, if imposed on pharmaceutical products, may result in increased costs for raw materials and contract manufacturing services, reduced ability to source critical contract manufacturing organizations, and a delay in our development timelines.

We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable foreign regulatory authority and may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

We are subject to export and import controls, economic sanctions and anti-corruption laws and regulations of the United States and other jurisdictions. We can face criminal liability and other serious consequences for violations of these laws and regulations, which can harm our business.

Because we plan to market our products, if approved, outside of the United States, our business is subject to risks associated with doing business outside of the United States including, an increase in our expenses, diversion of our management’s attention from the acquisition or development of product candidates or forgoing profitable licensing opportunities in these geographies. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including: efforts to develop an international sales, marketing, and distribution organization; changes in a specific country’s or region’s political and cultural climate or economic condition; unexpected changes in foreign laws and regulatory requirements; difficulty of effective enforcement of contractual provisions in local jurisdictions; inadequate intellectual property protection in foreign countries; trade-protection measures,

import or export licensing requirements such as Export Administration Regulations promulgated by the U.S. Department of Commerce and fines, penalties or suspension or revocation of export privileges; the effects of applicable foreign tax structures and potentially adverse tax consequences; and significant adverse changes in foreign currency exchange rates.

In addition to FDA and related regulatory requirements in the United States and abroad, we are subject to extensive additional federal, state and foreign anti-bribery regulations, which include the U.S. Foreign Corrupt Practices Act, U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the UK Bribery Act 2010 and similar laws in other countries outside of the United States. We are developing and implementing a corporate compliance program based on what we believe are current best practices in the biotechnology industry for companies similar to ours, but we cannot guarantee that we, our employees, our consultants or our third-party contractors are or will be in compliance with all federal, state and foreign regulations regarding bribery and corruption. Moreover, our collaboration partners and third-party contractors located outside the United States may have inadequate compliance programs or may fail to respect the laws and guidance of the territories in which they operate. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operations.

The insurance coverage and reimbursement status of newly approved products, including those in a new category of medicines, is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments such as the products that we hope to develop and sell. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment in any of our products. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is: a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; and neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. The Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"), determines whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for products.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for our product candidates that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many biopharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

Outside the United States, certain countries, including a number of member states of the EU (the "Member States"), set prices and reimbursement for pharmaceutical products, or medicinal products, as they are commonly referred to in the EU, with limited participation from the marketing authorization holders. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. We cannot be sure that such prices and reimbursement will be acceptable to us or our collaboration partners. If the regulatory authorities in these foreign jurisdictions set prices or reimbursement levels that are not commercially attractive for us or our collaboration partners, our revenues from sales by us or our collaboration partners and the potential profitability of our products in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world but have been most drastic in the European Union.

Additionally, the requirements governing product pricing vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed, while in others, the pricing review period begins after marketing or product licensing approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then may experience delays in the reimbursement approval of our product or be subject to price regulations that would delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for our product candidates. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates.

We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

For more information on the laws and regulations that may impact coverage and reimbursement of our product candidates, see the sections titled “*Business—Government Regulation—Coverage and Reimbursement*” and “*—Healthcare Reform*” included elsewhere in the prospectus.

Healthcare legislative reform discourse and potential or enacted measures may have a material adverse impact on our business and results of operations and legislative or political discussions surrounding the desire for and implementation of pricing reforms may adversely impact our business.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. See the sections titled “*Business—Government Regulation—Coverage and Reimbursement*” and “*—Healthcare Reform*” included elsewhere in this prospectus.

The containment of healthcare costs has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products.

For example, the Inflation Reduction Act of 2022 (the “IRA”) includes several provisions that will impact our business to varying degrees, including provisions that allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs without generic or biosimilar competition, among others.

Further, the IRA also imposed rebates with respect to certain drugs covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our revenue generated from the sale of any approved products.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. The U.S. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment (“HTA”) amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and became applicable in January 2025, is intended to boost cooperation among Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation will permit Member States to use common HTA tools, methodologies and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual Member States will continue to be responsible for assessing nonclinical (e.g., economic, social, ethical) aspects of health technologies and making decisions on pricing and reimbursement.

These laws, and future supranational, national state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

The estimates of market opportunity and forecasts of market growth included in documents that we file with the SEC may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all. Although we are initially focused on developing and commercializing zolucetide for the treatment of desmoid tumors, we also plan to evaluate developing zolucetide for the treatment of FAP, HCC and other rare solid tumors and cancer-related conditions. We expect this evaluation will take into account expected clinical timelines, regulatory feedback, costs and the clinical data from our Phase 1/2 trial. In addition, an important area of focus of our research and product development activities is the development of treatments for severe rare genetic diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates and independent market research, industry and general publications obtained from third parties. Market opportunity estimates and growth forecasts included in this prospectus and the other documents that we file with the SEC are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these indications. Additionally, the potentially addressable patient population may not ultimately be amenable to treatment with our product candidate if we cannot achieve our intended dosing interval. Our market opportunity may also be limited by current and future products of our competitors that are already available in the market or may enter the market for such patients. If any of our estimates prove to be inaccurate, the market opportunity for our product candidates could be significantly diminished and have an adverse material impact on our business.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, and false claims laws. If we are unable to comply, or have not fully complied with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations that will impact, among other things, our proposed sales, marketing, and educational programs. The laws that will affect our operations include, but are not limited to the following:

- The federal Health Care Program Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, and formulary managers on the other. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.

- The federal civil and criminal false claims laws and civil monetary penalty laws prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.
- The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- The FDCA, which prohibits, among other things, the adulteration or misbranding of drugs and medical devices.
- Federal transparency laws, including the federal Physician Payments Sunshine Act, which require disclosure of payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.
- Federal government price reporting laws, which require drug makers to calculate and report complex pricing metrics in an accurate and timely manner to government programs.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- State law equivalents of each of the above federal laws and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures are also applicable to us and many of them differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including certain consulting agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options could be subject to challenge under one or more such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, mandatory or discretionary exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician’s employer, his or her competent professional organization or the regulatory authorities of the individual Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.

We face an inherent risk of product liability exposure related to the testing of any of our current or future product candidates in clinical trials, and we may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against allegations that our product candidates caused injuries, or we failed to warn of potential injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, allegations of liability may result in decreased demand for any product candidate that we may develop; loss of revenue; substantial monetary awards to patients, healthy volunteers or their children; significant time and costs to defend the related litigation; withdrawal of clinical trial participants; the inability to commercialize any product candidate(s) that we may develop; and injury to our reputation and significant negative media attention.

We carry product liability insurance which we believe to be sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Risks Related to Our Business Operations and Employee Matters

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biotechnology industry depends upon our ability to attract and retain highly qualified managerial, scientific, technical and medical personnel. We are highly dependent upon members of our management, including our Chief Executive Officer, as well as technology and scientific teams, many of whom have been instrumental for us and have substantial experience with developing therapies, identifying potential product candidates and building the technologies related to the development of our Helicon discovery platform and our pipeline. Each of the members of our management team, and all of our employees, including key technical personnel, scientists and clinicians, are employed “at will,” meaning we or each officer or employee may terminate the employment relationship at any time. The loss of any of these persons’ services may adversely impact the achievement of our research, development, financing and commercialization objectives. We currently do not have “key person” insurance on any of our employees. Many of our key employees, including members of our leadership team, have been with us for several years, and have a significant amount of fully vested stock options or other long-term equity incentives which may become valuable and will be publicly tradable if we become a public company. We may not be able to retain these employees due to the competitive environment in the biotechnology industry, particularly in the greater Boston, Massachusetts region.

In addition, we rely on consultants, contractors and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory approval and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The loss of the services of one or more of our current employees or advisors might impede the achievement of our research, development, regulatory approval and commercialization objectives. In addition, we have flexibly added capability and capacity through the use of contractors. We may not be able to retain the services of such personnel, which might result in delays in the operation of our business.

Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. Competition for skilled personnel, including in AI, research, clinical operations, regulatory affairs, therapeutic area management and manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on favorable terms given the competition among numerous biotechnology companies and academic institutions for individuals with similar skill sets. In addition, adverse publicity, failure to succeed in preclinical or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse impact on our business, financial condition, results of operations and prospects.

We expect to continue to expand our development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We have experienced significant growth since our inception in 2015. We expect continued growth in the number of our employees and the scope of our operations, particularly to continue our planned clinical operations, preclinical and IND-enabling studies or studies approved by comparable foreign authorities, establish regulatory, quality, and manufacturing supply chain logistics and facility operations.

To manage our anticipated future growth, we will continue to seek to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the complexity in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

In addition, future growth imposes significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining, and motivating new employees; managing our internal development efforts effectively, including the clinical and FDA, or comparable foreign regulatory authority, review process for zolucetide and any current or future product candidates, while complying with our contractual obligations to third parties; and improving our operational, financial and management controls, reporting systems, and procedures.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors, and consultants to provide certain services, including strategic, financial, business development, and research and development services, as well as certain aspects of regulatory approval and manufacturing. There can be no assurance that the services of independent organizations, advisors, and consultants will continue to be available to us on a timely basis when needed or on reasonable terms, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants, CROs, CDMOs or contract manufacturing organizations (“CMOs”) is compromised for any reason, our preclinical or clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of zolucetide or any of our other current or future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new qualified employees and expanding our groups of consultants and contractors, we may experience delays or may not be able to successfully implement the tasks necessary to further develop and commercialize zolucetide for desmoid tumors and any other rare tumors and any future product candidates we develop and, accordingly, we may not achieve our research, development, and commercialization goals.

Our information technology systems or our infrastructure may fail or experience security breaches and incidents that could adversely impact our business and operations and subject us to liability.

Our information technology systems and data are vulnerable to compromise or damage from cybersecurity attacks or accidents. We have experienced significant growth in the complexity of our data and the software tools that our hardware infrastructure supports. We rely significantly upon information technology systems and infrastructure owned and maintained by us or by third-party providers to generate, collect, store and transmit confidential and proprietary information and data (including but not limited to intellectual property, proprietary business information and personal information) and to operate our business. We also outsource elements of our operations to, and obtain products and services from, third-parties and engage in collaborations for drug design with third parties, each of which has or could have access to our confidential or proprietary information. Our employees on occasion travel to countries which are at elevated risk of cyber-intrusion, data theft and expropriation.

We deploy and operate an array of technical and procedural controls to reduce the risks to our information technology (“IT”) systems, infrastructure and data and to work to maintain the availability, confidentiality and integrity of our data, and we expect to continue to incur significant costs on such detection and prevention efforts. While we continue to make investments to improve the protection of data and information technology, including in the hiring of qualified IT personnel, periodic cyber security awareness trainings, improvements to IT infrastructure and controls, and conduct regular testing of our systems, there can be no assurance that our efforts will prevent service interruptions or security breaches. Despite these measures, our information technology and other internal infrastructure systems face the risk of failures, interruptions, security breaches and incidents or other harm from various causes or sources, and third parties with whom we share confidential or proprietary information face similar risks and may experience similar events that materially impact us. These causes or sources include but are not limited to the following:

- service interruptions;
- system malfunctions;
- computer viruses and other malicious code;
- natural disasters and force majeure events;
- global political instability;
- warfare;
- cyber-intrusions by hostile nation-state actors;
- telecommunication and electrical failures;
- inadvertent or intentional actions by our employees or third-party providers; and
- cyber-attacks by malicious third parties, including the deployment of ransomware and malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information.

With respect to cyber-attacks, the techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups and individuals with a range of motives (including industrial espionage) and expertise, such as organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. These risks may be heightened in connection with geopolitical events such as the conflict between Russia and Ukraine. The costs to investigate and mitigate actual and suspected cybersecurity breaches and incidents could be significant. We may not be able to anticipate all types of security threats and implement preventive measures effective against all such threats. In addition, an increased amount of work is occurring remotely, including through the use of mobile devices. This could increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions.

We have experienced, and we may continue to experience, cyber-attacks, security breaches and incidents and other system failures, although to our knowledge we have not experienced any material interruption or incident. The loss, corruption, unavailability of or damage to our data would interfere with and undermine the insights we draw from our Helicon discovery platform and could impair the integrity of our clinical trial data, leading to regulatory delays or the inability to get our product candidates approved. If we do not accurately predict and identify our infrastructure requirements and failures and timely enhance our infrastructure, or if our remediation efforts are not successful, it could result in a material disruption of our business operations and development programs, including the loss or unauthorized disclosure of our know-how, individuals' personal information or other proprietary or sensitive data. A security breach or incident that leads to unauthorized acquisition, disclosure or other processing of our intellectual property or other proprietary information could also affect our intellectual property rights and enable competitors to compete with us more effectively.

Likewise, as we rely on third parties such as CROs, contractors and consultants, including for the manufacture of our product candidates and for the conduct of our clinical trials, similar events relating to their systems and operations could also have a material adverse effect on our business and lead to regulatory agency actions. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in or denials of our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any security compromise affecting us, our collaborators or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures, and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed, result in substantial costs and distract management.

Failures, disruptions, security breaches and incidents, cyber-attacks and other harmful events impacting data processed or maintained in our business, or information technology systems or infrastructure used in our business, including those resulting in a loss of or damage to our information technology systems or infrastructure, or the loss of or inappropriate acquisition, disclosure or other processing of confidential, proprietary or personal information, or the perception any of these has occurred, could expose us to a risk of loss, enforcement measures, regulatory agency investigations, proceedings and other actions, penalties, fines, indemnification allegations, litigation, potential civil or criminal liability, collaborators' loss of confidence, damage to our reputation and other consequences, which could materially adversely affect our business and results of operations. While we maintain insurance coverage for certain expenses and liabilities related to failures or breaches of our information technology systems, it may not be adequate to cover all losses associated with such events. In addition, such insurance may not be available to us in the future on satisfactory terms or at all. Furthermore, if the information technology systems of third parties with whom we do business become subject to disruptions or security breaches or incidents, we may have insufficient recourse against them.

Interruptions in the availability of server systems or communications with internet or cloud-based services, or failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems, could harm our business.

We rely on third-party data centers and telecommunications solutions, including cloud infrastructure services such as Amazon Web Services, to host substantial portions of our Helicon discovery platform and to support our business operations. We have limited control over these cloud-based service or other third-party providers, although we attempt to reduce risk by minimizing reliance on any single third party or its operations. We have experienced, and expect we may in the future again experience system interruptions, outages or delays due to a variety of factors, including infrastructure changes, human or software errors, website hosting disruptions and capacity constraints. A prolonged service disruption affecting our cloud-based solutions could damage our reputation or otherwise materially harm our business.

Further, if the security measures of our third-party data center or cloud infrastructure providers are breached by cyber-attacks or other means and unauthorized access to our information technology systems or data occurs, it could result in interruptions to our operations and the loss of proprietary or confidential information, which could damage our reputation, cause us to incur substantial costs, divert our resources from other tasks and subject us to significant legal and financial exposure and liabilities, any one of which could materially adversely affect our business, results of operations, and prospects. Such third-party providers may also be subject to

natural disasters, global political instability, warfare, power losses, telecommunications failures or other disruptive events that could negatively affect our business and require us to incur significant costs to secure alternate cloud-based solutions. In addition, any changes in our third-party providers' service levels or features that we utilize or the termination of our agreements could also adversely affect our business.

Our employees, principal investigators and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators and consultants. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions, provide accurate information to Regulatory Authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with Regulatory Authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate and plan to operate in a highly regulated industry and although we are not currently a party to any material proceedings or claims, we could in the future be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other allegations and legal proceedings which may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations. Even if such a proceeding, investigation or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources and cause reputational harm.

Employee litigation and unfavorable publicity could negatively affect our future business.

Our employees may, from time to time, bring lawsuits against us regarding injury, creating a hostile workplace, discrimination, wage and hour disputes, sexual harassment or other employment issues. In recent years there has been an increase in the number of discrimination and harassment allegations generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these allegations have had a significant negative impact on some businesses. Certain companies that have faced employment- or harassment-related lawsuits have had to terminate management or other key personnel and have suffered reputational harm that has negatively impacted their business. If we were to face any employment-related allegations, our business could be negatively affected.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter and insurance coverage is becoming increasingly expensive. We do not know if we will be able to maintain existing insurance with adequate levels of coverage in the future, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. If we obtain marketing approval for any product candidates that we or our collaborators may develop, we intend to

acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. The coverage or coverage limits currently maintained under our insurance policies may not be adequate. If our losses exceed our insurance coverage, our financial condition would be adversely affected. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that we or our collaborators may identify. Additionally, operating as a public company has made it more expensive for us to obtain directors and officers liability insurance. If we do not maintain adequate levels of directors' and officers' liability insurance, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors and in our leadership team.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We and our current and future CDMOs are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations will involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We generally anticipate contracting with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort allegations that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our current and any future CDMOs, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates. In addition, our supply chain may be adversely impacted if any of our CDMOs become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

We or the third parties upon whom we depend may be adversely affected by natural disasters or other business interruptions such as cybersecurity attacks and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations, and have a material adverse impact on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, cybersecurity attack or other force majeure event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as the manufacturing facilities of our CDMOs, limited our ability to access or use our Helicon discovery platform or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. Cybersecurity liability insurance is difficult to obtain and may not cover any damages we would sustain based on any breach of our computer security protocols or other cybersecurity attack. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse impact on our business.

Risks Related to Ownership of Our Common Stock and This Offering

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations with the underwriters. An active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares, or at all. An inactive market may also impair our ability to raise capital by selling shares, which in turn could materially adversely affect our business.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

Our stock price is likely to be volatile. The stock market in general, and the market for biotechnology companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including: the commencement, enrollment, completion or results of preclinical and clinical trials of our product candidates or those of our competitors; the success of competitive products or technologies; commencement or termination of partnership, collaboration, and licensing arrangements; regulatory or legal developments in the United States and other countries; developments or disputes concerning patent applications, issued patents or other proprietary rights; significant lawsuits, including patent or stockholder litigation; the recruitment or departure of key personnel; the level of expenses related to any of our product candidates or clinical development programs; the results of our efforts to discover, develop, acquire or in-license additional product candidates; actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; variations in our financial results or those of companies that are perceived to be similar to us; changes in the structure of healthcare payment systems; market conditions in the biotechnology and high-tech sectors, including high interest rates and borrowing costs; general economic, industry and market conditions; and the numerous product candidates in our pipeline, the development of which could each generate news or significant adverse events that could impact financial results or recommendations by securities analysts.

If our quarterly or annual results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our results may, in turn, cause the price of our stock to fluctuate substantially. We believe that period-to-period comparisons of our results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such allegations and divert management's attention and resources, which could seriously harm our business, financial condition, results of operations and prospects.

We may not be able to satisfy listing requirements of Nasdaq or obtain or maintain a listing of our common stock on Nasdaq.

We must meet certain financial and liquidity criteria to maintain our common stock's listing on The Nasdaq Global Select Market ("Nasdaq"). If we violate Nasdaq's listing requirements, our common stock may be delisted. If we fail to meet any of Nasdaq's listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. The delisting of our common stock from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of your investment.

Future sales of our common stock in the public market could cause our common stock price to fall.

Our common stock price could decline as a result of sales of a large number of shares of common stock after this offering or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

Upon the completion of this offering and the concurrent private placement, 118,145,780 shares of common stock and non-voting common stock will be outstanding (or 123,170,780 shares if the underwriters exercise their overallotment option in full), based on the number of shares outstanding as of March 31, 2026, after giving effect to the conversion of 102,814,601 shares of our convertible preferred stock into an aggregate of 73,992,071 shares of our common stock and 1,581,210 shares of our non-voting common stock and outstanding SAFE into an aggregate of 2,777,777 shares of our common stock, based on the initial offering price of \$20.00 per share.

Substantially all shares of common stock expected to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended (the “Securities Act”), unless held by our “affiliates” as defined in Rule 144 under the Securities Act. The resale of the remaining shares, or approximately 71.6% of our outstanding shares of common stock following this offering, is currently prohibited or otherwise restricted as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with this offering. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning 181 days after the date of this prospectus. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements and/or lock-up agreements, as well as Rules 144 and 701 under the Securities Act. For more information, see the section titled “*Shares Eligible for Future Sale*.”

Upon the completion of this offering and the concurrent private placement, the holders of approximately 73,992,071 shares of our common stock and 1,581,210 shares of our non-voting common stock, or approximately 64.0% of our outstanding capital stock shares following this offering, will have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares (or, in the case of the non-voting common stock, the voting common stock to be received upon conversion of the non-voting common stock) or to include their shares in registration statements that we may file for ourselves or our other stockholders. See the section titled “*Description of Capital Stock—Registration Rights*” for more information. We also intend to register the offer and sale of all shares of common stock that we may issue under our equity compensation plans. Once we register the offer and sale of shares for the holders of registration rights and shares that may be issued under our equity incentive plans, these shares will be able to be sold in the public market upon issuance, subject to the lock-up agreements described under the section titled “*Underwriting*.”

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

You will suffer immediate and substantial dilution in the net tangible book value of our common stock if you purchase in this offering. Based on the initial public offering price of \$20.00 per share, after giving effect to this offering and the concurrent private placement, purchasers of common stock in this offering will experience immediate dilution of \$11.64 per share in net tangible book value of our common shares. In addition, after giving effect to this offering and the concurrent private placement, investors purchasing common stock in this offering will contribute 41.6% of the total amount invested by stockholders since inception but will only own 28.4% of the common stock outstanding. In the past, we issued options and other securities to acquire common stock at prices significantly below the initial public offering price. To the extent these outstanding securities are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. See the section titled “*Dilution*” appearing elsewhere in this prospectus for a more detailed description of the dilution to new investors in the offering.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration, and licensing arrangements, or a combination of these approaches. To the extent that we raise additional capital through the sale of stock or convertible or exchangeable debt securities, warrants or other similar equity securities, your ownership interest could be diluted and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations and alliances and licensing arrangements with third parties or through asset sales, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or financial analysts. If no, or few, analysts commence coverage of us, the trading price of our stock may decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or

more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, five percent stockholders and their affiliates beneficially own approximately 61.1% of our common stock and, upon closing of this offering and the concurrent private placement, that same group will beneficially own approximately 40.7% of our outstanding common stock and non-voting common stock (assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options and without giving effect to (i) any potential purchases by such persons in this offering or (ii) issuance of options granted to certain of our employees and non-employee directors upon the pricing of this offering). Therefore, even after this offering, these stockholders will have the ability to influence us through their ownership positions. For example, these stockholders, acting together, may be able to exert significant influence over matters such as elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

In addition, certain of our stockholders hold non-voting common stock that is convertible at the stockholder's discretion into common stock, subject to certain restrictions. To the extent holders of our non-voting common stock exercise their option to make this conversion, the relative voting power of such stockholder will increase and the relative voting power of all other holders of common stock will decrease, which may limit your ability to influence matters subject to stockholder approval.

Participation in this offering by our existing stockholders and their affiliated entities may reduce the public float for our common stock.

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and principal stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

We have broad discretion in the use of our cash and cash equivalents, including the net proceeds from this offering and the concurrent private placement, and may not use them effectively.

Our management will have broad discretion in the application of our cash and cash equivalents, including the net proceeds from this offering and the concurrent private placement, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse impact on our business, cause the price of our common stock to decline, and delay the development of our product candidates. Pending their use, we may invest our cash and cash equivalents, including the net proceeds from this offering and the concurrent private placement, in a manner that does not produce income or that loses value. See the section titled "Use of Proceeds" appearing elsewhere in this prospectus.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Provisions in our seventh amended and restated certificate of incorporation, which will be in effect immediately prior to the closing of this offering, and amended and restated bylaws, which became effective upon the effectiveness of this registration statement of which this prospectus forms a part, may significantly reduce the value of our shares to a potential acquiror or make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors will have the authority to issue up to 10,000,000 shares of preferred stock and may fix the price, rights, preferences, privileges and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. The issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our seventh amended and restated certificate of incorporation will contain, and our amended and restated bylaws will contain, other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- stockholders will not be entitled to remove directors other than by a two-thirds vote and only for cause;
- stockholders will not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (“DGCL”), which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Any provision of our seventh amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We do not currently intend to declare or pay cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends.

As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us.

Our amended and restated bylaws, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws (including the interpretation, validity or enforceability thereof) or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery of the State of Delaware having personal jurisdiction over the indispensable parties named as defendants therein (the “Delaware Forum Provision”). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act (the “Federal Forum Provision”). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers, or employees, which may discourage such lawsuits against us and our directors, officers, and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

General Risk Factors

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. We will be subject to financial reporting and other requirements for which our accounting and other management systems and resources may not be adequately prepared.

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the federal securities laws, including the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including requirements to file annual, quarterly and event driven reports with respect to our business and financial condition, and to establish and maintain effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. We may not be able to produce reliable financial statements or file these financial statements as part of a periodic report in a timely manner with the SEC or comply with the Nasdaq listing requirements. In addition, we could make errors in our financial statements that could require us to restate our financial statements.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an EGC, as defined in the JOBS Act. We will remain an EGC until the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.235 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the last day of the fiscal year in which the market value of our common stock and non-voting common stock that is held by non-affiliates exceeds \$700.0 million. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include: not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act ("Section 404"); not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; reduced disclosure obligations regarding executive compensation; and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this prospectus. In particular, we have not included all of the executive compensation information that would be required if we were not an EGC. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive, as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an EGC may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an EGC we may not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not EGCs.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with this offering, we intend to begin the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404, which will require annual management assessment of the effectiveness of our internal control over financial reporting starting with our second filing of an Annual Report on Form 10-K.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy or consequent inability to produce accurate financial statements on a timely basis could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis cause investors to lose confidence in the accuracy and completeness of our financial reports and could cause the market price of our common stock to decline significantly.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the closing of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our future ability to utilize our NOL carryforwards and certain other tax attributes may be limited.

Since our inception, we have incurred losses and we may never achieve profitability. As of December 31, 2025, we had U.S. federal NOL carryforwards of \$357.9 million (of which \$348.9 million can be carried forward indefinitely and the remainder of which begins to expire in 2036) and state NOL carryforwards of \$347.4 million (of which \$2.7 million can be carried forward indefinitely and the remainder of which begin to expire in 2036). We also had U.S. federal research and development tax credit carryforwards of \$17.2 million available to offset future U.S. federal income taxes, which begin to expire in 2030. As of December 31, 2025, we had state tax credit carryforwards of \$7.7 million which begin to expire in 2030. To the extent that we continue to generate taxable losses, under current law, our unused U.S. federal NOLs may be carried forward to offset a portion of future taxable income, if any. Additionally, we continue to generate business tax credits, including research and development tax credits, which generally may be carried forward to offset a portion of future taxable income, if any, subject to expiration of such credit carryforwards. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," generally defined as one or more shareholders who own at least five percent of the corporation's equity increasing their equity ownership in the aggregate by more than 50 percentage points (by value) over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. Similar rules may apply under state tax laws. We may experience ownership changes in the future as a result of this offering or subsequent shifts in our stock ownership, some of which are outside of our control. As a result, if we earn net taxable income, our ability to use our pre-change NOLs or other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. There is a risk that due to changes under the tax law, regulatory changes or other unforeseen reasons, our existing NOLs or business tax credits could expire or otherwise be unavailable to offset future income tax liabilities. At the state level, there may also be periods during which the use of NOLs or business tax credits is suspended or otherwise limited, which could accelerate or permanently increase state taxes. For these reasons, we may not be able to realize a tax benefit from the use of our NOLs or tax credits, even if we attain profitability.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service (the “IRS”) and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our business and our financial condition. In recent years, many such changes have been made and changes are likely to continue to occur in the future. We cannot predict whether, when, in what form or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided or whether they could increase our tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability. Future changes in tax law could have a material adverse effect on our business, cash flow, financial condition or results of operations.

We and our service providers are subject to a variety of stringent and evolving privacy and data security laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. Any actual or perceived failure to comply with such obligations could expose us to significant fines or other penalties and otherwise harm our business and operations.

In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store or otherwise process personal data, including information we may collect about participants in our clinical trials. Our data processing activities subject us to numerous, evolving privacy and data security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to privacy and data security.

The legislative and regulatory framework for the processing of personal data worldwide is rapidly evolving in a manner that is increasingly stringent and, globally, this legal and regulatory framework is likely to remain uncertain for the foreseeable future. We must devote significant resources to understanding and complying with the changing landscape in this area. Each law is also subject to various interpretations by courts and Regulatory Authorities, creating additional uncertainty, and we may fail to comply with the evolving data protection laws, which may expose us to risk of enforcement actions taken by authorities, private rights of action in some jurisdictions and potential significant penalties if we are found to be non-compliant. Some of these laws and regulations also carry the possibility of criminal sanctions.

In the United States, numerous federal, state and local laws and regulations, including federal health information privacy laws, state information security and data breach notification laws, federal consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), state consumer protection and privacy laws and other similar laws (e.g., wiretapping and communications interception laws) govern the processing of health-related and other personal data. At the state level, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording individuals certain rights concerning their personal data. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While existing state comprehensive privacy laws exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Additionally, we may be subject to new laws governing the privacy of consumer health data. These various privacy and data security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. Regulators and legislators in the United States are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Biden Administration’s executive order Preventing Access to Americans’ Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern as implemented by the Department of Justice’s final rule issued in December 2024, effective April 8, 2025, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data and biospecimens, to certain countries of concern, including China. The final rule also restricts certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. The final rule does not exempt key-coded or otherwise anonymized, pseudonymized, de-identified or encrypted data. Actual or alleged violations of the final rule may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

Outside the United States, an increasing number of laws, regulations and industry standards may govern privacy, data security and the transfer of personal data between jurisdictions. For example, the EU’s General Data Protection Regulation (“EU GDPR”) and the United Kingdom’s General Data Protection Regulation (“UK GDPR” and, together with the EU GDPR, “GDPR”) impose strict requirements for processing personal data including relating to processing of sensitive data (such as health data), ensuring there is a legal basis or condition to justify the processing of personal data, where required requirements relating to obtaining consent of individuals, disclosures about how personal data is to be used, limitations on retention of information, implementing safeguards to protect the security and confidentiality of personal data, where required providing notification of data breaches, maintaining records of processing activities and documenting data protection impact assessments where there is high risk processing and taking certain measures when engaging third party processors. Under GDPR, companies may face temporary or definitive bans on data processing and other corrective activities, fines of up to €20.0 million (£17.5 million GBP) or 4% of annual global revenues, whichever is greater,

and private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Non-compliance could also result in a material adverse effect on our business, financial position and results of operations.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (“EEA”) and the United Kingdom (“UK”) have significantly restricted the transfer of personal data to the United States and other countries. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA’s standard contractual clauses, the UK’s International Data Transfer Agreement / Addendum and the EU-U.S. Data Privacy Framework (“Framework”) and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States (or other countries), or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants and activities activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR’s cross-border data transfer limitations.

Although the UK is regarded as a third country under the EU GDPR, the European Commission has adopted an adequacy decision in favor of the UK, a decision recognizing the UK as providing adequate protection under the EU GDPR and enabling data transfers from Member States to the UK without additional safeguards. The UK adequacy decision was renewed in December 2025 and will automatically expire in December 2031. The EU GDPR and the UK GDPR currently impose substantially similar obligations. However, the European Commission retains the authority to monitor developments in UK law, including implementation of the Data (Use and Access) Act 2025, and may amend, suspend or repeal the adequacy decisions if it determines that the UK no longer ensures an essentially equivalent level of protection. Any such action, or a successful legal challenge to the adequacy decisions could lead to additional compliance costs and could increase our overall risk.

Additionally in the EEA, the NIS 2 Directive (“NIS 2”) is replacing the cybersecurity legal framework under the current NIS framework, aiming to ensure a high level of cybersecurity in the region. NIS 2 brings new medium and large organizations providing services in the EEA within scope of the legal framework. It extends to additional sectors and expands the list of in-scope healthcare organizations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in-scope organization’s compliance with NIS 2, requires covered organizations to put in place certain cyber risk management measures, strengthens incident reporting requirements and provides supervisory authorities with greater oversight. The majority of obligations will come into force when national legislation implementing NIS 2 becomes effective in the relevant Member State. Member States had until October 17, 2024 to transpose NIS 2 into national legislation, although many countries have still not completed the transposition. As such, the cybersecurity regulatory landscape in the EEA is currently fragmented and uncertain. To the extent we are subject to NIS 2, we will require additional investment of our resources in compliance programs. Under NIS 2 companies may be subject to administrative fines of up to the higher amount of €10.0 million or 2% of worldwide turnover.

In addition to privacy and data security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to privacy and data security, and our efforts to comply with such obligations may not be successful. We publish privacy policies and other statements, such as compliance with certain certifications or self-regulatory principles, regarding privacy and data security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to privacy and data security are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems and practices and to those of any third parties that process personal data on our behalf.

We may at times fail in our efforts to comply with our privacy and data security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely, including CROs supporting our clinical trials, clinical trial sites with whom we have contracted and other third parties supporting our clinical trials, may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable privacy and data security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-action claims), and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for significant statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, financial condition, results of operations and growth prospects, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Unfavorable U.S. or global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and financial markets. The global economy and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, rising inflation, uncertainty from changes in tariff policies, fluctuating interest rates, declines in economic growth, global supply chain disruptions and uncertainty about economic stability. The global economy and financial markets may also be adversely affected by the current or anticipated impact of military conflict, terrorism or other geopolitical events, including the ongoing wars in Ukraine and the Middle East, and the increasingly strained relationship between the United States and China. Sanctions imposed by the United States and other countries in response to such conflicts may adversely impact the financial markets and the global economy, and the economic countermeasures by the affected countries or others could exacerbate market and economic instability.

There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for any product candidates or products we may develop and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. If the equity and credit markets deteriorate, it may make any necessary equity or debt financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could impair our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled “*Prospectus Summary*,” “*Risk Factors*,” “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*,” and “*Business*,” contains express or implied forward-looking statements that are based on our management’s belief and assumptions and on information currently available to our management. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of preclinical studies, clinical trials, research and development costs, regulatory approvals, commercial strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “would,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “believe,” “estimate,” “predict,” “potential,” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the initiation, timing, progress and results of our research and development programs, preclinical studies and clinical trials;
- the ability of clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results, and the ability of our preclinical studies to predict later clinical trial results;
- the timing, scope and likelihood of regulatory filings and approvals of our product candidates;
- the implementation of our business model, and strategic plans for our business, platform, programs, and current and future product candidates;
- our ability to obtain additional cash and the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our potential and ability to successfully manufacture and supply our current and future product candidates for clinical trials and for commercial use, if approved;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- expectations regarding future events under collaboration and licensing agreements, including potential future payments, as well as our plans and strategies for entering into further collaboration and licensing agreements;
- general economic, industry and market conditions, including fluctuating interest rates and rising inflation;
- our ability to attract and retain the continued service of our key personnel and to identify, hire and then retain additional qualified personnel;
- our expectations regarding the period during which we will qualify as an EGC under the JOBS Act;
- the terms and completion of the concurrent private placement; and
- our anticipated use of our existing cash and cash equivalents and the proceeds from this offering and the concurrent private placement.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described in “*Risk Factors*” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. No forward-looking statement is a guarantee of future performance. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events or otherwise. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures, or investments that we may make or enter into.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately \$618.2 million (or approximately \$711.7 million if the underwriters exercise their overallotment option in full) based on the initial public offering price of \$20.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We also expect to receive net proceeds of approximately \$75.0 million from the sale of shares of our common stock in the concurrent private placement, after deducting estimated private placement expenses payable by us.

The principal purposes of this offering are to create a public market for our common stock and thereby facilitate future access to the public equity markets, increase our visibility in the marketplace, and obtain additional capital to support our operations. We currently intend to use the net proceeds from this offering as follows:

- Approximately \$150.0 million to continue the ongoing clinical development of zolucetide in desmoid tumors, including continuation of dose expansion and the initiation of a Phase 3 registrational trial to topline data;
- Approximately \$120.0 million to continue the ongoing clinical development of zolucetide across several additional indications, including dose escalation and expansion in FAP, HCC, and other rare tumors to collect data to support our registrational trial;
- Approximately \$190.0 million to advance our pipeline of additional programs, including our ERG, AR^{ON}, and β -catenin degraders to Phase 1 clinical data; and
- the remainder for continued evolution of the Helicon platform and for general corporate purposes, including additional development efforts, working capital, and operating expenses.

We may also use a portion of the remaining net proceeds and our existing cash and cash equivalents to in-license, acquire, or invest in complementary businesses, technologies, products, or assets. However, we have no current commitments, agreements, understandings or obligations to do so. Assuming completion of the concurrent private placement in accordance with Regeneron's contractual obligations, we expect to receive additional proceeds that would be available to fund any of the foregoing uses.

We believe that our existing cash and cash equivalents, together with the anticipated net proceeds from this offering and the upfront payment of \$50.0 million we expect to receive from Regeneron, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2029. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. Even if this offering and the concurrent private placement are successful, we will require additional funding in order to finance operations and complete our ongoing and planned clinical trials. Access to such funding on acceptable terms cannot be assured.

Our expected use of proceeds from this offering and the concurrent private placement described above represents our current intentions based on our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering and the concurrent private placement or the actual amounts that we will spend on the uses set forth above. We expect that we will require additional funds in order to fully accomplish the specified uses of the proceeds of this offering and the concurrent private placement. The amounts and timing of our actual expenditures will depend on numerous factors, including progress of our research and development, the status of and results from preclinical studies and clinical trials that we are conducting or may conduct in the future, and other factors described in the section titled "*Risk Factors*" in this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes.

We will have broad discretion over how to use the net proceeds to us from this offering and the concurrent private placement and investors will be relying on the judgment of our management regarding the application of the net proceeds. Pending our use of the net proceeds from this offering and the concurrent private placement, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term and long-term interest-bearing instruments, investment-grade securities, and direct or guaranteed obligations of the U.S. government. We cannot predict whether the proceeds invested will yield a favorable return.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws, and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects, and other factors our board of directors may deem relevant.

In addition, our ability to pay cash dividends on our capital stock is limited by our term loan from Silicon Valley Bank and may in the future be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

CAPITALIZATION

The following table sets forth our existing cash and cash equivalents, excluding restricted cash, and our total capitalization as of March 31, 2026:

- on an actual basis;
- on a pro forma basis, giving effect to (i) the conversion of all outstanding shares of convertible preferred stock into an aggregate of 73,992,071 shares of our common stock and 1,581,210 shares of our non-voting common stock upon the closing of this offering, (ii) the conversion of our outstanding SAFE into 2,777,777 shares of our common stock, including a change in the fair value of the SAFE liability of \$5.6 million after March 31, 2026 based on the initial public offering price of \$20.00 per share, and (iii) the filing and effectiveness of our seventh amended and restated certificate of incorporation, which will occur immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis, giving effect to (i) the pro forma adjustments set forth above, (ii) the issuance and sale of 33,500,000 shares of common stock in this offering at the initial public offering price of \$20.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and (iii) the issuance and sale of 4,166,666 shares of common stock in the concurrent private placement at a price per share equal to 90% of the initial public offering price per share of the shares offered in this offering, after deducting estimated private placement expenses payable by us.

You should read this information together with our consolidated financial statements and the related notes included elsewhere in this prospectus, and the section titled “*Management’s Discussion and Analysis of Financial Condition and Results of Operations.*”

(in thousands, except share and per share data)	As of March 31, 2026		
	Actual	Pro Forma	Pro Forma, As Adjusted
Cash and cash equivalents	\$ 329,039	\$ 329,039	\$ 1,022,239
Current liabilities:			
Term loan, net of discount	\$ 9,401	\$ 9,401	\$ 9,401
Simple agreement for future equity	50,000	—	—
Convertible preferred stock (Series A, Series B, Series C, Series D, Series E and Series F), \$0.0001 par value; 102,814,601 shares authorized and 102,814,601 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	814,540	—	—
Stockholders’ (deficit) equity:			
Preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized, and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, \$0.0001 par value; 150,132,000 shares authorized and 2,128,056 shares issued and outstanding, actual; 600,000,000 shares authorized and 78,897,904 shares issued and outstanding, pro forma; 600,000,000 shares authorized and 116,564,570 shares issued and outstanding, pro forma as adjusted	—	8	12
Non-voting common stock, \$0.0001 par value; no shares authorized, issued or outstanding, actual; 200,000,000 shares authorized, and 1,581,210 shares issued and outstanding, pro forma and pro forma as adjusted	—	—	—
Additional paid-in capital	16,500	886,588	1,579,784
Accumulated deficit	(586,820)	(592,376)	(592,376)
Total stockholders’ (deficit) equity	(570,320)	294,220	987,420
Total capitalization	\$ 303,621	\$ 303,621	\$ 996,821

The number of shares of our common stock and non-voting common stock that will be outstanding after this offering and the concurrent private placement on a pro forma and pro forma as adjusted basis is based on 80,479,114 shares of common stock outstanding as of March 31, 2026, after giving effect to (i) the conversion of all outstanding shares of our convertible preferred stock into the aggregate of 73,992,071 shares of common stock and 1,581,210 shares of non-voting common stock upon the closing of this offering, and (ii) the conversion of our outstanding SAFE into 2,777,777 shares of our common stock, based on the initial public offering price of \$20.00 per share, and excludes:

- 8,823,077 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2026 under our 2016 Plan, with a weighted average exercise price of \$2.67 per share;

- 5,986,341 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2026 under our January 2026 Plan, with a weighted average exercise price of \$3.15 per share;
- 1,174,922 shares of common stock issuable upon exercise of outstanding stock options granted after March 31, 2026 pursuant to our January 2026 Plan, with a weighted average exercise price of \$4.09 per share;
- 3,069,339 shares of common stock reserved for future issuance as of March 31, 2026 under the January 2026 Plan, which ceased to be available for issuance at the time that our 2026 Plan became effective;
- 1,110,000 shares of common stock reserved for future issuance under our ESPP, which became effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP;
- 11,070,000 shares of our common stock that became available for future issuance under our 2026 Plan, which became effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any shares underlying outstanding stock awards granted under the January 2026 Plan and 2016 Plan that expire or are repurchased, forfeited, cancelled, or withheld; and
- 24,152 shares of our common stock issuable upon exercise of warrants outstanding as of March 31, 2026 at an exercise price of \$4.82 per share.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering and the concurrent private placement.

Our historical net tangible book deficit as of March 31, 2026 was \$571.8 million, or \$(268.70) per share of our common stock. Our historical net tangible book deficit represents the amount of our total tangible assets less our total liabilities, excluding the deferred offering costs, and the carrying value of our convertible preferred stock, which is not included within stockholders' deficit. Historical net tangible book deficit per share represents historical net tangible book deficit divided by 2,128,056 shares of our common stock outstanding as of March 31, 2026.

Our pro forma net tangible book value as of March 31, 2026 was \$292.7 million, or \$3.64 per share of our common stock (including shares of non-voting common stock). Pro forma net tangible book value per share represents the amount of our total tangible assets less our total liabilities, excluding the deferred offering costs, divided by the number of shares of our common stock outstanding as of March 31, 2026, after giving effect to (i) the conversion of all outstanding shares of convertible preferred stock into 73,992,071 shares of common stock and 1,581,210 shares of non-voting common stock upon the closing of this offering and (ii) the conversion of our outstanding SAFE into 2,777,777 shares of our common stock, based on the initial offering price of \$20.00 per share.

After giving further effect to (i) the sale of 33,500,000 shares of common stock that we are offering at the initial public offering price of \$20.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us and (ii) the sale of 4,166,666 shares of common stock in the concurrent private placement at a price per share equal to 90% of the initial public offering price per share of the shares offered in this offering, after deducting estimated private placement expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2026 would have been \$987.4 million, or \$8.36 per share of our common stock (including shares of non-voting common stock). This amount represents an immediate increase in pro forma net tangible book value of \$4.72 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of \$11.64 per share to new investors purchasing shares of common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering and the concurrent private placement from the initial public offering price per share paid by new investors. The following table illustrates this dilution (without giving effect to any exercise by the underwriters of their overallotment option):

Initial public offering price per share	\$ 20.00
Historical net tangible book deficit per share as of March 31, 2026	\$ (268.70)
Increase per share as of March 31, 2026 attributable to the pro forma adjustments described above	<u>272.34</u>
Pro forma net tangible book value per share as of March 31, 2026	3.64
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering and the concurrent private placement	<u>4.72</u>
Pro forma as adjusted net tangible book value per share after this offering and the concurrent private placement	8.36
Dilution per share to new investors participating in this offering	<u><u>\$ 11.64</u></u>

If the underwriters exercise their overallotment option in full, our pro forma as adjusted net tangible book value after the offering and the concurrent private placement would be \$8.78 per share, representing an immediate increase in pro forma as adjusted net tangible book value of \$5.14 per share to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value dilution of \$11.22 per share to new investors, in each case based on the initial public offering price of \$20.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, on the pro forma as adjusted basis described above, as of March 31, 2026, the total number of shares of common stock purchased from us, the total consideration paid or to be paid to us, and the average price per share paid by existing stockholders or to be paid by new investors in this offering and the concurrent private placement, based on the initial public offering price of \$20.00 per share, before deducting underwriting discounts and commissions and estimated expenses payable by us. New investors purchasing shares of our common stock in this offering and the concurrent private placement will pay an average price per share substantially higher than our existing stockholders paid.

(in thousands, except share and per share data, and percentages)	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percentage	Amount	Percentage	
Existing stockholders	80,479,114	68.1%	\$ 864,482	53.7%	\$ 10.74
Concurrent private placement investor	4,166,666	3.5%	75,000	4.7%	\$ 18.00
New investors purchasing shares in this offering	33,500,000	28.4%	670,000	41.6%	\$ 20.00
Total	118,145,780	100.0%	\$ 1,609,482	100.0%	\$ 13.62

The table above assumes no exercise of the underwriters' overallotment option. If the underwriters exercise their overallotment option in full, our existing stockholders would own 65.3%, and new investors purchasing shares of our common stock in this offering would own 31.3%, of the total number of shares of our common stock outstanding immediately after the completion of this offering and the concurrent private placement.

The number of shares of our common stock and non-voting common stock that will be outstanding after this offering and the concurrent private placement is based on 80,479,114 shares of common stock outstanding as of March 31, 2026, after giving effect to (i) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 73,992,071 shares of common stock and 1,581,210 shares of non-voting common stock immediately prior to the completion of this offering and (ii) the conversion of our outstanding SAFE into 2,777,777 shares of our common stock, based on the initial offering price of \$20.00 per share, and excludes:

- 8,823,077 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2026 under our 2016 Plan, with a weighted average exercise price of \$2.67 per share;
- 5,986,341 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2026 under our January 2026 Plan, with a weighted average exercise price of \$3.15 per share;
- 1,174,922 shares of common stock issuable upon exercise of outstanding stock options granted after March 31, 2026 pursuant to our January 2026 Plan, with a weighted average exercise price of \$4.09 per share;
- 3,069,339 shares of common stock reserved for future issuance as of March 31, 2026 under the January 2026 Plan, which ceased to be available for issuance at the time that our 2026 Plan became effective;
- 1,110,000 shares of common stock reserved for future issuance under our ESPP, which became effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP;
- 11,070,000 shares of our common stock that became available for future issuance under our 2026 Plan, which became effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as shares underlying outstanding stock awards granted under the January 2026 Plan and 2016 Plan that expire or are repurchased, forfeited, cancelled, or withheld; and
- 24,152 shares of our common stock issuable upon exercise of warrants outstanding as of March 31, 2026 at an exercise price of \$4.82 per share.

To the extent any outstanding options are exercised, new options or other equity awards are issued under our equity incentive plans, or we issue additional shares of common stock in the future, there will be further dilution to new investors. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, strategies, objectives, expectations, intentions and beliefs. As a result of many factors, including those factors set forth in the "Special Note Regarding Forward-Looking Statements" and "Risk Factors" sections of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company built to develop transformative medicines addressing some of the most consequential, yet historically undruggable, protein targets driving human disease. We leverage our proprietary platform to pioneer a novel therapeutic modality, Helicons, which are stabilized helical peptides engineered to bind and precisely modulate proteins that have long been beyond the reach of conventional medicines.

To our knowledge, our lead product candidate, zolucetide, is the first-ever drug to directly target the interaction between β -catenin and the T-cell factor ("TCF") family of transcription factors. This is the central node in the Wnt/ β -catenin cell signaling pathway which regulates cell proliferation and differentiation and whose hyperactivation is a driver of millions of cancer cases annually across many tumor types. Drugging this critical node eluded three decades of intensive efforts to do so across the pharmaceutical industry. Zolucetide has been evaluated in over 150 patients to date and has generated promising clinical data in a range of solid tumors driven by alterations in the Wnt/ β -catenin pathway. In our lead indication, desmoid tumors, we have observed tumor reductions in 100% of patients with a 74% objective response rate ("ORR") in patients who have had at least two post-baseline scans.

Objective responses have been observed across patients who have failed γ -secretase inhibitors ("GSIs") and those who have never taken GSIs. Importantly, zolucetide has been able to generate this rate of response with a tolerability profile that we believe is more favorable than that of currently available drug therapy. We plan to initiate a global registrational Phase 3 trial for zolucetide in patients with desmoid tumors in the first half of 2027.

We believe zolucetide provides clinical validation of our first-in-industry Helicon approach and represents an expansive opportunity for medical and commercial impact. Our preclinical pipeline provides additional examples of the repeatability of our Helicon approach and includes programs targeting two key drivers of prostate cancer, the ETS-related gene ("ERG") and the androgen receptor in its active state ("AR^{ON}"). Our current pipeline is focused on various cancers and tumor types; however, we believe Helicons could also have broad applicability against targets in many diseases with substantial unmet need outside oncology, and we plan to evaluate other therapeutic areas in the future.

An estimated 80% of biologically validated disease targets are considered undruggable, largely because the majority reside inside cells and present flat interaction surfaces. Small molecules can enter cells but cannot bind flat surfaces, and antibodies and other highly-selective biologics can selectively bind flat protein surfaces but cannot enter cells to access these targets. To our knowledge, Helicons are the only modality to date that can consistently solve this problem as they are engineered for cell penetration and capable of binding to flat intracellular protein target surfaces with high specificity. Helicons combine the precision of antibodies and biologics with the intracellular access and tunability of small molecules in a single modality – enabling direct engagement of historically inaccessible protein targets. Our proprietary Helicon discovery platform allows us to integrate ligands and additional functionalities at multiple positions to precisely tune potency, selectivity, and pharmacologic properties. While our initial programs are focused on disrupting protein-protein interactions and inducing targeted protein degradation, we believe our platform can incorporate other advances in small molecule drug design and extend them to targets that are likely to remain out of reach for other modalities.

Our Helicon discovery platform integrates advanced artificial intelligence ("AI") and physics-based computational modeling with high-throughput peptide synthesis and experimental screening to discover and develop drug candidates. Since our founding, we have advanced computational models as well as custom design, synthesis, handling and manufacturing know-how to position us to produce Helicons reliably and at scale. A decade of applying these capabilities to Helicon drug discovery has generated vast proprietary datasets, comprising millions of data points for hundreds of thousands of Helicons across dozens of drug-like properties. These data power a continuous learning loop that refines our models from target selection through lead optimization, enhancing our speed, precision, and ability to generate high quality molecules against difficult targets. As a result, our platform produces unique complex synthetic molecules at scale and a compounding advantage that we believe is difficult to replicate.

We are advancing a wholly-owned pipeline of Helicon-based product candidates against high-value targets.

To date, we have funded our operations primarily with proceeds from sales of our convertible preferred stock, borrowings under a term loan and the issuance of a Simple Agreement for Future Equity (“SAFE”). As of March 31, 2026, we received aggregate gross cash proceeds of \$876.8 million, including \$811.8 million from sales of our convertible preferred stock, \$15.0 million from borrowings under our term loan and \$50.0 million from the issuance of a SAFE. In May 2026, we entered into a license and collaboration agreement with Regeneron Pharmaceuticals, Inc. (“Regeneron”), and in connection therewith, we expect to receive a non-refundable upfront payment in the amount of \$50.0 million. In addition, Regeneron has agreed to purchase \$75.0 million of our common stock in the concurrent private placement or our next equity financing.

We have incurred significant operating losses since inception and we expect to continue to incur substantial losses for the foreseeable future. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates and any additional product candidates we may develop. Our net losses were \$117.9 million and \$145.9 million for the years ended December 31, 2024 and 2025, respectively, and \$38.3 million and \$45.3 million for the three months ended March 31, 2025 and 2026, respectively. As of March 31, 2026, we had an accumulated deficit of \$586.8 million.

We anticipate that our expenses and operating losses will increase substantially for the foreseeable future if and as we:

- expand the number of our development programs;
- continue or expand our scope of research or development of our current programs and product candidates in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical, clinical or other studies or trials for our programs and product candidates, including pursuant to our licensing and collaboration arrangements;
- change or add additional manufacturers or suppliers;
- add additional infrastructure to our quality control and quality assurance groups to support our operations as we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts;
- seek marketing approvals and reimbursement for our product candidates and products;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- acquire or in-license technologies;
- make payments under any in-license agreements;
- maintain, protect and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

We will not generate revenue from product sales unless and until we successfully initiate and complete clinical development and obtain regulatory approval for one or more of our product candidates, which may not occur for several years, if at all. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, manufacturing, marketing, market access and distribution.

Our net losses may fluctuate significantly from period to period, depending on the timing of our planned clinical trials and expenditures related to our research and developmental activities. Furthermore, following the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant audit, legal, and regulatory expenses, as well as director and officer insurance premiums and investor relations costs that we did not incur as a private company. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt or royalty financings, and collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on

favorable terms, or at all. Our failure to raise capital or enter into such agreements or arrangements as, and when, needed, could have a material adverse effect on our business, results of operations, and financial condition, including requiring us to delay, reduce or eliminate product development or future commercialization efforts, or grant rights to develop and market development product candidates that we would otherwise prefer to develop and market ourselves.

As there are numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As a result, we will need substantial additional capital to support our continuing operations and pursue our strategy. As of March 31, 2026, we had total cash and cash equivalents of \$329.0 million. We believe that our existing cash and cash equivalents, together with the anticipated net proceeds from this offering and the upfront payment of \$50.0 million we expect to receive from Regeneron, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2029. See the section titled “—*Liquidity and Capital Resources*” below and Note 1 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus.

Components of Results of Operations

Revenue

We have not generated any product revenue. We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which may not occur for several years, if at all. If our development efforts for our product candidates are successful and result in regulatory approval or we successfully enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales or payments from such collaboration or license agreements, or any combination thereof.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Research and development expenses consist primarily of costs incurred in connection with the research and development of our programs. These expenses include:

- external expenses, including expenses incurred under arrangements with third parties, such as contract research organizations (“CROs”), contract manufacturing organizations (“CMOs”), consultants and our clinical and scientific advisors;
- personnel-related costs, including salaries, bonuses, benefits, and stock-based compensation for employees engaged in research and development functions;
- expenses incurred for the procurement of materials, third-party license fees, laboratory supplies and non-capital equipment used in the research and development process; and
- depreciation, amortization and other direct and allocated expenses, including rent, insurance, maintenance of facilities and other operating costs, incurred as a result of our research and development activities.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific deliverables using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid expenses or accrued research and development expenses. Significant judgments and estimates are made in determining the accrued expense balances at the end of any reporting period. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

We use our personnel and infrastructure resources for our research and development efforts, including the advancement and development of our product candidates and managing external research and development efforts. A significant portion of our research and development costs have been, and will continue to be, external costs. Because we are working on multiple research and development programs at one time, we track many of our external expenses on a program-by-program basis. Due to our ability to use

certain resources across several programs, personnel-related expenses and indirect or shared operating costs incurred for our research and development programs are not recorded or maintained on a program-by-program basis.

We expect that our research and development expenses will increase substantially in connection with our ongoing clinical trials and our planned clinical development activities in the near term and in the future. However, we cannot reasonably estimate the costs or timing of the efforts that will be necessary to complete the development of any of our product candidates due to the numerous risks and uncertainties associated with their development, including the uncertainty of:

- the scope, timing, costs and progress of clinical development activities related to zolucetide, our ERG degrader and our allosteric AR^{ON} degrader, including expansion into other indications, and our other product candidates;
- the number and scope of additional preclinical and clinical programs we decide to pursue, and the number of product candidates we decide to develop further;
- our successful enrollment in and completion of clinical trials;
- seeking regulatory approvals for any of our product candidates that successfully complete clinical trials;
- securing access rights to external products, technologies or intellectual property;
- hiring additional clinical, quality control, manufacturing and other scientific personnel;
- the terms and timing of any partnership, collaboration, or license arrangement, including the terms and timing of any milestone payments thereunder, if any; and
- general economic conditions, including inflation.

Any changes in the outcome of any of these variables with respect to the development of our product candidates or any future product candidates that we may identify could result in a significant change in the costs and timing associated with the development of that product candidate. We may never succeed in achieving regulatory approval for any of our product candidates or any future product candidates that we may identify.

General and Administrative

General and administrative expenses consist primarily of personnel-related expenses, including salaries, bonuses, benefits, and stock-based compensation expense for employees in certain executive, accounting and finance, business development, human resources, information technology, legal, and other administrative functions. Other significant general and administrative expenses include allocated facility and related costs, legal fees relating to corporate and intellectual property matters, professional fees for accounting, audit and tax services, consulting fees, information technology costs and insurance costs. General and administrative costs are expensed as incurred. These costs relate to the operation of the business, unrelated to the research and development function, or any individual program.

We expect that our general and administrative expenses will increase substantially for the foreseeable future as we increase our headcount to support the expected growth in our research and development activities and the potential commercialization of our product candidates, if approved. We also expect to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and the U.S. Securities and Exchange Commission (“SEC”) requirements, director and officer insurance costs, and investor and public relations costs. Additionally, we expect to incur additional intellectual property-related expenses as we file patent applications to protect innovations arising from our research and development activities.

Interest Income

Interest income consists of interest earned from our cash, cash equivalents and marketable securities.

Interest Expense

Interest expense consists of interest incurred on our term loan, as amended, including amortization of debt discount and debt issuance costs, and interest expense associated with our finance leases for certain laboratory equipment.

Sublease Income - Related Party

Sublease income – related party consists of income earned from our sublease of office and laboratory space to a related party. The sublease expired in December 2025.

Change in Fair Value of Preferred Stock Tranche Right Liability

The purchase agreement for our Series E convertible preferred stock entered into in February 2024 provided us with an obligation to issue additional shares of Series E convertible preferred stock in a subsequent closing upon the satisfaction of certain conditions. We classified the preferred stock tranche right as a liability on our consolidated balance sheet as the preferred stock tranche right was determined to be a freestanding financial instrument that may have required us to transfer assets to settle our obligation upon events outside of our control. The preferred stock tranche right liability was initially recorded at fair value at the issuance date and was subsequently remeasured to fair value at each reporting date and immediately prior to settlement in January 2025.

Other Income

Other income consists of income associated with an award received from a Massachusetts state agency that provides incentives to life science companies.

Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2024 and 2025 or for the three months ended March 31, 2025 and 2026 due to our net losses and maintenance of a full valuation allowance against our net deferred tax assets. As of December 31, 2025, we had net operating loss carryforwards for federal income tax purposes of \$357.9 million, of which \$348.9 million can be carried forward indefinitely and the remainder of which begins to expire in 2036. In addition, we had state net operating loss carryforwards of \$347.4 million as of December 31, 2025, of which \$2.7 million can be carried forward indefinitely and the remainder of which begins to expire in 2036.

As of December 31, 2025, we had federal and state research and development tax credit carryforwards of \$17.2 million and \$7.7 million, respectively, which are available to reduce future tax liabilities, and which begin to expire in 2030.

Results of Operations

Comparison of the three months ended March 31, 2025 and 2026

The following table summarizes our results of operations for the periods presented (in thousands, except percentages):

	Three Months Ended March 31,		Change	
	2025	2026	\$	%
Operating expenses:				
Research and development	\$ 33,905	\$ 37,753	\$ 3,848	11.3%
General and administrative	6,336	9,700	3,364	53.1%
Total operating expenses	40,241	47,453	7,212	17.9%
Loss from operations	(40,241)	(47,453)	(7,212)	17.9%
Other income (expense):				
Interest income	1,257	2,429	1,172	93.2%
Interest expense	(399)	(292)	107	(26.8%)
Sublease income - related party	1,057	—	(1,057)	(100.0%)
Total other income, net	1,915	2,137	222	11.6%
Net loss	\$ (38,326)	\$ (45,316)	\$ (6,990)	18.2%

Research and Development Expense

The following table summarizes our research and development expense for the periods presented (in thousands, except percentages):

	Three Months Ended March 31,		Change	
	2025	2026	\$	%
External research and development expenses				
by program:				
Zolucetide	\$ 13,145	\$ 13,094	\$ (51)	(0.4%)
β-Catenin Degradar	719	416	(303)	(42.1%)
ERG Degradar	1,640	2,912	1,272	77.6%
AR ^{ON} Degradar	865	1,406	541	62.5%
Early discovery and other programs	994	994	—	—%
Unallocated research and development expenses:				
Personnel-related expenses	9,350	10,701	1,351	14.4%
Other research and development expenses	4,329	5,089	760	17.6%
Facility-related expenses	2,863	3,141	278	9.7%
Total research and development expense	<u>\$ 33,905</u>	<u>\$ 37,753</u>	<u>\$ 3,848</u>	<u>11.3%</u>

Research and development expense was \$33.9 million for the three months ended March 31, 2025, as compared to \$37.8 million for the three months ended March 31, 2026. The increase of \$3.8 million, or 11.3%, was primarily due to:

- an increase in external expenses for our ERG degrader preclinical program of \$1.3 million, which was primarily due to increases in costs for *in vivo* development studies and manufacturing;
- an increase in personnel-related expenses of \$1.4 million, which primarily was the result of an increase in headcount to support our research and development operations; and
- an increase in other research and development expenses of \$0.8 million, which was primarily due to increases in laboratory supplies, consumables, external services, and other operating costs incurred as a result of our research and development activities.

General and Administrative Expense

The following table summarizes our general and administrative expense for the periods presented (in thousands, except percentages):

	Three Months Ended March 31,		Change	
	2025	2026	\$	%
Personnel-related expenses	\$ 3,051	\$ 3,944	\$ 893	29.3%
Professional and consulting fees	1,613	3,423	1,810	112.2%
Other general and administrative expenses	1,672	2,333	661	39.5%
Total general and administrative expense	<u>\$ 6,336</u>	<u>\$ 9,700</u>	<u>\$ 3,364</u>	<u>53.1%</u>

General and administrative expense was \$6.3 million for the three months ended March 31, 2025, as compared to \$9.7 million for the three months ended March 31, 2026. The increase of \$3.4 million, or 53.1%, was primarily due to:

- an increase in personnel-related expenses of \$0.9 million, which primarily was the result of an increase in headcount within our general and administrative function and severance charges;
- an increase in professional and consulting fees of \$1.8 million, which primarily was the result of additional external costs incurred in preparation of our planned initial public offering (“IPO”) and intellectual property legal fees; and
- an increase in other general and administrative expenses of \$0.7 million, which was primarily driven by increases in information technology costs.

Interest Income

Interest income was \$1.3 million for the three months ended March 31, 2025, as compared to \$2.4 million for the three months ended March 31, 2026. The increase of \$1.2 million, or 93.2%, was primarily due to increases in our cash and cash equivalents balances.

Interest Expense

Interest expense was \$0.4 million for the three months ended March 31, 2025, as compared to \$0.3 million for the three months ended March 31, 2026. The decrease of \$0.1 million, or 26.8%, was primarily attributable to a decrease in interest expense on our term loan, which matures in October 2026.

Sublease Income - Related Party

Sublease income – related party was \$1.1 million for the three months ended March 31, 2025. The sublease expired in December 2025 and as a result, no sublease income was recognized during the three months ended March 31, 2026.

Comparison of the years ended December 31, 2024 and 2025

The following table summarizes our results of operations for the years presented (in thousands, except percentages):

	Year Ended December 31,		Change	
	2024	2025	\$	%
Operating expenses:				
Research and development	\$ 100,829	\$ 125,583	\$ 24,754	24.6%
General and administrative	25,296	26,496	1,200	4.7%
Total operating expenses	126,125	152,079	25,954	20.6%
Loss from operations	(126,125)	(152,079)	(25,954)	20.6%
Other income (expense):				
Interest income	6,408	3,386	(3,022)	(47.2%)
Interest expense	(1,486)	(1,522)	(36)	2.4%
Sublease income - related party	4,166	4,228	62	1.5%
Change in fair value of preferred stock tranche right liability	(975)	—	975	(100.0%)
Other income	98	98	—	—%
Total other income, net	8,211	6,190	(2,021)	(24.6%)
Net loss	\$ (117,914)	\$ (145,889)	\$ (27,975)	23.7%

Research and Development Expense

The following table summarizes our research and development expenses for the years presented (in thousands, except percentages):

	Year Ended December 31,		Change	
	2024	2025	\$	%
External research and development expenses by program:				
Zolucetide	\$ 32,633	\$ 41,798	\$ 9,165	28.1%
β-Catenin Degradar	4,067	1,132	(2,935)	(72.2%)
ERG Degradar	4,594	7,355	2,761	60.1%
AR ^{ON} Degradar	1,358	4,043	2,685	197.7%
Early discovery and other programs	4,432	4,765	333	7.5%
Unallocated research and development expenses:				
Personnel-related expenses	27,577	35,347	7,770	28.2%
Other research and development expenses	14,850	19,431	4,581	30.8%
Facility-related expenses	11,318	11,712	394	3.5%
Total research and development expense	\$ 100,829	\$ 125,583	\$ 24,754	24.6%

Research and development expense was \$100.8 million for the year ended December 31, 2024, as compared to \$125.6 million for the year ended December 31, 2025. The increase of \$24.8 million, or 24.6%, was primarily due to:

- an increase in external expenses for our lead product candidate, zolucetide, of \$9.2 million, which was primarily attributable to increases in fees paid to CROs, CMOs and consultants as we continued to advance zolucetide through a Phase 1/2 clinical trial in patients with advanced solid tumors;
- increases in external expenses for two of our preclinical programs, ERG and AR^{ON}, of \$2.8 million and \$2.7 million, respectively, which was primarily due to increases in costs for *in vivo* and *in vitro* development studies and consulting fees;
- an increase in personnel-related expenses of \$7.8 million, which primarily was the result of an increase in headcount to support our research and development operations; and
- an increase in other research and development expenses of \$4.6 million, which was primarily due to increases in laboratory supplies, consumables, external services, and other operating costs incurred as a result of our research and development activities.

The increases were partially offset by a decrease in external expenses associated with our β -catenin degrader program of \$2.9 million, which was primarily due to a reduction in costs for *in vivo* and *in vitro* development studies and consumables during 2025.

General and Administrative Expense

The following table summarizes our general and administrative expenses for the years presented (in thousands, except percentages):

	Year Ended December 31,		Change	
	2024	2025	\$	%
Personnel-related expenses	\$ 11,545	\$ 11,640	\$ 95	0.8%
Professional and consulting fees	6,919	7,316	397	5.7%
Other general and administrative expenses	6,832	7,540	708	10.4%
Total general and administrative expense	\$ 25,296	\$ 26,496	\$ 1,200	4.7%

General and administrative expense was \$25.3 million for the year ended December 31, 2024, as compared to \$26.5 million for the year ended December 31, 2025. The increase of \$1.2 million, or 4.7%, was primarily due to:

- an increase in professional and consulting fees of \$0.4 million, which primarily was the result of additional external costs required to support our growing operations; and
- an increase in other general and administrative expenses of \$0.7 million, which was primarily driven by increases in information technology costs.

Interest Income

Interest income was \$6.4 million for the year ended December 31, 2024, as compared to \$3.4 million for the year ended December 31, 2025. The decrease of \$3.0 million, or 47.2%, was due to decreases in our cash, cash equivalents and marketable securities balances and decreases in yields.

Interest Expense

Interest expense was \$1.5 million for each of the years ended December 31, 2024 and 2025. Interest expense on our finance leases that were entered into in September through December 2024 increased \$0.2 million, which was offset by a \$0.2 million decrease of interest expense on our term loan, which matures in October 2026.

Sublease Income - Related Party

Sublease income – related party was \$4.2 million for each of the years ended December 31, 2024 and 2025. The sublease expired in December 2025.

Change in Fair Value of Preferred Stock Tranche Right Liability

Change in fair value of preferred stock tranche right liability for the year ended December 31, 2024 consisted of an increase in the fair value of the liability of \$1.0 million. In January 2025, the preferred stock tranche right was settled. No change in fair value of the related liability was recognized during the year ended December 31, 2025 prior to settlement.

Other Income

Other income remained consistent at \$0.1 million for each of the years ended December 31, 2024 and 2025.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant losses. We have not yet commercialized any of our product candidates, which are in clinical or preclinical development, and we do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which may not occur for several years, if at all.

To date, we have funded our operations primarily with proceeds from sales of our convertible preferred stock, borrowings under a term loan, and issuance of a SAFE. As of March 31, 2026, we received aggregate gross cash proceeds of \$876.8 million, including \$811.8 million from sales of our convertible preferred stock, \$15.0 million from borrowings under our term loan and \$50.0 million from the issuance of a SAFE. In May 2026, we entered into a license and collaboration agreement with Regeneron, and in connection therewith, we expect to receive a non-refundable upfront payment in the amount of \$50.0 million. In addition, Regeneron has agreed to purchase \$75.0 million of our common stock in the concurrent private placement or our next equity financing.

Cash Flows

Comparison of the three months ended March 31, 2025 and 2026

The following table provides information regarding our cash flows for the periods presented (in thousands, except percentages):

	Three Months Ended March 31,		Change	
	2025	2026	\$	%
Net cash (used in) provided by:				
Operating activities	\$ (34,154)	\$ (49,200)	\$ (15,046)	44.1%
Investing activities	6,689	(369)	(7,058)	*
Financing activities	67,289	350,897	283,608	421.5%
Net increase in cash, cash equivalents and restricted cash	\$ 39,824	\$ 301,328	\$ 261,504	656.6%

* Not meaningful

Operating Activities

Our cash flows from operating activities are greatly influenced by our use of cash for operating expenses and working capital requirements to support our business. We have historically experienced negative cash flows from operating activities as we invested in developing our Helicon platform, drug discovery and development efforts and related infrastructure. The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges, which are generally due to stock-based compensation, depreciation and amortization and non-cash lease expense, as well as changes in components of operating assets and liabilities, which are generally due to increased expenses and timing of vendor payments.

For the three months ended March 31, 2025, net cash used in operating activities was \$34.2 million, primarily due to a net loss of \$38.3 million, which was offset by net non-cash expenses of \$3.3 million and changes in operating assets and liabilities. The changes in operating assets and liabilities were primarily driven by an increase in accounts payable, accrued expenses and other liabilities of \$3.4 million, partially offset by a decrease in operating lease liabilities of \$1.5 million and an increase in prepaid expenses and other assets of \$1.1 million.

For the three months ended March 31, 2026, net cash used in operating activities was \$49.2 million, primarily due to a net loss of \$45.3 million and changes in operating assets and liabilities, which was offset by net non-cash expenses of \$3.6 million. The changes in operating assets and liabilities were primarily driven by a decrease in accounts payable, accrued expenses and other liabilities of \$3.2 million, a decrease in operating lease liabilities of \$1.7 million and an increase in prepaid expenses and other assets of \$2.8 million.

Investing Activities

During the three months ended March 31, 2025, net cash provided by investing activities was \$6.7 million, which primarily consisted of maturities of marketable securities of \$23.4 million, partially offset by purchases of marketable securities of \$16.7 million.

During the three months ended March 31, 2026, net cash used in investing activities was \$0.4 million which was attributable to purchases of property and equipment.

Financing Activities

During the three months ended March 31, 2025, net cash provided by financing activities was \$67.3 million, which primarily consisted of gross proceeds from the issuance of our Series E convertible preferred stock and the settlement of a related preferred stock tranche right of \$67.5 million.

During the three months ended March 31, 2026, net cash provided by financing activities was \$350.9 million, which primarily consisted of gross proceeds from the issuance of our Series F convertible preferred stock of \$305.2 million and gross proceeds from the issuance of a SAFE of \$50.0 million, partially offset by principal payments on our term loan of \$3.8 million.

Comparison of the years ended December 31, 2024 and 2025

The following table provides information regarding our cash flows for the years presented (in thousands, except percentages):

	Year Ended December 31,		Change	
	2024	2025	\$	%
Net cash (used in) provided by:				
Operating activities	\$ (103,613)	\$ (123,713)	\$ (20,100)	19.4%
Investing activities	30,242	39,758	9,516	31.5%
Financing activities	78,068	64,382	(13,686)	(17.5%)
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 4,697	\$ (19,573)	\$ (24,270)	*

* Not meaningful

Operating Activities

Our cash flows from operating activities are greatly influenced by our use of cash for operating expenses and working capital requirements to support our business. We have historically experienced negative cash flows from operating activities as we invested in developing our Helicon platform, drug discovery and development efforts and related infrastructure. The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges, which are generally due to stock-based compensation, depreciation and amortization and non-cash lease expense, as well as changes in components of operating assets and liabilities, which are generally due to increased expenses and timing of vendor payments.

For the year ended December 31, 2024, net cash used in operating activities was \$103.6 million, primarily due to a net loss of \$117.9 million, which was offset by net non-cash expenses of \$13.4 million and changes in operating assets and liabilities. The changes in operating assets and liabilities were primarily driven by an increase in accounts payable, accrued expenses and other liabilities of \$9.3 million, partially offset by a decrease in operating lease liabilities of \$5.5 million and an increase in prepaid expenses and other assets of \$2.5 million.

For the year ended December 31, 2025, net cash used in operating activities was \$123.7 million, primarily due to a net loss of \$145.9 million, which was offset by net non-cash expenses of \$13.1 million and changes in operating assets and liabilities. The changes in operating assets and liabilities were primarily driven by an increase in accounts payable, accrued expenses and other liabilities of \$13.6 million, partially offset by a decrease in operating lease liabilities of \$6.3 million.

Investing Activities

During the year ended December 31, 2024, net cash provided by investing activities was \$30.2 million, which primarily consisted of maturities of marketable securities of \$122.0 million, partially offset by purchases of marketable securities of \$90.9 million.

During the year ended December 31, 2025, net cash provided by investing activities was \$39.8 million, which primarily consisted of maturities of marketable securities of \$56.7 million, partially offset by purchases of marketable securities of \$16.7 million.

Financing Activities

During the year ended December 31, 2024, net cash provided by financing activities was \$78.1 million, which primarily consisted of gross proceeds from issuance of our Series E convertible preferred stock and preferred stock tranche right of \$77.5 million and proceeds from the exercise of stock options of \$1.1 million.

During the year ended December 31, 2025, net cash provided by financing activities was \$64.4 million, which primarily consisted of gross proceeds from issuance of our Series E convertible preferred stock and settlement of related preferred stock tranche right of \$67.5 million, partially offset by principal payments on our term loan of \$2.5 million.

Future Funding Requirements

We have not generated any revenue. We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which may not occur for several years, if at all. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue preclinical activities and studies, advance ongoing clinical trials of our product candidates and conduct future clinical trials. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to product sales, marketing, and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Further, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on the factors set out above.

Inflation generally affects us by increasing our cost of labor and certain services. We do not believe that inflation had a material effect on our consolidated financial statements included elsewhere in this prospectus. However, the United States has recently experienced historically high levels of inflation. If the inflation rate continues to increase, it may affect our expenses, such as employee compensation and research and development charges due to, for example, increases in the costs of labor and supplies.

As of March 31, 2026, we had total cash and cash equivalents of \$329.0 million. We believe that our existing cash and cash equivalents, together with the anticipated net proceeds from this offering and the upfront payment of \$50.0 million we expect to receive from Regeneron, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2029. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. Even if this offering and the concurrent private placement are successful, we will require additional funding in order to finance operations and complete our ongoing and planned clinical trials. Access to such funding on acceptable terms cannot be assured.

Because of the numerous risks and uncertainties associated with product development, and because the extent to which we may enter into collaborations with third parties for the development of our product candidates is unknown, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including, but not limited to:

- the progress, results and costs of, discovery and preclinical studies for our programs and development candidates;
- our ability to advance our clinical-stage product candidates into later-stage trials, which we expect will be required in order to seek marketing approval of our product candidates;

- the costs associated with maintaining and improving our Helicon platform;
- our ability to scale up our manufacturing processes and capabilities, or arrange for a third party to do so on our behalf, to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- our ability to seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials;
- the costs associated with acquiring or in-licensing products, product candidates or technologies or intellectual property;
- the costs associated with maintaining, expanding, enforcing, defending and protecting our intellectual property;
- the costs associated with hiring additional clinical, quality control, manufacturing and other scientific personnel;
- the costs and timing of establishing or securing sales and marketing capabilities if any current or future product candidate is approved; and
- the costs associated with making any milestone, royalty or other payments under any existing collaboration or license agreements or any that we enter into.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Our expectation with respect to our ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. Our operating plan may change as a result of many factors currently unknown to management and there can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, and we may need to seek additional funds sooner than planned. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate one or more of our research and development programs or other operations.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or issuance of convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute your ownership interest. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or development product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit or terminate our product development programs or any future commercialization efforts or grant rights to develop and market development product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Other Commitments

Leases

We lease office, research and manufacturing space in Cambridge, Massachusetts under a non-cancelable operating lease that expires in February 2031, as well as space at a vivarium facility under a non-cancelable operating lease that expires in December 2027. We also entered into finance lease agreements for laboratory equipment. Future minimum commitments under these leases are \$55.0 million as of December 31, 2025. These commitments are also recognized as operating lease liabilities and finance lease liabilities, respectively, on our consolidated balance sheets. Refer to Note 10 in our audited consolidated financial statements appearing elsewhere in this prospectus for more information on our lease obligations.

Term Loan

In September 2021, we entered into a Loan and Security Agreement with Silicon Valley Bank, which was subsequently amended (the “Loan Agreement”), under which we borrowed \$15.0 million. The term loan bears interest at a floating rate equal to the greater of (i) 6.75% and (ii) the prime rate plus a margin; provided that the interest rate will not exceed 6.75%. The amounts borrowed under the Loan Agreement are scheduled to mature on October 1, 2026. After triggering an interest-only extension upon the sale of our Series E convertible preferred stock in January 2025, we began paying principal in 12 equal monthly payments of approximately

\$1.3 million each on November 1, 2025. In addition, we will also be required to pay final payment fees of approximately \$0.8 million, due upon (a) the term loan maturity date, (b) the repayment of the term loan in full, (c) as required pursuant to permitted prepayment or mandatory prepayment upon an acceleration, or (d) the termination of the Loan Agreement. As of March 31, 2026, \$8.8 million of total principal remained outstanding under the Loan Agreement. Refer to Note 9 in our audited consolidated financial statements and Note 9 to our unaudited condensed consolidated financial statements appearing elsewhere in this prospectus for more information on our term loan.

Harvard License Agreement

In August 2017, we entered into a license agreement, as amended (the “Harvard License”), with the President and Fellows of Harvard College (“Harvard”), to obtain a worldwide, exclusive, royalty-bearing license to certain intellectual property which was developed by our founder.

Under the terms of the Harvard License, we are required to make payments to Harvard upon the achievement of certain development, regulatory and sales milestones up to an aggregate of \$18.3 million, as well as future royalty payments, based on a percentage of aggregate net sales ranging in the low single digits. In addition, we are required to make payments to Harvard for non-royalty income received under sublicenses or strategic partnerships with third parties, with the applicable payment based on the stage of development of the first licensed product at the time we enter into such agreement (before or after enrollment of the first patient in a Phase 2 clinical study of a licensed product), ranging from a single-digit percentage to a mid-teens percentage. We are also required to pay an annual maintenance fee for the duration of the Harvard License, which can be credited against future royalty payments. As of March 31, 2026, we have achieved milestones totaling \$0.3 million under the Harvard License. For a more detailed description of this agreement, see the section of this prospectus titled “*Business—License and Collaboration Agreements*.”

Purchase and Other Obligations

We enter into contracts in the normal course of business with third-party CROs, CMOs and other third-party vendors for preclinical, clinical trials and testing and manufacturing services. These contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation generally consist of payments for services provided or expenses incurred up to the date of cancellation, including non-cancelable obligations of our service providers and, in some cases, wind-down costs.

License and Collaboration Agreements

Below is a summary of the key terms of our license and collaboration agreements. For more information on our research collaboration agreement with ARTBIO, Inc. (“ARTBIO”), refer to Note 12 to our audited consolidated financial statements and Note 12 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus. For more information on our license and collaboration agreement with Regeneron, see the section of this prospectus titled “*Business—License and Collaboration Agreements*.”

ARTBIO Collaboration Agreement

In May 2024, we entered into a research collaboration agreement with ARTBIO, to co-develop multiple Helicon-enabled alpha particle radioligand therapies for the treatment of cancer. Under the terms of this agreement, we are responsible for equally participating on joint committees and carrying out at least four research programs with respect to each collaboration target. We and ARTBIO share in the costs of the research programs equally, with ARTBIO responsible for the first \$10.0 million of development costs incurred by both parties, and we are responsible for the second \$10.0 million of development costs incurred by both parties. Any further development costs beyond these initial funding amounts will be shared equally by both parties. Upon later regulatory approval and commercialization of related product(s), the parties will share equally in all net profits or losses. The agreement expires upon (i) the date on which products arising from the collaboration are no longer commercialized or developed for commercialization, or (ii) termination by one or both parties. As of March 31, 2026, we have incurred \$5.0 million of development costs under the collaboration arrangement, which have been reimbursed by ARTBIO.

Under certain circumstances, either party can terminate the agreement, or opt out of further participation in any research programs, and we may be obligated to refund amounts received during the initial funding periods to ARTBIO, such that the total costs incurred through the effective date of termination would be shared equally. As of March 31, 2026, we have recorded a liability of \$2.7 million representing fifty percent of the total costs incurred by both parties.

On April 16, 2026, ARTBIO sent notice of its intent to opt out of all the research programs under the research collaboration agreement. No eligible costs were incurred by us or ARTBIO during the three months ended March 31, 2026.

License and Collaboration Agreement with Regeneron

In May 2026, we entered into a license and collaboration agreement with Regeneron to discover, develop, and commercialize Helicons, with a particular focus on Antibody-Helicon Conjugates (“AHCs”), directed to a set of specified targets (each, a “Collaboration Target”).

Under the terms of the Regeneron Agreement and during the research term for each Collaboration Target, we will collaborate with Regeneron to perform certain research and preclinical development activities, including screening, generating, testing and evaluating new Helicons and AHCs directed to such Collaboration Target (each, a “Product”). Under the Regeneron Agreement, there are five initial Collaboration Targets, with Regeneron having the right to replace up to two targets and the option to nominate up to five additional Collaboration Targets, subject to an additional option payment from Regeneron. For one initial Collaboration Target, Regeneron may add one or more additional programs with respect to such Collaboration Target, subject to payment of additional program fees.

Under the terms of the Regeneron Agreement, Regeneron has agreed to make a \$50.0 million upfront payment and invest \$75.0 million in our next equity financing, subject to certain conditions, which investment is expected to be the private placement of common stock concurrent with our IPO at a price per share equal to 90% of the IPO price per share. For the initial Collaboration Targets, we are eligible to receive: (i) up to \$470.0 million in development milestone payments; (ii) up to \$575.0 million in regulatory milestone payments; (iii) up to \$1.15 billion in commercial milestone payments; and (iv) tiered royalty payments, ranging in the high single digits to low double digits during the period commencing upon the first commercial sale of such licensed product in a given country and expiring on the latest of: (a) expiration of the last valid claim of a royalty term-extending patent right of such licensed product in such country, (b) 12 years after the first commercial sale of such licensed product in such country, and (c) loss of regulatory exclusivity for such licensed product in such country, subject to customary reductions.

Critical Accounting Estimates and Significant Judgments

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States (“GAAP”). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements included elsewhere in this prospectus, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates.

Research and Development Expenses and Related Accruals

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, reviewing the progress of the studies or clinical trials, including the phase or completion of events, communicating with our personnel and with vendors to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time.

The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. The value of goods and services received from our vendors are estimated based on the level of services performed, and progress in the period in cases when we have not received an invoice from the supplier. In accruing these costs, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. To date, there have been no material differences between our estimates of such expenses and the amounts incurred.

Stock-Based Compensation

We have issued and continue to issue stock-based awards to our employees, non-employees, and directors in the form of incentive and nonqualified stock options. We account for stock-based compensation awards in accordance with the Financial Accounting Standards Board (“FASB”), ASC Topic 718, *Compensation—Stock Compensation* (“ASC 718”).

We generally issue stock option grants that are subject to service-based vesting conditions, and in limited instances awards are issued with either service-based and performance-based vesting conditions or market-based and performance-based vesting conditions. Compensation expense for awards issued to grantees with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated requisite service period of the award, which is generally the vesting term. Compensation expense for awards with performance-vesting conditions and either service-based or market-based vesting conditions is recognized based on the grant-date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. At each reporting date, we estimate the probability that specified performance criteria will be achieved and do not begin to recognize compensation expense until it is probable that the performance-based vesting condition will be achieved. We account for forfeitures of stock-based compensation awards as they occur.

We classify stock-based compensation expense in our consolidated statements of operations and comprehensive loss in the same manner in which the award recipient’s payroll costs or service payments are classified. In future periods, we expect stock-based compensation expense to increase due to our existing unrecognized stock-based compensation expense and due to additional stock-based awards we expect to grant to continue to attract new hires and retain our existing employees.

Determination of the Fair Value of Stock-Based Awards

We estimate the fair value of our stock option grants using the Black-Scholes option pricing model, which requires inputs of subjective assumptions, including: (i) the expected volatility of our common stock, (ii) the expected term of the award, (iii) the risk-free interest rate, (iv) expected dividends and (v) the fair value of our common stock. Due to the lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, we base the estimate of expected volatility on the historical volatilities of a representative group of publicly traded peer companies. For these analyses, we select companies with comparable characteristics and with historical share price information that approximates the expected term of the stock options. We compute the historical volatility data using the daily closing prices for the selected companies’ shares during the equivalent period that approximates the calculated expected term of our stock options. We will continue to apply this method until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We estimate the expected term of our stock options granted to employees and directors using the simplified method for awards that qualify as “plain-vanilla” options, whereby the expected term equals the midpoint between the vesting date and the end of the contractual term of the option. We utilize this method as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. If vesting is subject to a performance condition, the expected term is based on the mid-point between the explicit service period and the contractual term of the option. The expected dividend yield is assumed to be zero as we have no current plans to pay any dividends on common stock.

Determination of the Fair Value of Common Stock

As there has been no public market for our common stock to date, the historical estimated fair value of our common stock has been determined by our board of directors, with input from management, considering our most recently available third-party valuations of common stock, as well as additional factors that may have changed since the date of the most recent valuation through the date of grant.

In accordance with the guidance outlined in the American Institute of Certified Public Accountants’ *Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the “Practice Aid”), a third-party valuation firm prepared valuations of our common stock using a market approach to estimate our common stock value, using either the option-pricing method (“OPM”), or the hybrid method, both of which used a market approach to estimate our enterprise value. The market approaches used were either the recent transactions method or the market adjusted equity value method.

In accordance with the Practice Aid, the OPM method was the most appropriate method for determining the fair value of our common stock prior to March 31, 2024 and we determined the hybrid method was the most appropriate method for determining the fair value of our common stock based on our stage of development and other relevant factors for valuations as of March 31, 2024 and going forward. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company’s securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. The hybrid method is a

valuation methodology that combines the probability-weighted expected return method (“PWERM”) and the OPM, where the equity value in one or more of the scenarios is allocated between our equity securities using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of our future values, assuming various outcomes, including an IPO. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability-weighted to arrive at an indication of value for the common stock. These third-party valuations were performed at various dates which resulted in valuation of our common stock of \$1.22 per share as of February 29, 2024, \$1.88 per share as of June 30, 2024, \$1.91 per share as of September 30, 2024, \$2.42 per share as of January 22, 2025, \$3.14 per share as of January 8, 2026, and \$4.09 per share as of March 3, 2026.

Given the absence of a public market for our common stock to date, our board of directors, with input from management, considered various objective and subjective factors to determine the fair value of our common stock as of each grant date. The factors included, but were not limited to:

- our operating results and financial performance;
- the progress of our research and development efforts, including the status of preclinical and clinical studies for our product candidates;
- the lack of marketability of our equity as a private company;
- the prices of our preferred stock sold to or exchanged between new and existing investors, and the rights, preferences and privileges of our preferred stock as compared to those of our common stock;
- our stage of development and business strategy and the material risks related to our business and industry;
- the achievement of enterprise milestones, including entering into strategic alliance and license agreements;
- the valuation of publicly-traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- any external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- the likelihood of achieving a liquidity event, such as an IPO or a sale of our company, given prevailing market conditions;
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry; and
- the third-party valuations described above.

There are significant judgments and estimates inherent in these valuations. These judgments and estimates include assumptions regarding our future operating performance, and the stage of development of our product candidates. If our board of directors had made different assumptions, our stock-based compensation expense, net loss allocable to common stockholders and net loss per share allocable to common stockholders could have been significantly different.

Once a public trading market for our common stock has been established in connection with the consummation of this offering, it will no longer be necessary for our board of directors, or a committee thereof, to estimate the fair value of our common stock in connection with our accounting for granted stock options and other awards, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

On the effective date of the registration statement of which this prospectus forms a part, we granted certain directors and consultants an aggregate of up to 357,392 options to purchase shares under the 2026 Plan, subject to continued service through such grant date. Based on a fair value of \$20.00 per share, and after application of the aggregate value thresholds we estimate that the aggregate grant-date fair value of the awards granted in connection with this offering is \$3.5 million, which is expected to be recognized as stock-based compensation expense over a period of one to four years. See the sections titled “*Director Compensation*” and “*Certain Relationships and Related Person Transactions*” for additional information.

JOBS Act Transition Period and Smaller Reporting Company Status

We qualify as an “emerging growth company” (“EGC”) as defined in the Jumpstart Our Business Startups Act (the “JOBS Act”). As an EGC, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this prospectus;
- reduced disclosure about our executive compensation arrangements;
- not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on the financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

Additionally, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an EGC we may not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not EGCs. As a result of this election, our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We have in the past chosen and may in the future choose to early adopt any new or revised accounting standards whenever such early adoption is permitted.

We are also a “smaller reporting company,” as defined in the Securities Exchange Act of 1934, as amended (the “Exchange Act”). We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) the market value of our common stock and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our common stock and non-voting common stock held by non-affiliates is less than \$700.0 million as measured on the last business day of our second fiscal quarter.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company built to develop transformative medicines addressing some of the most consequential, yet historically undruggable, protein targets driving human disease. We leverage our proprietary platform to pioneer a novel therapeutic modality, Helicons, which are stabilized helical peptides engineered to bind and precisely modulate proteins that have long been beyond the reach of conventional medicines.

To our knowledge, our lead product candidate, zolucetide, is the first-ever drug to directly target the interaction between β -catenin and the T-cell factor (“TCF”) family of transcription factors. This is the central node in the Wnt/ β -catenin cell signaling pathway which regulates cell proliferation and differentiation and whose hyperactivation is a driver of millions of cancer cases annually across many tumor types. Drugging this critical node eluded three decades of intensive efforts to do so across the pharmaceutical industry. Zolucetide has been evaluated in over 150 patients to date and has generated promising clinical data in a range of solid tumors driven by alterations in the Wnt/ β -catenin pathway. In our lead indication, desmoid tumors, we have observed tumor reductions in 100% of patients with a 74% objective response rate (“ORR”) in patients who have had at least two post-baseline scans.

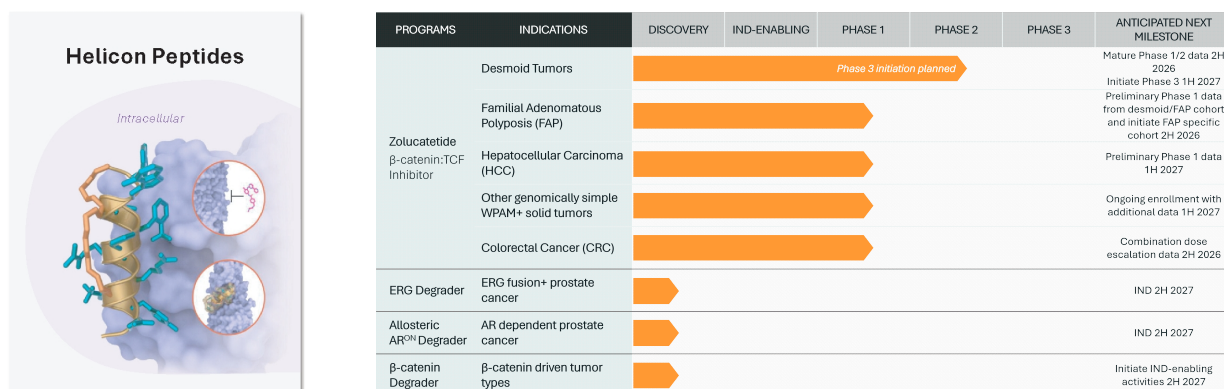
Objective responses have been observed across patients who have failed γ -secretase inhibitors (“GSIs”) and those who have never taken GSIs. Importantly, zolucetide has been able to generate this rate of response with a tolerability profile that we believe is more favorable than that of currently available drug therapy. We plan to initiate a global registrational Phase 3 trial for zolucetide in patients with desmoid tumors in the first half of 2027.

We believe zolucetide provides clinical validation of our first-in-industry Helicon approach and represents an expansive opportunity for medical and commercial impact. Our preclinical pipeline provides additional examples of the repeatability of our Helicon approach and includes programs targeting two key drivers of prostate cancer, the ETS-related gene (“ERG”) and the androgen receptor (“AR”) in its active state (“AR^{ON}”). Our current pipeline is focused on various cancers and tumor types; however, we believe Helicons could also have broad applicability against targets in many diseases with substantial unmet need outside oncology, and we plan to evaluate other therapeutic areas in the future.

An estimated 80% of biologically validated disease targets are considered undruggable, largely because the majority reside inside cells and present flat interaction surfaces. Small molecules can enter cells but cannot bind flat surfaces, and antibodies and other highly-selective biologics can selectively bind flat protein surfaces but cannot enter cells to access these targets. To our knowledge, Helicons are the only modality to date that can consistently solve this problem as they are engineered for cell penetration and capable of binding to flat intracellular protein target surfaces with high specificity. Helicons combine the precision of antibodies and biologics with the intracellular access and tunability of small molecules in a single modality-enabling direct engagement of historically inaccessible protein targets. Our proprietary Helicon discovery platform allows us to integrate ligands and additional functionalities at multiple positions to precisely tune potency, selectivity, and pharmacologic properties. While our initial programs are focused on disrupting protein-protein interactions and inducing targeted protein degradation, we believe our platform can incorporate other advances in small molecule drug design and extend them to targets that are likely to remain out of reach for other modalities.

Our Helicon discovery platform integrates advanced artificial intelligence (“AI”)- and physics-based computational modeling with high-throughput peptide synthesis and experimental screening to discover and develop drug candidates. Since our founding, we have advanced computational models as well as custom design, synthesis, handling and manufacturing know-how to position us to produce Helicons reliably and at scale. A decade of applying these capabilities to Helicon drug discovery has generated vast proprietary datasets, comprising millions of data points for hundreds of thousands of Helicons across dozens of drug-like properties. These data power a continuous learning loop that refines our models from target selection through lead optimization, enhancing our speed, precision, and ability to generate high quality molecules against difficult targets. As a result, our platform produces unique complex synthetic molecules at scale and a compounding advantage that we believe is difficult to replicate.

We are advancing a wholly-owned pipeline of Helicon-based product candidates against high-value targets.



Our lead product candidate, zolucetide, is, to our knowledge, the first and only investigational therapy that inhibits the β-catenin:TCF interaction, the critical downstream node of the Wnt/β-catenin pathway. Activating mutations in this pathway, gain of function β-catenin mutations, or loss of function Adenomatous Polyposis Coli (“APC”) mutations, are present in over 10% of all cancers and span a broad range of tumor types.

We are evaluating zolucetide in ongoing clinical trials across multiple solid tumor indications, with more than 150 patients dosed to date. Zolucetide has been observed to be well tolerated across the therapeutic dose range. We believe the data generated to date, along with our understanding of the underlying Wnt/β-catenin pathway, support zolucetide’s potential to benefit patients across multiple tumor types driven by β-catenin or APC alterations and its advancement into a Phase 3 registrational trial. Our target indications include:

- Desmoid Tumors:** Our lead indication for zolucetide is desmoid tumors, which are rare, locally invasive soft tissue tumors driven by somatic or germline β-catenin pathway mutations. We estimate that approximately 11,000 desmoid tumor patients in the United States are actively managed under physician care. Desmoid tumors impose substantial morbidity, including pain, functional, and mobility impairment, and the potential for life-threatening complications depending on tumor location. Given the chronic nature of the disease and onset in a predominantly young patient demographic with a near-normal life expectancy, prolonged or lifelong management is typically required. The only existing FDA-approved therapy for desmoid tumors, a GSI, does not address the underlying Wnt/β-catenin-driven disease biology. In our ongoing clinical trials, as of February 16, 2026, 38 desmoid patients have been enrolled and treated with zolucetide, of which 25 had sufficient follow up to be response-evaluable, and all 25 patients showed tumor reductions (DCR 100%). Of the 19 patients with at least two post-baseline scans, 74% (14/19) had an objective response per RECIST 1.1. We have observed responses in patients naive to GSI therapy, those who had progressed on GSI therapy, as well as patients that discontinued GSI therapy due to tolerability issues. To date, we have observed a tolerability profile that we believe compares favorably to the tolerability profile associated with GSIs and other off-label therapies, and supports continued development. We believe a medicine for the treatment of desmoid tumors with a superior efficacy and safety profile compared to the existing systemic therapy could significantly improve patient outcomes and expand the desmoid tumor commercial opportunity. We plan to initiate a registrational Phase 3 trial for zolucetide in patients with desmoid tumors in the first half of 2027.
- Familial Adenomatous Polyposis (“FAP”):** We are evaluating zolucetide’s potential in FAP, an orphan disease that impacts an estimated 34,000 people in the United States. FAP is characterized by extensive precancerous polyps in the gastrointestinal tract, with a near-inevitable risk of polyp progression to colorectal cancer in the absence of life-altering colon-removal surgery. There is currently no approved treatment for FAP. Desmoid tumors and FAP share common β-catenin biology, and approximately 10% of desmoid tumor patients also have FAP. In the desmoid tumor cohort of our ongoing Phase 1/2 clinical trial, administration of zolucetide in two patients with underlying FAP and an associated desmoid tumor demonstrated significant improvement in duodenal polyposis burden at 10 and 60 weeks, respectively, following initiation of treatment. As of February 16, 2026, we have enrolled six desmoid tumor patients with FAP in our ongoing clinical trial and are also planning to enroll a separate dedicated cohort of patients with FAP beginning in the second half of 2026.

- **Hepatocellular Carcinoma (“HCC”):** We are evaluating zolucetide’s potential in HCC, the most common type of primary liver cancer. HCC accounts for approximately 80-90% of liver cancer cases globally, with an estimated 38,000 new HCC cases annually in the United States and approximately 700,000–800,000 new cases worldwide. Approximately 30% of HCC tumors harbor β -catenin mutations and are otherwise relatively low in mutational burden. In a heavily pre-treated patient with CTNNB1-mutant HCC treated with zolucetide, we observed a confirmed partial response for nine months. Based on this observation, we began enrolling an HCC-specific cohort in our ongoing Phase 1/2 clinical trial.
- **Additional Rare Tumors:** There are over 70 different cancer types with documented APC or β -catenin mutations, equating to approximately 10% of all tumors and a prevalence in the United States of approximately 1.8 million patients. In pursuit of this significant opportunity, we are evaluating zolucetide in additional rare Wnt/ β -catenin-driven tumors that harbor APC loss or activating β -catenin mutations, including adamantinomatous craniopharyngioma (“ACP”), solid pseudopapillary neoplasm, salivary gland tumors, and ameloblastoma where we have observed partial responses to date. For these and potentially other rare tumor types, we are evaluating various regulatory strategies, including potentially accelerated development approaches based on a shared genomic signature of Wnt/ β -catenin pathway activation or, where appropriate, histologic characteristic clustering. Tumor-agnostic or molecularly defined approval pathways have been used selectively in oncology, and we believe targeting the root genetic cause of Wnt/ β -catenin pathway activation-driven disease may support a similar approach.
- **Colorectal Cancer (“CRC”):** We are also evaluating the potential for zolucetide in CRC, the third most commonly diagnosed cancer globally with approximately two million new cases annually. APC mutations, which drive aberrant β -catenin activation, occur in more than 80% of microsatellite stable CRC patients, representing the most prevalent mutations observed in this tumor type. In our ongoing clinical trials, we have observed disease stabilization and ctDNA reductions in a subset of CRC patients treated with zolucetide monotherapy, and we are currently evaluating multiple rational combination regimens, based on the results of paired tumor biopsies showing tumor differentiation and a dose responsive functional pathway inhibition. Our ongoing rational combination regimen includes anti-Vascular Endothelial Growth Factor (“VEGF”), DNA-damaging chemotherapy, and anti-programmed cell death protein 1 (“PD-1”) agents, as supported by preclinical and early translational data. We have also generated preclinical evidence for a rational combination with a RAS inhibitor.

Taken together, we believe the breadth of clinical activity and tolerability profile observed to date reinforce zolucetide’s potential as a pipeline-in-a-product with the ability to address significant unmet need across multiple tumor types. We expect to generate substantial additional clinical data as we advance zolucetide into registrational development in desmoid tumors and continue to expand our understanding of its therapeutic potential across additional indications.

Beyond zolucetide, we are advancing two preclinical stage Helicon programs in prostate cancer: an ERG degrader and an allosteric AR^{ON} degrader. Both programs seek to leverage the unique properties of Helicons to address areas of unmet need in prostate cancer treatment by targeting degradation of the historically undruggable ERG protein, an oncogenic driver present in approximately 40-50% of prostate cancer patients, and of the androgen receptor via a novel AR binding site that seeks to overcome the primary drivers of resistance to AR targeted therapies.

- **ERG:** We have identified novel peptide binding sites on ERG and developed bifunctional degraders that have been observed to drive potent, selective ERG degradation in cells and *in vivo* tumor models. We have observed that patient-derived tumor models are dependent on ERG protein expression and activity for growth, which we believe supports the clinical therapeutic potential of our ERG degrader in ERG fusion-positive prostate cancer. We are now testing our lead Helicon in Investigational New Drug (“IND”)-enabling studies and continue to advance additional Helicons for optionality.
- **AR^{ON}:** Our AR^{ON} degrader is designed to overcome resistance driven by AR mutations and amplification, both of which limit the effectiveness of current AR-targeted therapies. In approximately 80% of patients, resistance to AR-targeted therapies is associated with amplification of the AR gene and point mutations at the drug binding site of AR. Approved AR antagonists and clinical-stage AR degraders of which we are aware target the same ligand binding pocket, making them non-combinable and vulnerable to the same resistance mechanisms. Our AR degrader binds to an historically undruggable allosteric co-activator protein binding site that is accessible only when androgen is bound to the receptor. By selectively targeting this active pool of AR, we believe our AR^{ON} degrader can more effectively address AR amplification, which we consider the most clinically significant driver of resistance in metastatic castration-resistant prostate cancer (“mCRPC”). Importantly, because it binds at the allosteric co-activator protein binding site, the AR^{ON} degrader is uniquely suited for combination with existing AR antagonists. These therapies all bind the androgen-binding pocket and are not currently combinable with one another. We believe that such a combination therapy approach could slow the development of resistance, improve efficacy and meaningfully extend treatment duration. Our AR^{ON} degrader program is in late lead optimization and advancing toward IND-enabling studies.

In addition to pursuing additional targets, we are continuing to develop novel approaches to target β -catenin, building on the foundational biology established with zolucetide.

- **β -catenin Degradar:** Two avenues have emerged from our efforts to maximize the clinical potential of β -catenin targeting agents. First, we have identified multiple binding sites on β -catenin beyond the site leveraged by zolucetide and are exploring how β -catenin target engagement at these sites may impact different aspects of tumor biology. The downstream biology affected by Helicon binding to these sites is dependent on the multitude of intracellular protein complexes in which β -catenin resides within the tumor cell. Second, we have successfully applied our bifunctional degrader technology to develop β -catenin degraders using both zolucetide and the additional binding site Helicons as the anchor for this approach. The degrader functionality has the potential for improved potency via a catalytic mechanism of action and has the potential to drive unique biology by virtue of removing β -catenin protein rather than inhibiting protein-protein interactions.

We intend to advance multiple additional discovery-stage programs that target genetically validated, historically undruggable proteins where we believe Helicons may offer a meaningful advantage over existing modalities. We apply a rigorous framework to evaluate and prioritize programs that may result in substantial therapeutic and commercial opportunities before committing substantial resources toward those that we believe have the highest probability of clinical and commercial success. Given the versatility of the Helicon platform, we also believe there may be opportunities to selectively explore additional therapeutic approaches on our own and through strategic collaborations where a partner's complementary expertise could be leveraged. We recently entered into a collaboration with Regeneron with a focus on evaluating Antibody-Helicon Conjugates ("AHCs"), a potentially novel approach that combines antibody targeting capabilities with Helicon payloads designed to modulate intracellular proteins. We view this collaboration as an opportunity to explore the broader applicability of Helicons in a focused and capital-efficient manner alongside a leading partner.

Our Strategy

We intend to advance differentiated and potentially high value Helicon medicines that address genetically validated, yet historically undruggable, targets in areas of high unmet medical need. To pursue our vision, we are focused on the following key priorities:

- **Complete clinical development of, and if approved, commercialize, zolucetide in desmoid tumors globally.** We intend to complete our ongoing Phase 1/2 trial of zolucetide to support the potential start of a Phase 3 registrational trial in the first half of 2027. If the Phase 3 trial is successful and we obtain marketing approval, we intend to commercialize zolucetide for the treatment of desmoid tumors.
- **Continue developing zolucetide in FAP through both our current Phase 1/2 enrollment of FAP-desmoid patients as well as a dedicated FAP cohort. Evaluate registrational path with regulatory agencies and, if approved, commercialize zolucetide in FAP.** We plan to advance clinical development in FAP, both through continued enrollment of FAP-desmoid patients and by opening a dedicated FAP cohort in the second half of 2026. Once more mature data are available, we plan to discuss the registrational path regulatory agencies as there is no approved systemic regimen as of today.
- **Continue developing zolucetide in HCC and other β -catenin and APC driven diseases, including ACP and ameloblastoma.** We intend to continue developing zolucetide in HCC and other β -catenin and APC-driven diseases in our ongoing Phase 1/2 study in addition to evaluating the optimal path for further development, including potential accelerated development approaches.
- **Maintain and expand our position as a leader in drugging the Wnt/ β -catenin pathway.** We have demonstrated the ability to target the key node of the Wnt/ β -catenin pathway, the interaction between β -catenin and TCF, and intend to continue discovery efforts that enable the identification of additional differentiated product candidates against the broad range of diseases driven by β -catenin and APC mutations.
- **Progress our ERG and allosteric AR^{ON} degraders, the next two programs in our pipeline of Helicon drug candidates, into IND-enabling toxicology studies.** We have identified ERG and allosteric AR^{ON} degraders that we believe leverage the strengths of our Helicon technology to create potentially differentiated medicines for patients with prostate cancer.
- **Continue to expand our pipeline of product candidates leveraging our proprietary Helicon discovery platform.** We believe the Helicon platform positions us to develop differentiated product candidates against high-value targets often inaccessible to existing modalities, across target classes and mechanisms. We intend to leverage this platform to continue to expand a pipeline of compelling medicines, initially in oncology.

- **Continuously improve our Helicon discovery platform to protect and extend our competitive advantage.** We intend to continue to invest in the computational, experimental, and manufacturing capabilities to maintain the distinctiveness of our Helicon platform. This includes the development of the Helicon Foundry (our single, integrated AI/hardware engine), expansion into new mechanisms and applications, and protection of proprietary data, intellectual property, and know-how, that serve as our competitive moat.
- **Further develop integrated computational, translational, and clinical capabilities to efficiently, precisely and effectively progress our product candidates through internal development.** We are committed to deploying the most effective computational, translational, and clinical tools at every stage of drug development in our pipeline — from target identification through clinical and commercial patient identification — building the organizational capabilities that allow us to do so with increasing efficiency and precision over time.
- **Explore and deliver on opportunities to extend the reach of our platform and capabilities through selective strategic partnerships.** We intend to opportunistically evaluate partnerships, in oncology and beyond, with collaborators that can bring specific expertise, capabilities, or infrastructure that may accelerate patient impact and broaden our pipeline in a capital efficient manner.

Our Team

Our work requires a unique kind of organization. Tackling high-difficulty biology and building a new therapeutic modality demands a team with the judgment to identify the right problems, the technical depth to solve them, and the persistence to see them through. We apply a first principles approach to solve the complex issues that impact our business and are unafraid to challenge industry norms in our pursuit. At Parabilis, we have built a deeply integrated team of drug hunters, data scientists, and clinical and operational experts who are aligned around a shared goal of translating ambitious science into real medicines for patients.

Our team is led by Mathai Mammen, M.D., Ph.D., President, Chairman, and CEO of Parabilis. Previously, Dr. Mammen served as Global Head of R&D and a member of the Executive Committee at Johnson & Johnson. There, he led and evolved one of the world's largest pharmaceutical R&D organizations and spearheaded the strategic integration of data science and AI across the company's portfolio. During his tenure, his team secured global approvals for nine medicines, including Darzalex Faspro™, Balversa™, Carvykti™, Rybrevant™, and Tecvayli™ in oncology; Tremfya™ and Ponvory™ in immunology; and Spravato™ and Invega Hafyera™ in neuroscience. Before J&J, Dr. Mammen was a Senior Vice President at Merck, and contributed to the development of Keytruda™ and the discovery of enlicitide. Earlier in his career, he co-founded Theravance, Inc., where he led R&D toward five approved therapies. In total, he has led the discovery/development of 19 approved medicines.

Our leadership team includes additional members with deep domain expertise, such as our Chief Medical Officer, Fawzi Benzaghrou, M.D., who most recently served as Senior Vice President and Global Head of Oncology R&D at Ipsen, where he contributed to the development and approval of multiple oncology therapies, including Cabometyx™ and Onivyde™. Our Scientific Co-founder and Executive Vice President of Platform Technology, John McGee, holds a Ph.D. in biochemistry from Harvard University, where he worked on both the *de novo* screening and multiplexing platforms that form the core of Parabilis' discovery engine. Our Chief Financial Officer, Tom Kotarakos, previously led two biotech companies through IPOs. Our Chief Business and Strategy Officer, Helen Ho, Ph.D., previously served as Chief Business Officer at Blueprint Medicines, where she, among other responsibilities, oversaw portfolio strategy and new product planning. Our Executive Vice President of Discovery Science, Markus Haerberlein, Ph.D., previously served as Head of Research at Alkermes. Our Executive Vice President of Discovery Biology, Jonathan Hurov, Ph.D., previously worked at Agios Pharmaceuticals and Cygnal Therapeutics, where he oversaw platform development and the company's early research.

Company History

We were founded in 2015 based on technology in-licensed from the laboratory of Greg Verdine, Ph.D., at Harvard University. This technology served as the foundation of our Helicon platform, which we have subsequently advanced and expanded through continued internal development, as we advance our proprietary capabilities and pursue our mission to develop transformative medicines for patients in need. Since our founding, we have developed a substantial portfolio of wholly owned intellectual property, including patents and proprietary trade secrets. The current state and operation of the Helicon platform are not dependent on the continued use of the originally in-licensed technology or any other third party intellectual property.

Our platform was purpose-built over a decade to enable Helicon discovery. The first five years were devoted to developing and scaling high-throughput synthesis and data collection methods, generating proprietary datasets comprising millions of data points across hundreds of thousands of Helicons and dozens of drug-like properties. Over the subsequent five years, we leveraged these data to build a suite of AI- and physics-based computational models, and to rigorously test and refine them in the context of active

discovery programs. These models are now deployed at every stage of discovery, from target selection through lead optimization. Each program we pursue feeds new data back into model training, creating a continuous learning loop. The result is a fully integrated discovery engine that has delivered repeated success against challenging targets and that we believe represents a durable competitive moat.

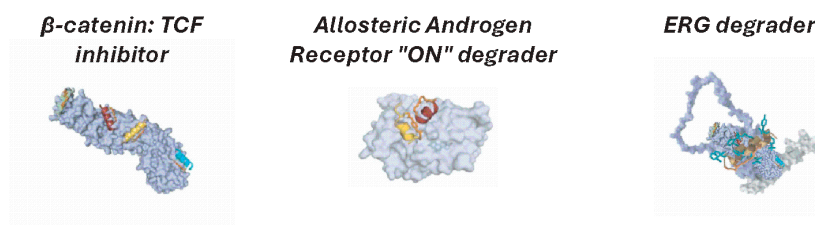
Since our inception, we have raised over \$800 million in financing from world class investors, including ARCH Venture Partners, Cormorant Asset Management, Fidelity Investments, GV, Milky Way Investments Group Limited, Nextech, RA Capital and venBio. Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and in certain cases received their shares in prior offerings at prices lower than the price offered to the public in this offering.

Our Proprietary Helicon Discovery Platform

Helicon Technology

Helicons are a new class of therapeutic candidates designed to target disease drivers that conventional modalities cannot effectively reach. Helicons can enter cells and selectively bind to flat protein surfaces, thereby combining the precision and targeting power of biologics with the tunability and intracellular access of small molecules. Despite tremendous investment and years of effort, other modalities like small-molecule glues, covalents, and degraders have had little success in accessing some of the most prevalent targets in human disease. Using our Helicon discovery platform, as set forth below, we have identified and developed multiple drug candidates with observed *in vivo* activity, including zolucetide, against high-value targets historically considered undruggable.

Figure 1: Select Helicon platform candidates.



Helicons are stabilized alpha-helical peptides, taking inspiration from nature's frequent use of alpha helices to bind to flat protein surfaces to traverse cellular membranes. We stabilize Helicons through proprietary crosslinkers and optimize their properties with a broad diversity of synthetic organic chemistry, including non-natural amino acids and a wide range of functionalization chemistries. The Helicon scaffold is highly modular and has the potential to readily incorporate additional functionalities beyond the inhibition of undruggable protein-protein interactions. These functionalities include the recruitment of E3 ubiquitin ligases for targeted protein degradation, the recruitment of essential proteins for targeted selective cell killing, and the delivery of payloads such as radionuclides.

Helicons, in contrast to most small molecules, often have the versatility to integrate ligands and additional functionalities at multiple possible positions. This provides substantial flexibility to tune potency, selectivity, and other drug-like properties. Helicons are also capable of achieving high selectivity for both target binding and degradation via formation of a ternary complex between target and E3 ligase machinery. Target binding selectivity is possible due to the larger and more polar contact surface areas Helicons use to engage proteins of interest. Selectivity for efficient target degradation that goes beyond target binding selectivity is further enabled by optimization of subtle features of target and E3 ligase complex orientation that differ even between highly related target proteins. These features of Helicon drug discovery enable the development of drug candidates that modulate the desired target while sparing closely related proteins with a high degree of biological precision. We believe that existing and future advances in small molecule drug discovery have the potential to be compatible with Helicons, which could enable us to apply emerging approaches to undruggable protein targets that we expect to remain challenging for other modalities.

The chemical and structural versatility of Helicons supports highly precise tuning of their properties and activity. However, this versatility requires effective and efficient methods of navigating the astronomical universe of over 10^{50} possible Helicon structures. Unlike small molecules, the modular and automated nature of our Helicon synthesis platform enables us to synthesize nearly any one of these 10^{50} possible structures within days in our laboratories. We have built a stack of complementary experimental and computational capabilities designed to allow us to efficiently assess a vast number of molecules and identify the most promising chemical series to pursue. These investments have resulted in a fully integrated Helicon discovery platform that has repeatedly identified biologically active molecules for targets and binding sites that have been inaccessible to other drug modalities.

Helicon Discovery Platform

All of our assets, including zolucateptide, were discovered using our Helicon discovery platform. This platform generates both drug candidates and large amounts of proprietary data. Each target we prosecute adds new and diverse information that is then fed back into model training, creating a continuous learning loop that improves our AI models and design processes. These platform advances have significantly improved our success rates in discovery, with all of the new programs we have initiated over the last three years resulting in cell-active compounds (seven distinct series for four target proteins).

We built our platform over the span of a decade specifically to enable the discovery of Helicons. The platform's physical foundation incorporates an advanced chemistry toolkit, custom experimental methods, and extensive manufacturing and development know-how. A decade of applying these capabilities to Helicon drug discovery has generated vast proprietary datasets, comprising millions of data points for hundreds of thousands of Helicons across dozens of drug-like properties. We have used these data to construct a comprehensive suite of AI- and physics-based computational models, proprietary to Parabilis, which are now integrated into every step of our discovery process from target selection through lead optimization. This platform has enabled us to pursue multiple high-value opportunities and broaden our pipeline in recent years. We believe that the combination of our know-how, expansive platform capabilities, intellectual property, and large datasets creates a substantial barrier for other entrants.

Our platform's core physical capabilities include the following:

- **Our chemistry toolkit** comprises hundreds of proprietary helix-stabilizing chemical crosslinkers and over a thousand non-natural amino acids, providing access to vast chemical diversity.
- **Our display screening systems** evaluate billions of Helicons for binding to target proteins, creating the potential to discover multiple, high-quality chemical series for new targets.
- **Our multiplexed screening methods** integrate combinatorial chemistry with mass-spectrometry-based multiplexed screening, enabling the synthesis and screening of multi-thousand-member Helicon libraries for a range of drug-like properties.
- **Our customized suite of cytosolic exposure assays** generates granular, quantitative data on one of the most critical properties for the successful discovery of peptides that can enter cells and access undruggable targets.
- **Our full complement of in-house laboratory capabilities** is used to generate datasets on additional properties, including potency, selectivity, cellular activity, physicochemical behavior, *in vivo* pharmacodynamic activity and efficacy, and drug, metabolism and pharmacokinetics ("DPMK") parameters.

We have used the large and proprietary multi-parameter datasets resulting from these laboratory systems to build a set of AI- and physics-based models for dozens of different drug-like properties, which are coupled with generative AI methods both to aid human designers and to autonomously guide the design of next-generation molecules. These range from local, program-specific models for binding affinity and cellular potency to global models that predict cytosolic exposure and physicochemical properties. The first generations of our AI models were developed and integrated into discovery programs beginning in 2021, followed by years of close collaboration between data science and experimental teams to iteratively assess performance, adjust data collection, and update model architecture and training. This extended period of refinement has led both to an improved and expanded set of models and to effective, prediction-centric collaboration frameworks within teams. Both our ERG and AR^{ON} degraders were discovered by leveraging these computational capabilities.

Each stage of our Helicon drug discovery process tightly couples these high-throughput laboratory systems and AI- and physics-based computational methods to enable rapid optimization of drug candidates. The graphic below summarizes our discovery platform process.

Figure 2: Helicon discovery and optimization platform.



- 1. Target Evaluation.** Our discovery process begins by evaluating potential targets for structural features that favor Helicon binding, which we refer to as Helisites. We have built a machine learning model that is able to predict the presence and location of Helisites on protein structures, including predicted structures, with high prospective accuracy. This capability enables us to identify proteins that are likely to be targetable by Helicons, and to select the binding sites that we believe are best suited to elicit the desired biological effect, since many proteins contain multiple Helisites. Using this model, we have identified Helisites across a wide range of protein classes including transcription factors, scaffolding proteins, E3 ubiquitin ligases, extracellular proteins, kinases, and other enzymes. Our Helicon platform is not intrinsically limited to any particular mechanism, and we believe that it has the potential to generate impactful medicines across disease areas where there is a strong scientific rationale for pursuing an intracellular disease driver that is challenging to target with other therapeutic modalities.
- 2. Hit Discovery.** Once a target is selected, we deploy both experimental and computational approaches to discover hits for those targets. Our experimental screening methods include the phage display methodology used to discover the chemical series that led to zolucetide, as well as a newer mRNA display capability that can screen up to 10 billion Helicons in a single experiment. Both our phage and mRNA display screening methods were built specifically for Helicons using custom library construction techniques and are run entirely in-house. We also apply a computational *de novo* hit discovery technique that we custom built specifically for Helicons to identify target-binding Helicons composed of non-natural amino acids, including all-D amino acids. The application of our experimental and computational hit discovery methods routinely leads to the identification of multiple chemical series for target proteins, often at multiple distinct Helicon binding sites on the protein surface. This optionality allows us to increase the probability of technical success for each program and enables us to tailor our targeting approach by selecting the binding sites or mechanisms that are best aligned with the biological selectivity or function that is needed.
- 3. Hit-to-Lead** is anchored by our multiplexed screening capabilities. We utilize automated parallel peptide synthesis and combinatorial chemistry to rapidly generate libraries of thousands of highly complex Helicon peptides in less than a week, using only a single synthesizer. We then apply a suite of mass spectrometry-based assays to efficiently measure multiple drug-like properties, including target binding affinity, cell penetration, selectivity, physicochemical properties such as LogD, and stability to plasma, cell lysate, and other matrices. A particularly crucial multiplexed measurement is our proprietary cytosolic exposure assay, which quantifies whether a Helicon traverses cellular membranes and accesses intracellular targets. Using a machine learning model trained on these cytosolic exposure measurements for more than 40,000 Helicons, we use predicted cytosolic exposure to guide the selection and design of Helicons that can enter cells. This unique capability has enabled us to reliably optimize a range of properties including cell penetration, which is arguably the most formidable barrier to developing peptides that can target intracellular proteins.
- 4. Lead Optimization.** Hits are optimized into leads and candidates through iterative AI-enabled design cycles, where local and global AI models guide multi-objective optimization across potency, solubility, selectivity, DMPK, and *in vivo* efficacy and pharmacodynamic activity. Our design process integrates *in silico* mutational scanning specific to Helicon staple and side-chain substitutions, identifying the modifications most likely to improve binding and other drug-like properties before a molecule is made. We can access a combinatorial space many orders of magnitude larger than standard peptide chemistry by combining the full range of available small molecule chemistry with our library of more than 1,000 non-natural amino acids, hundreds of staple chemistries, and a broad range of E3 ligands to a wide variety of E3 ligases. Non-natural amino acids expand the chemical design space far beyond the 20 natural amino acids, enabling precise optimization of potency, selectivity, solubility, and cell permeability.

As Helicons (or Helicon degraders) progress toward a short list of potential development candidates, we conduct an increasingly comprehensive evaluation to guide final selection. This includes formulation screening to identify viable dosing routes and delivery strategies, expanded DMPK profiling across species covering exposure predictions, pharmacodynamic and efficacy studies to confirm target engagement and dose-response relationships in relevant models, and toxicological profiling to establish preliminary safety margins. Together, this data package informs development candidate nomination and readiness for IND-enabling studies.

We are further developing our discovery platform with the goal of unifying these components into a single, integrated AI/hardware engine – the “Helicon Foundry” – designed to combine automated experimentation and high-throughput measurement with integrated data capture and continuous learning, as well as AI-driven design/optimization loops. We aim to leverage the Helicon Foundry to prosecute many targets and series in parallel with dramatically improved scalability and cycle times. As this system matures, we expect it will continue to reinforce our platform flywheel: each program can add data, improve models, refine automation, and increase the speed and quality of subsequent programs for potentially higher rates of drug development success.

Our computational capabilities extend beyond molecular drug discovery, both to upstream therapeutic hypothesis generation and downstream clinical development. Upstream, data science and AI are applied to both public and proprietary biological datasets – including the Helisite machine learning model to predict Helicon binding sites on protein structures with high accuracy. While we believe this application of data science and AI to robust biological datasets has the potential to allow us to identify high-quality targets with an increased probability of technical execution and clinical success, there can be no guarantee that this process will lead to actual clinical success or that any clinical success will result in regulatory approval. Downstream, we integrate real-world data to contextualize clinical trial outcomes, leveraging multi-modal datasets including omics, imaging, and patient-derived xenograft (“PDX”) models to support biomarker discovery and adaptive trial design. In translational science, we are leveraging the latest computational biology models to improve our understanding of which medicines are likely to work in which patients and indications, enabling us to refine our biomarker strategies and patient selection to increase the precision and efficiency of our clinical programs. In clinical development, we are building the biomarker-integrated operational infrastructure that targeted medicines require, from biomarker design through cutting-edge clinical operations designed to scale across indications as our pipeline grows.

Our Product Candidates

We are developing a range of Helicon product candidates for the treatment of solid tumors, including our lead product candidate, zolucetide. We also have several preclinical programs, including an ERG degrader and an AR^{ON} degrader targeting prostate cancer, a β -catenin degrader effort and multiple earlier discovery-stage programs.

Zolucetide

Zolucetide was discovered using our platform and is, to our knowledge, the first and only investigational therapy that inhibits the interaction between β -catenin and transcriptional co-activators of the TCF family. By doing so, it inhibits tumorigenesis at the most critical downstream node of the Wnt/ β -catenin pathway. We have generated early efficacy and safety data in our ongoing clinical trials in a variety of tumor types and expect to report further data in the second half of 2026.

Wnt/ β -catenin pathway

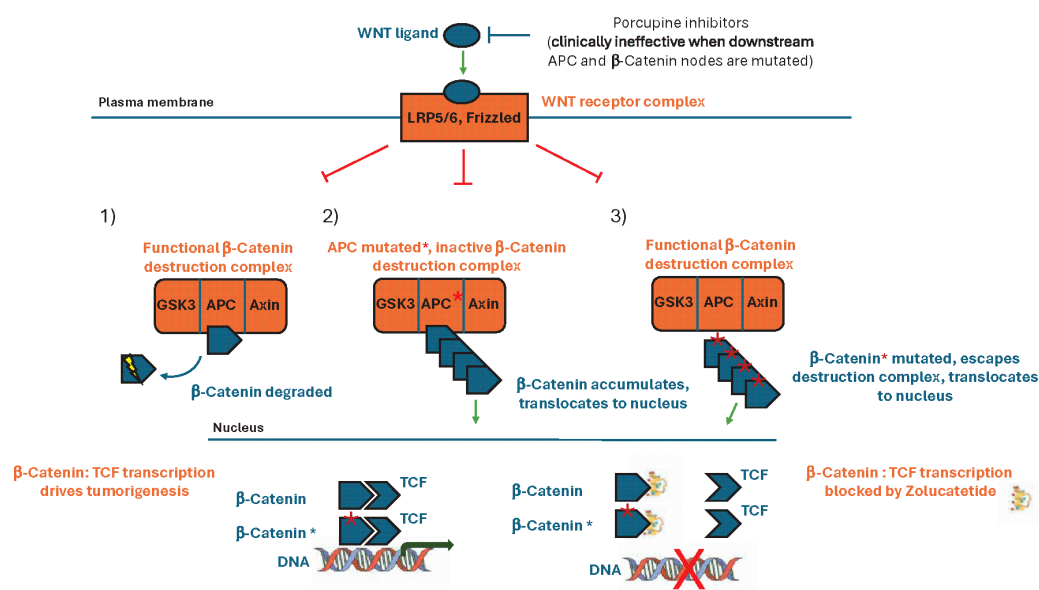
The Wnt/ β -catenin signaling pathway is one of the most extensively studied signaling cascades in biology, governing essential cellular processes including proliferation, differentiation, migration, and development, and is among the most broadly implicated drivers in human cancer. β -catenin activating pathway mutations are present in over 10% of all cancers.

Under normal physiological conditions, the Wnt pathway operates as a tightly regulated molecular switch. In the absence of a Wnt ligand signal, β -catenin is captured by a multiprotein assembly known as the “destruction complex”, which is comprised of Axin and APC scaffolding proteins and glycogen synthase kinase 3 β . This complex targets β -catenin for proteasomal degradation when Wnt target and gene transcription is suppressed. Upon binding of a Wnt ligand to its receptors (FZD, LRP5/6) the destruction complex is inactivated, and degradation of β -catenin ceases, leading to its accumulation in the cytoplasm and subsequent translocation to the nucleus. In the nucleus, β -catenin binds to the TCF family of transcription factors, forming a transcription complex that drives expression of Wnt target genes. Many of these target genes (e.g. c-MYC, LGR5) drive cell proliferation and maintain a stem-cell state.

Wnt pathway activation in tumor cells can happen in multiple ways, most often due to loss-of-function mutations in APC and gain-of-function mutations in CTNNB1 (β -catenin). Loss-of-function APC mutations impair the ability of the destruction complex to degrade β -catenin. Gain-of-function CTNNB1 mutations allow β -catenin to escape degradation normally driven by the destruction complex. In both cases, the resulting constitutive stabilization of β -catenin and activation of Wnt target genes occurs independently of extracellular Wnt ligand signaling, rendering these tumors ligand-independent. APC mutations in individuals have been associated with higher cancer risk across multiple tumor types, including colorectal, gastric, small bowel, thyroid, liver, and desmoid tumors, among others. CTNNB1 mutations are the predominant mechanism of Wnt activation in desmoid tumors, HCC, ACP, endometrial cancer, and several other tumor types.

The β -catenin/TCF protein-protein interaction represents the most downstream effector node of the canonical Wnt pathway. Upstream activating signals, whether arising from Wnt ligand binding, loss of destruction complex function through APC mutations, or stabilizing mutations in β -catenin itself, all converge to drive a tumorigenic transcriptional program. The downstream position of the β -catenin/TCF complex in this pathway provides the mechanistic rationale for zolucetide and is the basis of our therapeutic strategy.

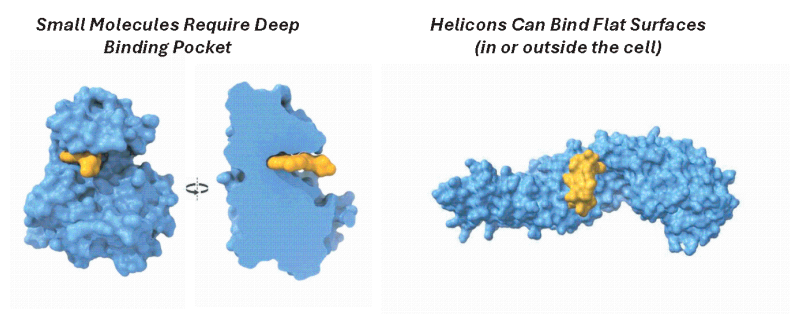
Figure 3: Downstream inhibition of Wnt/ β -catenin signaling by zolucetide.



Historical Challenges in Targeting the Wnt/ β -catenin pathway

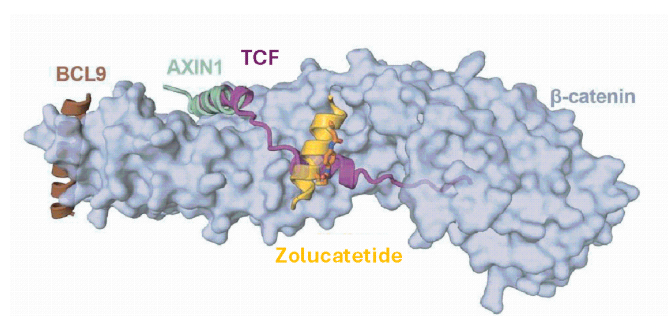
Despite compelling biological and clinical rationale and more than three decades of drug discovery effort, investigational therapeutics that directly and selectively target β -catenin have not been successful in clinical development to date. Furthermore, β -catenin itself has historically been considered undruggable due to its structural and functional properties. The protein lacks deep, well-defined binding pockets and relies on large, shallow protein-protein interaction surfaces within its armadillo repeat domain to engage partners such as TCF, APC, Axin, and E-cadherin. These overlapping interaction interfaces make selective disruption of oncogenic β -catenin:TCF signaling difficult without impairing essential cellular functions like adhesion. Additionally, as an intracellular protein localized to the cytoplasm and nucleus, β -catenin has remained inaccessible to biologics, while traditional small molecules have lacked the size and structural complexity to effectively engage its large interaction surface. We have specifically engineered zolucetide to bind the relatively flat protein-protein interaction surface of β -catenin and directly disrupt the β -catenin:TCF interaction, as illustrated in the figure below.

Figure 4: Zolucetide's differentiated binding capabilities.



As shown in the figure below, zolucetide inhibits the interaction between β -catenin and TCF without disrupting other interactions.

Figure 5: Zolucetide inhibition.

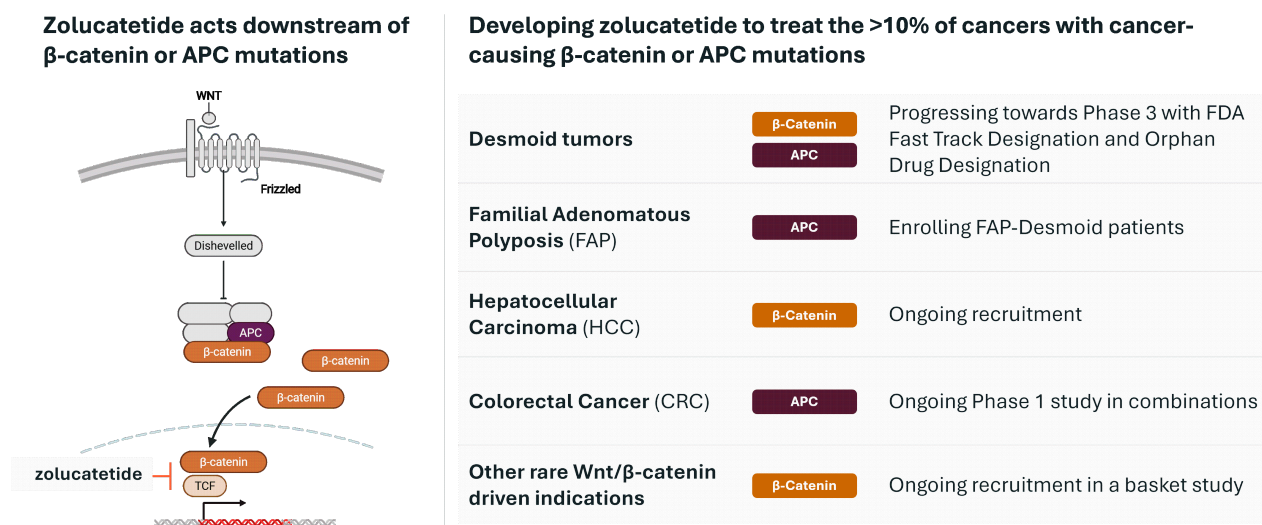


Certain historical efforts focusing on modulating β -catenin proliferation, such as the use of porcupine inhibitors, failed due to limited efficacy since these inhibitors targeted the Wnt/ β -catenin pathway upstream of β -catenin itself. In tumors harboring APC or β -catenin mutations, β -catenin activity becomes independent of ligand- or receptor-mediated signaling, rendering upstream interventions largely ineffective (see Figure 3). Additionally, systemic or nonselective inhibition of the pathway as demonstrated by frizzled-targeting antibodies and decoy receptors targeting Wnt receptors has resulted in significant on-target toxicities such as bone loss and dysgeusia. Like porcupine inhibitors, these agents target the receptor-ligand axis and are therefore not expected to address tumors with downstream pathway activation. We believe zolucetide addresses these limitations by directly targeting the β -catenin:TCF interaction at the critical downstream node of the pathway.

Our Solution – Zolucetide

To overcome the historical challenges described above, we specifically engineered zolucetide to enter cells without altering the cell membrane and bind to the relatively flat protein-protein interaction surface of β -catenin, directly disrupting the β -catenin:TCF interaction at the critical downstream node of the pathway. We believe zolucetide has the potential to block β -catenin-dependent Wnt signaling in tumors mutated at APC and β -catenin, by acting at the β -catenin/TCF interface. As set forth in the graphic below, zolucetide acts downstream of both APC loss-of-function and β -catenin gain-of-function mutations, and as a result we believe cancers driven by mutations in either of these genes will be responsive to zolucetide. Multiple high-value indications are known to be driven by direct β -catenin activation, including desmoid tumors, FAP, HCC, CRC, and numerous other rare Wnt/ β -catenin-driven indications. The figure below summarizes these indications.

Figure 6: Zolucetide acts downstream of mutations.



Although Wnt/ β -catenin pathway alterations occur across a wide range of cancers, we have been disciplined and deliberate in choosing where to focus. We are prioritizing indications based on three criteria: (i) the Wnt/ β -catenin pathway mutation is highly prevalent, (ii) β -catenin is the key driver of disease, and (iii) we have seen high levels of activity to date in our preclinical studies and clinical trials. These indications are often genomically simple tumors in which a Wnt/ β -catenin pathway mutation is the main oncogenic driver detected. These indications include desmoid tumors and FAP, settings in which a monotherapy approach to direct inhibition at the β -catenin:TCF node has historically been observed to be effective. We are also exploring HCC, where we believe zolucetide is well positioned to treat a molecularly defined subset of patients that harbor activating β -catenin mutations, as well as additional rare indications such as ACP and ameloblastoma. We also believe that zolucetide has potential as part of combination regimens in more genomically complex tumors, such as colorectal cancer, where additional mutations beyond β -catenin are also implicated in driving disease.

We are committed to advancing zolucetide in indications where the underlying biology supports the potential for meaningful clinical benefit and where we see potential for patient impact. We believe that the clinical data obtained to date provide evidence of successful targeting of β -catenin and therapeutic utility across multiple tumor types. We have set forth below the design of our ongoing Phase 1/2 clinical trial of zolucetide.

Our ongoing Phase 1/2 clinical trial of zolucetide (Study FOG-001-101) is a multi-arm, open-label study evaluating zolucetide administered as an intravenous (“IV”) infusion, both as a monotherapy and in combination, in patients with locally advanced or metastatic solid tumors harboring Wnt pathway-activating mutations (“WPAM”), including APC and CTNNB1 mutations. The primary objectives of Part 1 are to assess the safety and tolerability of zolucetide across a range of dose levels and dosing schedules, characterize the pharmacokinetic (“PK”) profile, identify a preliminary recommended Phase 2 dose and schedule, and evaluate preliminary antitumor activity. The trial consists of a dose-escalation and dose-optimization phase (Part 1), followed by a dose-expansion phase (Part 2). Figure 7 summarizes the trial design, enrolled patient populations, evaluated dose cohorts, and primary and secondary endpoints.

Figure 7. Zolucetide study cohorts as of February 16, 2026.

	Indication(s)	Patients Enrolled (N)	Zolucetide Dose Ranges Tested (All IV) *	Primary Endpoints	Secondary Endpoints
Part 1a Solid Tumors Dose Escalation	Locally advanced or metastatic solid tumors (incl. desmoid tumors) harboring Wnt-pathway activating mutations (WPAM+)	67	DL1 - DL6 (75 mg – 900 mg QW)	Safety & tolerability; determine MTD or maximum feasible dose (AEs, labs, vitals, ECGs, bone mineral density, physical exam)	PK profile; preliminary RP2D & schedule; preliminary antitumor activity (ORR, BOR, DOR, DCR, TTP per RECIST 1.1)
Part 1b MSS-CRC Biomarker Cohorts	Microsatellite stable colorectal cancer (MSS CRC)	43	DL2 – DL6 (150 mg – 900 mg QW)		PK/PD profile; preliminary RP2D & schedule; preliminary antitumor activity (ORR, BOR, DOR, DCR, TTP per RECIST 1.1)
Part 1c HCC Dose Escalation	Barcelona Clinic Liver Cancer (BCLC) stage C or BCLC stage and Child-Pugh A hepatocellular carcinoma (HCC) [#] with APC or CTNNB1 pathogenic mutations	0 (Patients in Screening)	Not yet evaluated Planned: DL4 – DL5 (450 mg – 700 mg QW)		
Part 1d Desmoid Tumors	Progressing desmoid tumors [^]	22 (total)	DL2 (150 mg) DL4 (450 mg)		PK profile; preliminary RP2D & schedule; preliminary antitumor activity (ORR, BOR, DOR, DCR, TTP per RECIST 1.1)
	<i>Safety</i>	3	DL4 (450 mg QW)		
	<i>Dose Optimization</i>	19	Randomized to 3 induction -> maintenance regimens: (i) DL4 QW x2 cycles → DL4 Q2W (n=5) (ii) DL4 QW x4 cycles → DL2 QW (n=7) (iii) DL2 QW x4 cycles → DL2 Q2W (n=7)		
Part 1f MSS CRC Combinations with SoC Dose Escalation	MSS CRC**	34 (total)			PK/PD profile; preliminary RP2D & schedule; preliminary antitumor activity (ORR, BOR, DOR, DCR, TTP per RECIST 1.1)
	1 st Line MSS CRC Combo with FOLFOX + Bev	6	DL2 (150 mg QW), DL4 (450 mg QW), & DL6 (900 mg Q2W)		
	3 rd Line CRC Combo with Nivolumab	17	DL2 (150 mg QW), DL4 (450 mg QW), & DL6 (900 mg Q2W)		
	3 rd Line MSS CRC Combo with Lonsurf + Bev	11	DL2 (150 mg QW), DL4 (450 mg QW), & DL6 (900 mg Q2W)		
Total		166			

All sites are U.S.-based. Part 1 not powered for statistical significance; antitumor activity results are exploratory.

Bev = Bevacizumab; Combo = Combination; CRC = Colorectal Cancer; DL = dose level; IV = Intravenous(ly); QW = weekly; Q2W = every 2 weeks; RP2D = recommended phase 2 dose.

* One cycle = 28 days

not amenable to locoregional therapy or relapsed after locoregional therapy and not amenable to curative treatment

[^] with an increase of ≥10% by RECIST 1.1 or in the active component of the tumor within 12 months of the first dose of zolucetide

** (Part 1f-2 open to WPAM+ solid tumors for which immunotherapy with anti-PD-1/PD-L1 +/-CTLA-4 therapy is Standard of Care (SoC) and have primary resistance or secondary resistance (within 6 months of the first dose) on anti-PD1/PD-L1 therapy or ineligible for SoC

Figure 8: Zolucetide fixed dose equivalents for each BSA-based dose level

Dose Level	Zolucetide Fixed Dose (mg)	Zolucetide BSA-based Dose (mg/m ²)
1	75	36
2	150	72
3	300	144
4	450	240
5	700	360
5.5	800	420
6	900	480

BSA = Body Surface Area

Part 1A was designed as a standard monotherapy dose-escalation study evaluating patients with desmoid tumors, microsatellite stable colorectal cancer (“MSS CRC”), and other advanced solid tumors harboring WPAM alterations. Desmoid tumor patients were enrolled across multiple dose levels, including DL2, DL4, and DL6. Based on the clinical activity observed in desmoid tumor patients during Part 1A, Part 1D was initiated to accelerate development in this setting and optimize the zolucetide dose and schedule for potential later-stage development. Part 1D evaluates three randomized induction and maintenance dosing regimens across DL2 and DL4 weekly and every-other-week schedules in desmoid tumors.

All patients enrolled in the study to date have been treated at clinical sites in the United States. Part 1 was not designed or powered to assess for statistical significance. Antitumor activity results are reported as exploratory observations and include objective response rate (“ORR”), best overall response (“BOR”), duration of response (“DOR”), disease control rate (“DCR”), and time to progression (“TTP”), assessed using disease-appropriate response criteria, including RECIST 1.1 for desmoid tumors and other solid tumors. The clinical data presented in Figures 9 through 14 reflect patients enrolled and treated in Part 1A (dose escalation) and Part 1D (dose optimization) as of February 16, 2026, with a primary focus on the desmoid tumor indication, which currently represents the lead development opportunity for zolucetide.

Indications

Genomically Simple Tumors

We consider genomically simple tumors to be those in which a Wnt/ β -catenin pathway mutation is highly prevalent, serves as the key driver of disease, and represents the primary oncogenic alteration detected. To date we have observed meaningful responses at dose levels DL2 to DL4, or 150-450 mg weekly.

Desmoid Tumors

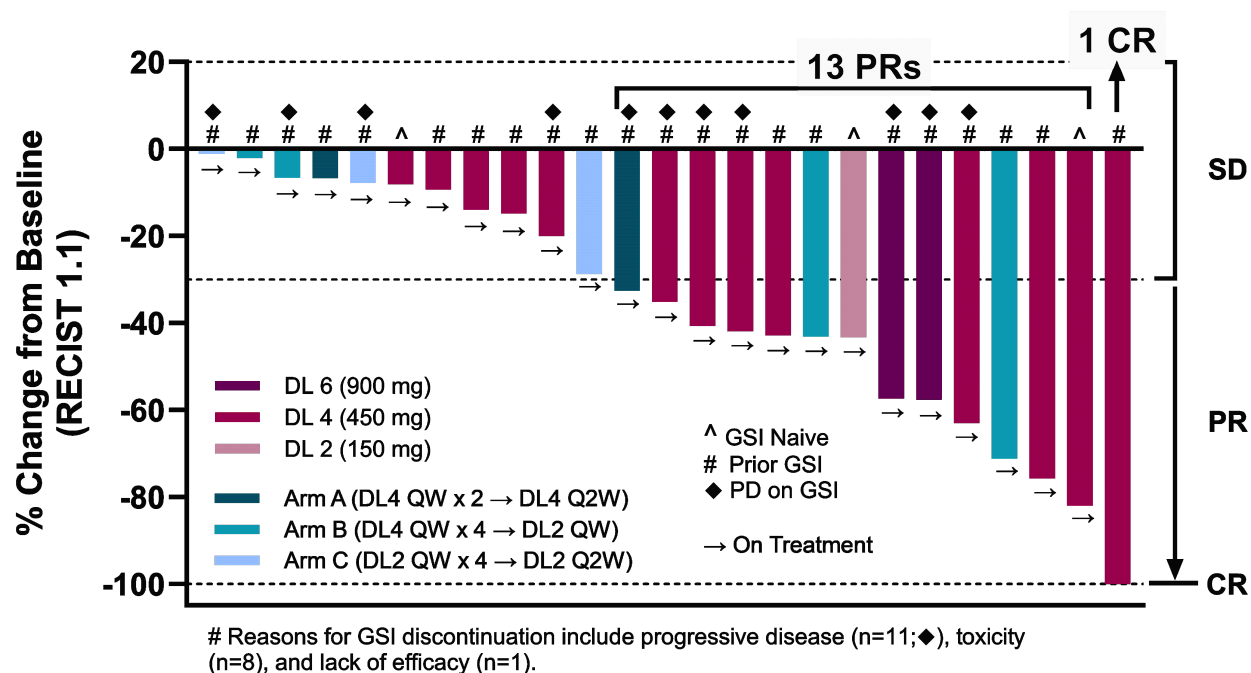
Our lead indication for zolucetide is desmoid tumors, which are rare, locally invasive soft tissue tumors driven by somatic or germline β -catenin pathway mutations. We estimate that approximately 11,000 desmoid tumor patients in the United States are actively managed under physician care. Desmoid tumors are typically diagnosed in young adults, with peak incidence in individuals aged 30 to 40 years, and a higher prevalence in females. Desmoid tumors impose substantial morbidity, with pain, functional and mobility impairment, and the potential for life-threatening complications depending on tumor location. Given the chronic nature of the disease and the onset in a predominantly young patient demographic, who have a near-normal life expectancy, prolonged or lifelong management is typically required.

Although there is an FDA-approved therapy, with others in development or prescribed off-label, there remains a large unmet medical need, as many patients either do not respond to therapy or have significant side effects. The only FDA-approved therapy, Ogsiveo (nirogacestat), is a GSI that demonstrated a significant progression free survival improvement versus placebo (HR:0.29) and a 41% objective response rate measured at the end of its Phase 3 trial, with responses accrued over a median duration of 20.6 months. It was associated with high rates of adverse events, including diarrhea in 84% of patients, maculopapular rash in 32% of patients, and ovarian dysfunction in 75% of female patients of reproductive potential. More than half of desmoid tumor patients treated with this therapy do not achieve objective responses and among those who do, the median time to response is 5.6 months among those that did eventually respond. 20% of patients discontinued Ogsiveo treatment due to adverse events. Another GSI, varegacestat was the subject of an NDA submitted to the FDA in April 2026. Based on topline Phase 3 data presented at the 2026 American Society of Clinical Oncology Annual Meeting, varegacestat demonstrated a significant improvement in progression-free survival versus placebo (HR: 0.16) and a 56% objective response rate, with a median time to response of 8.2 months among patients who responded. Varegacestat was associated with similarly high rates of GSI-related adverse events, including diarrhea in 82% of patients, fatigue in 44% of patients, maculo-papular rash in 25% of patients, and ovarian dysfunction in 55.6% of premenopausal women. 20% of patients in the varegacestat Phase 3 trial discontinued treatment due to adverse events, consistent with the discontinuation rate observed with Ogsiveo. Up to 50% of desmoid tumor patients treated with varegacestat did not achieve objective responses. The Phase 3 trials of Ogsiveo and varegacestat described above were conducted at a later stage in the development process using different trial designs than our Phase 1/2 clinical trial of zolucetide. Accordingly, the trial results of Ogsiveo and varegacestat may not be directly comparable to those we have observed in our clinical trial of zolucetide to date and described elsewhere in this prospectus, nor to those that we may observe in our planned Phase 3 registrational trial. We have not conducted, and do not currently plan to conduct, any head-to-head clinical trials with Ogsiveo or varegacestat.

The high threshold to initiate systemic therapy in desmoid tumors today may be driven in large part by toxicity and treatment burden, rather than disease biology alone. The availability of more effective and better-tolerated therapies could lower this treatment threshold, potentially significantly expanding the treated population and revealing a larger underlying market than is currently observed.

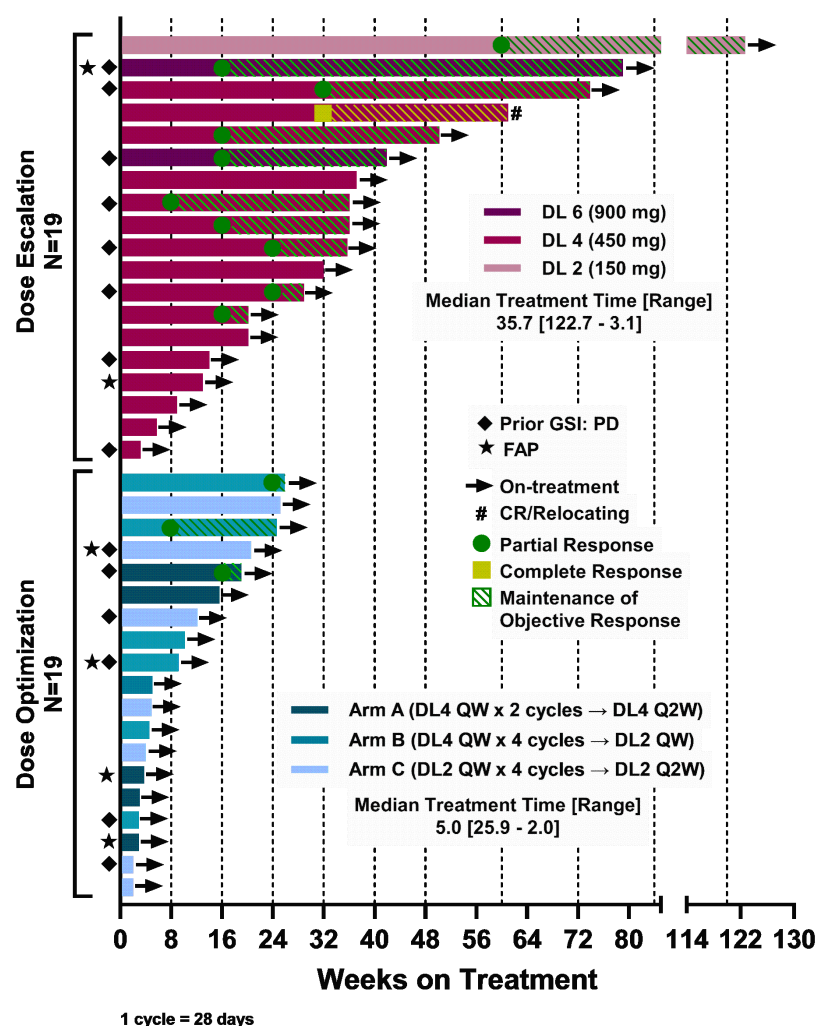
The figures below set forth data from our ongoing Phase 1/2 trial, as of February 16, 2026.

Figure 9: Observed best percentage change from baseline and overall response in desmoid tumor patients receiving zolucetide.



CR : Complete Response DL: dose level; PR: partial response; QW: weekly dosing; Q2W: every other week dosing.

Figure 10: Observed time on study treatment per patient in zolucetide Phase 1/2 trial in desmoid tumors as of February 16, 2026.



Patient achieved a complete response and voluntarily discontinued treatment due to relocation away from study center.

Vertical dashed lines indicate timing of on treatment scans. Scans occur every eight weeks for the first 12 months, and then every 12 weeks thereafter. Across both the dose escalation and dose optimization groups, 25 patients had at least one post-baseline scan, and 19 have more than one scan (16 weeks and beyond). Dose optimization arms are as follows: (1) Arm A = DL4 weekly for 2 cycles, followed by DL4 every 2 weeks; (2) Arm B = DL4 weekly for 4 cycles followed by DL2 weekly; and (3) Arm C = DL2 weekly for 4 cycles followed by DL2 every 2 weeks. One cycle is 28 days.

38 desmoid patients have been enrolled and treated with zolucetide, of which 25 had sufficient follow up to be response-evaluable, with all 25 patients showing tumor reductions (DCR 100%). Of the 19 patients with at least two post-baseline scans, 74% (14/19) had an objective response per RECIST 1.1 (a 30% or greater tumor reduction from baseline), including one complete response (CR:5.2%), with a median time to response of 3.8 months. In all patients who have achieved a partial response and who have had a subsequent scan, the partial response has been confirmed. Partial responses were observed in desmoid tumor patients regardless of prior exposure to GSIs. Patient prior treatment categories include: (1) no prior GSI exposure (GSI-naïve), (2) disease progression after treatment with a GSI, and (3) discontinuation of prior GSI due to toxicity or other reasons. We believe the ability of zolucetide to drive responses in desmoid tumors regardless of prior GSI therapy supports our differentiated approach of targeting the direct underlying cause of desmoid tumors, mutations in β -catenin or APC, underscoring zolucetide's potential.

To date, data in the zolucetide desmoid tumor program demonstrate deep and durable responses across dose levels, assessed by both RECIST 1.1 per investigator and volumetric measurements per central reader. We currently have volumetric measurements on eight patients from the central reader. Figure 11 shows substantial tumor reduction across all three dose cohorts (72, 240, and 480 mg/m²), including in patients with prior GSI progressive disease. Figure 11 tracks percent change from baseline through Week 96 and demonstrates rapid, steep tumor regression in the 240 and 480 mg/m² cohorts, with responses evident within the first weeks of treatment. A slower but consistent pattern of reduction over time, was observed in the 72 mg/m² cohort. Volumetric data from the central reader corroborate and in all cases exceed the depth of response captured by RECIST 1.1, further supporting our view of the clinical meaningfulness of the observed tumor reductions.

Figure 11. Volumetric data -- responses by dose level and prior GSI as of October 27, 2025

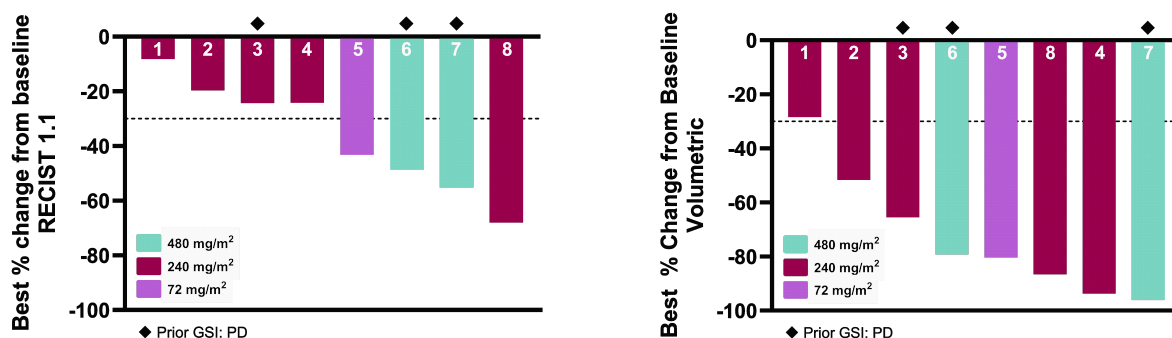
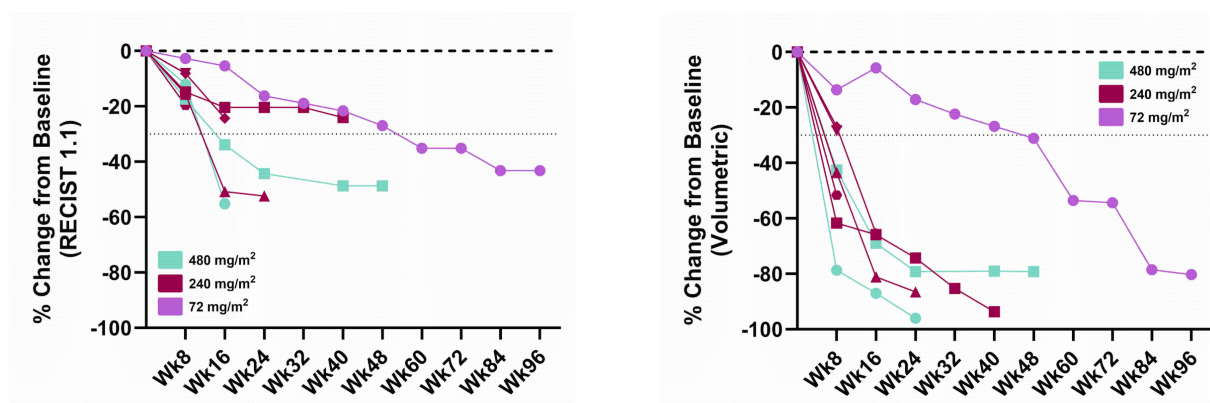


Figure 12. Volumetric data -- time to response by dose level as of October 27, 2025



To date, we have observed chronic administration of zolucetide to be well tolerated and to reduce tumor size over time. Additional information regarding tolerability and treatment-related adverse events (“TRAEs”) can be found below in Figure 13. We are developing a new formulation of zolucetide to be used as a self-administered injection, either with an autoinjector, pre-filled syringe or an on-body device for ease of administration, which we believe may further support chronic use and adoption. We are currently evaluating a number of lead formulations for zolucetide with the intention of taking the final formulation into bridging studies in healthy volunteers and patient populations. Although we plan to continue working toward a self-administered injectable formulation, we intend to conduct our pivotal Phase 3 trial of zolucetide in desmoid tumors initially using only the current intravenous (“IV”) infusion presentation. We currently plan on launching zolucetide, if approved, in a self-administered injectable product formulation. We expect regulatory authorities will require us to conduct, among other things, PK compatibility studies to bridge the IV infusion presentation to these new planned injection presentations, human factors testing to support self-administration of zolucetide, and potentially a separate Phase 2 trial to validate the equivalence of the current IV formulation to the injectable formulation. Any of these additional steps could delay marketing approval of zolucetide in one or more formulations. We expect to identify our final formulation and engage in a discussion with the FDA relating to a bridging trial to allow for approval of the self-administered injectable formulation to be approved.

Preliminary Clinical Safety Data

The table below sets forth preliminary clinical safety data for all desmoid tumor patients as of February 16, 2026. We have observed zolucetide at optimal doses between DL2 and DL4 to have the potential for significant improvement in tolerability over GSIs and other available therapies for the treatment of desmoid tumors. The most commonly reported TRAEs at optimal doses between DL2 and DL4 were low-grade (Grade 1 or 2), with mild symptoms or asymptomatic laboratory abnormalities that were reversible. There were no treatment-related Grade 3 or higher gastrointestinal (“GI”), skin toxicities, or ovarian toxicities reported. No TRAEs have resulted in treatment discontinuation. All patients remain on trial with durable responses.

Figure 13: Treatment-related Adverse Events (“TRAE”) in desmoid tumor patients dosed in Part 1 in greater than or equal to 15% of patients, observed as of February 16, 2026.

Treatment-related Adverse Events (TRAEs) in Part 1 in ≥ 15% Patients

TRAEN(%)	Dose Escalation (N = 19)						Dose Optimization (N = 19)						All Participants (N=38)	
	DL 2 (150 mg) N=1		DL 4 (450 mg) N = 16		DL6 (900 mg) N = 2		DL4 – DL4 (Q2W) Arm A (N=5)		DL4 – DL2 (QW) Arm B (N=7)		DL2 – DL2 (Q2W) Arm C (N=7)			
	All Grade	Grade ≥3	All Grade	Grade ≥3	All Grade	Grade ≥3	All Grade	Grade ≥ 3	All Grade	Grade ≥ 3	All Grade	Grade ≥ 3	All Grade	Grade ≥ 3
Fatigue	0	0	10 (62.5)	0	2 (100)	0	2 (40.0)	0	1 (14.3)	0	1 (14.3)	0	16 (42.1)	0
Nausea	0	0	10 (62.5)	0	1 (50.0)	0	1 (20.0)	0	2 (28.6)	0	1 (14.3)	0	15 (39.5)	0
Alopecia	1 (100)	0	8 (50.0)	0	2 (100)	0	1 (20.0)	0	2 (28.6)	0	0	0	14 (36.8)	0
AST Increase	0	0	8 (50.0)	0	2 (100)	0 ^a	0	0	1 (14.3)	0	0	0	11 (28.9)	0
Hyperbilirubinemia*	0	0	5 (31.3)	1 (6.7)	2 (100)	1 (50.0)	2 (40.0)	1 (20.0)^	1 (14.3)	0	0	0	10 (26.3)	3 (7.9)^
ALT Increase	0	0	5 (31.3)	0	2 (100)	0	1 (20.0)	0	1 (14.3)	1 (14.3)	0	0	9 (23.7)	1 (2.6)
Hyponatremia**	0	0	4 (25.0)	0	1 (50.0)	0	2 (40.0)	0	2 (28.6)	0	0	0	9 (23.7)	0
Epistaxis	0	0	7 (43.8)	0	0	0	1 (20.0)	0	0	0	0	0	8 (21.1)	0
Headache	0	0	1 (6.3)	0	0	0	0	0	3 (42.9)	0	4 (57.1)	0	8 (21.1)	0
Arthralgia	0	0	5 (31.3)	0	0	0	0	0	0	0	2 (28.6)	0	7 (18.4)	0
Constipation	0	0	2 (12.5)	0	1 (50.0)	0	2 (40.0)	0	2 (28.6)	0	0	0	7 (18.4)	0
Gingival bleeding	0	0	4 (25.0)	0	2 (100)	0	1 (20.0)	0	0	0	0	0	7 (18.4)	0
Pruritus	0	0	5 (31.3)	0	1 (50.0)	0	1 (20.0)	0	0	0	0	0	7 (18.4)	0
Rash: maculo-papular	0	0	3 (18.8)	0	2 (100)	0	1 (20.0)	0	0	0	1 (14.3)	0	7 (18.4)	0
Myalgia	0	0	2 (12.5)	0	0	0	1 (20.0)	0	2 (28.6)	0	1 (14.3)	0	6 (15.8)	0

*Includes blood bilirubin increased; **Includes blood sodium decreased;

^Grade 3 hyperbilirubinemia based on data error - corrected to Grade 2 after data cut date;

*N=1 Grade 3 AST increase occurred prior to data cut; current entry is a data entry error

ALT: alanine aminotransferase; AST: aspartate aminotransferase

Figure 14: TRAE summary: All desmoid patients as of February 16, 2026.

TRAE Summary: Number of Participants N (%)	Total (N=38)
Any Serious TRAE*	1 (2.6)
TRAE Grade ≥ 3**	5 (13.2)
TRAE leading to death (Grade 5)	0
TRAE leading to discontinuation of treatment	0

*One patient had a Serious TRAE that was grade 1 fever but was hospitalized for workup, and was found to be positive for cryptococcal antigen, which may be an alternative cause of fever. Fever resolved within two days and the patient remains on treatment. This is patient noted with Grade 3 ALT TRAE in one of our desmoid dose optimization cohorts (DL4 – DL2 (QW), Arm B).

**One patient had a grade 4 TRAE (CPK increase that resolved after seven days). Four patients had grade 3 TRAEs—blood bilirubin increase, platelet decrease, ALT increase (not in the same patient as the grade 3 blood bilirubin increase). All were reversible asymptomatic lab abnormalities without clinical sequelae.

Figures 15 and 16 below show the preliminary clinical safety data for all patients enrolled in our Phase 1/2 trial and who have been treated with zolucetide as a monotherapy, including patients whose indications are MSS CRC.

In summary, across multiple locally advanced or metastatic tumor types, including microsatellite-stable colorectal cancer (MSS CRC), zolucetide was observed to be tolerated during the dose-limiting toxicity (DLT) evaluation period (first 28 days) at dose levels up to DL6 (900 mg). A dose-dependent increase in Grade ≥3 treatment-related adverse events (TRAEs) was observed. No maximum tolerated dose (MTD) has been identified to date.

Grade ≥ 3 TRAEs were generally manageable with supportive care measures and dose interruptions. Patients were able to resume zolucetide treatment at the same or a reduced dose following resolution or improvement of adverse events. Preliminary observations suggest that proactive management of adverse events may reduce the need for dose interruptions.

No deaths attributable to TRAEs were reported.

A higher incidence of Grade ≥ 3 TRAEs was observed among patients with MSS CRC. We believe this finding is consistent with the more advanced disease status and overall clinical condition of this population compared with patients with desmoid tumors or FAP. In addition, a greater proportion of MSS CRC patients were treated at higher dose levels (above DL4), where we anticipated an increased frequency of adverse events based on our observed dose–response relationship.

Figure 15 : TRAEs in monotherapy in all tumor patients dosed in Part 1 in greater than or equal to 15% of patients, observed as of February 16, 2026.

	DL1 36 mg/m ² (N=3)		DL2 72 mg/m ² (N=15)		DL3 144 mg/m ² (N=11)		DL4 240 mg/m ² (N=40)		DL5 360 mg/m ² (N=25)		DL5.5 420 mg/m ² (N=13)		DL6 480 mg/m ² (N=25)		All Participants (N=132)	
	Any Grade n (%)	Grade ≥ 3 n (%)	Any Grade n (%)	Grade ≥ 3 n (%)	Any Grade n (%)	Grade ≥ 3 n (%)	Any Grade n (%)	Grade ≥ 3 n (%)	Any Grade n (%)	Grade ≥ 3 n (%)	Any Grade n (%)	Grade ≥ 3 n (%)	Any Grade n (%)	Grade ≥ 3 n (%)	Any Grade n (%)	Grade ≥ 3 n (%)*
Number of Participants with ≥ 1 TRAE	0	0	11 (73.3)	0	8 (72.7)	0	36 (90.0)	6 (15.0)	20 (80.0)	4 (16.0)	11 (84.6)	3 (23.1)	24 (96.0)	15 (60.0)	110 (83.3)	28 (21.2)
Hyperbilirubinemia / Blood bilirubin increased	0	0	1 (6.7)	0	1 (9.1)	0	14 (35.0)	3 (7.5)	7 (28.0)	2 (8.0)	8 (61.5)	1 (7.7)	19 (76.0)	11 (44.0)	50 (37.9)	17 (12.9)
Fatigue	0	0	1 (6.7)	0	2 (18.2)	0	19 (47.5)	0	7 (28.0)	1 (4.0)	3 (23.1)	0	11 (44.0)	1 (4.0)	43 (32.6)	2 (1.5)
Nausea	0	0	2 (13.3)	0	4 (36.4)	0	18 (45.0)	0	5 (20.0)	1 (4.0)	1 (7.7)	0	9 (36.0)	0	39 (29.5)	1 (0.8)
Aspartate aminotransferase increased	0	0	0	0	0	0	12 (30.0)	0	5 (20.0)	0	3 (23.1)	0	12 (48.0)	1 (4.0)	32 (24.2)	1 (0.8)
Hyponatremia / Blood sodium decreased	0	0	0	0	1 (9.1)	0	11 (27.5)	1 (2.5)	5 (20.0)	0	5 (38.5)	1 (7.7)	10 (40.0)	3 (12.0)	32 (24.2)	5 (3.8)
Alopecia	0	0	2 (13.3)	0	0	0	13 (32.5)	0	3 (12.0)	0	0	0	8 (32.0)	0	26 (19.7)	0
Epistaxis	0	0	0	0	0	0	11 (27.5)	0	4 (16.0)	0	1 (7.7)	0	4 (16.0)	0	20 (15.2)	0
Median Time on Treatment (Weeks) (Range)	8.0 (7-9)		8.0 (1-123)		7.0 (1-64)		14.5 (1-73)		8.0 (1-77)		6.0 (1-15)		8.0 (1-79)		8.0 (1-123)	

DL = Dose level; TRAE = Treatment-related adverse event

* Other $\geq$ Grade 3 AEs include: thrombocytopenia/blood platelet count decreased at DL6 (n=4, 3.0%), lipase increased [n=3 total, 2.3%; DL5.5 (n=1) and DL6 (n=2)], adrenal insufficiency at DL5.5 and DL6 (n=2, 1.5%), gamma-glutamyl transferase increased at DL6 (n=1, 0.8%), pyrexia at DL5 (n=1, 0.8%), blood creatine phosphokinase increased at DL4 (n=1, 0.8%), and alanine aminotransferase increased at DL3 (n=1, 0.8%).

Figure 16: Zolucetide summary of TRAEs in all monotherapy participants, observed as of February 16, 2026.

	DL1 36 mg/m ² (N=3)	DL2 72 mg/m ² (N=15)	DL3 144 mg/m ² (N=11)	DL4 240 mg/m ² (N=40)	DL5 360 mg/m ² (N=25)	DL5.5 420 mg/m ² (N=13)	DL6 480 mg/m ² (N=25)	Total (N=132)
Number of Participants With:								
Any TRAE Grade ≥ 3	0	0	0	6 (15.0)	4 (16.0)	3 (23.1)	15 (60.0)	28 (21.2)
Any Serious TRAE	0	0	0	1 (2.5) ^a	1 (4.0) ^b	1 (7.7) ^c	1 (4.0) ^d	4 (3.0)
Any TRAE Leading to Death	0	0	0	0	0	0	0	0

DL = Dose level; TRAE = Treatment-related adverse event.

^a Grade 1 fever but patient was hospitalized for workup and was found to be positive for cryptococcal antigen, which may be an alternative cause of the fever. The Grade 1 fever resolved within 2 days. Zolucetide was restarted at a lower dose and Q2W schedule and remains on treatment.

^b Grade 3 nausea and Grade 3 fever both initially reported as related to zolucetide leading to drug interruption. Subsequent to the February 16, 2026 data cutoff, the Investigator determined the events to be not related to zolucetide.

^c Grade 3 worsening adrenal insufficiency leading to dose interruption occurring in the setting of a COVID-19 infection (Grade 2 not related). Patient was treated with hydrocortisone and fludrocortisone. The SAE resolved after 11 days. Zolucetide was restarted at DL5 but the patient subsequently ended treatment due to disease progression.

^d Grade 3 adrenal insufficiency leading to drug interruption. Patient was treated with fludrocortisone and corticosteroids and SAE was recovered/resolved within three days. Zolucetide was restarted at DL5 Q2W. Patient remained on treatment for another three cycles being treated beyond progression before ending treatment due to withdrawal of consent. Note patient was taking spironolactone at the time the SAE started.

In desmoid tumors, we currently expect the chronic dose to be close to the DL2 dose, with a possible short-term induction dose close to the DL4 dose. These two doses are boxed in green above in Figure 15.

Of note, zolucetide is a known inhibitor of the OATP1B1 and OATP1B3 transporters which mediate the hepatic uptake of bilirubin. This may sometimes lead to asymptomatic, clinically not significant elevation in blood bilirubin. This impact on bilirubin uptake is a benign laboratory abnormality that is not associated with hepatocellular injury. This phenomenon is similar to that observed in Rotor's syndrome, a benign genetic condition characterized by OATP1B1 and OATP1B3 deficiency, which leads to elevated blood bilirubin levels without affecting overall liver function. Patients with Rotor's syndrome have normal liver function

without any associated morbidity or impact on quality of life. In addition, treatment-related increases in other liver function markers (ALT, AST, and ALP) are less common, transient and almost exclusively low-grade.

The Wnt signaling pathway is also involved in bone homeostasis, and inhibition of the Wnt signaling pathway is known to result in on-target bone toxicity in previous attempts to drug the pathway with PORCN and Frizzled receptor inhibitors. Therefore, patients in the trial also take prophylactic anti-resorptive therapy at three to six month intervals throughout the duration of the trial treatment. In addition, inhibition of β -catenin-TCF4 can result in on-target reduction of aldosterone production in the zona glomerulosa of the adrenal gland. Decreased production of aldosterone can clinically result in fatigue and imbalances in sodium and potassium. We have not seen any high grade TRAEs reported for bone toxicity or hypoaldosteronism. Patients may take an oral medication called fludrocortisone should they experience signs or symptoms of fatigue, hyponatremia or hypoaldosteronism.

Given the chronic and recurrent nature of desmoid tumors and the limitations of available treatments, there remains a significant unmet medical need for effective, safe and well-tolerated therapies. We believe zolucetide has the potential to meaningfully improve treatment across efficacy measures such as time to response and depth and durability of response. Zolucetide also has the potential for a substantially improved safety and tolerability profile over existing therapies, including sparing ovarian toxicity for female patients. We completed an End of Phase 1 meeting with the FDA where we and the FDA agreed on certain key aspects of our upcoming registrational Phase 3 trial design, including the study population (treatment naïve, recurrent, or refractory patients), a placebo-controlled comparator, and the non-clinical package. Our planned Phase 3 trial is designed as a randomized 1:1 study with dual primary endpoints of progression-free survival per RECIST 1.1 and objective response rate, with secondary endpoints including duration of response, change in patient-reported outcomes, and volumetric and T2 cellularity measures. Stratification factors will include prior GSI treatment (yes/no) and tumor location (intra-abdominal vs. other). We intend to hold an End of Phase 2 meeting with the FDA in the fourth quarter of 2026 to align on remaining key trial design aspects, including the elevation of ORR as a dual primary endpoint and the recommended optimization of induction and maintenance dose and schedule. We currently plan on launching zolucetide, if approved, in a self-administered injectable product formulation, and we plan to conduct a bioequivalence study to support the transition from the intravenous formulation used in our clinical trials to this self-administered injectable presentation. We intend to initiate our registrational Phase 3 trial for zolucetide in patients with desmoid tumors in the first half of 2027.

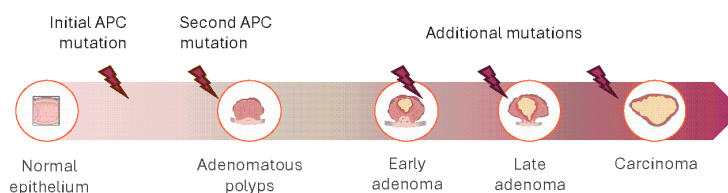
Familial Adenomatous Polyposis (“FAP”)

We are also developing zolucetide for FAP, an orphan disease that impacts an estimated 34,000 people in the United States. FAP is a chronic, lifelong disease characterized by an evolving burden resulting in substantial morbidity and reduced quality of life with limited management options. FAP is typically diagnosed in adolescence and most commonly through family history, as it is inherited in approximately 70% of cases with the remaining approximately 30% arising *de novo*. Polyps can develop as early as age ten when patients begin to develop hundreds to thousands of pre-cancerous polyps in the gastrointestinal tract. In the absence of regular and aggressive polyp removal and life-altering colon-removal surgery (colectomy), patients generally have near-inevitable progression to colorectal cancer.

FAP is driven, in all cases, by germline loss-of-function mutations in the *APC* gene, leading to persistent activation of Wnt/ β -catenin signaling. There is currently no approved drug treatment for FAP. Management relies on prophylactic colectomy at a young age. Importantly, recurrence is common even after surgery, as this aggressive intervention does not prevent continued Wnt-driven duodenal and rectal polyposis, necessitating lifelong surveillance, repeated endoscopic procedures, and often additional debilitating surgical interventions.

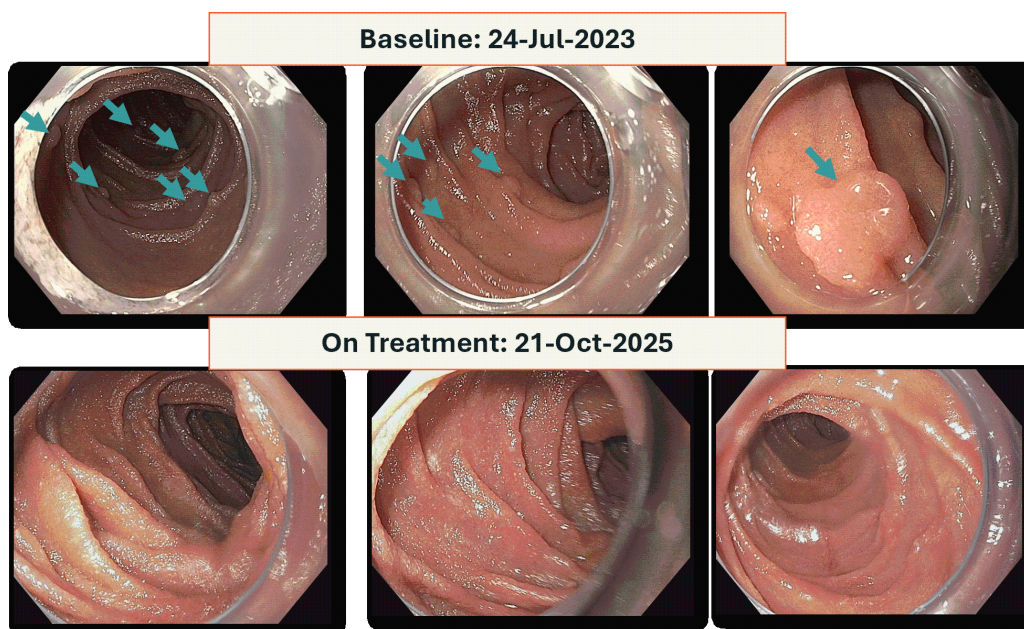
Desmoid tumors and FAP share common β -catenin biology, and approximately 10% of desmoid tumor patients also have FAP. Similar to its potential application in desmoid tumors, we believe that zolucetide has the potential to be used as a chronic therapy in FAP patients.

Figure 17: In FAP, APC mutations in Wnt/ β -catenin pathway drive growth of polyps and progression to colorectal cancer.



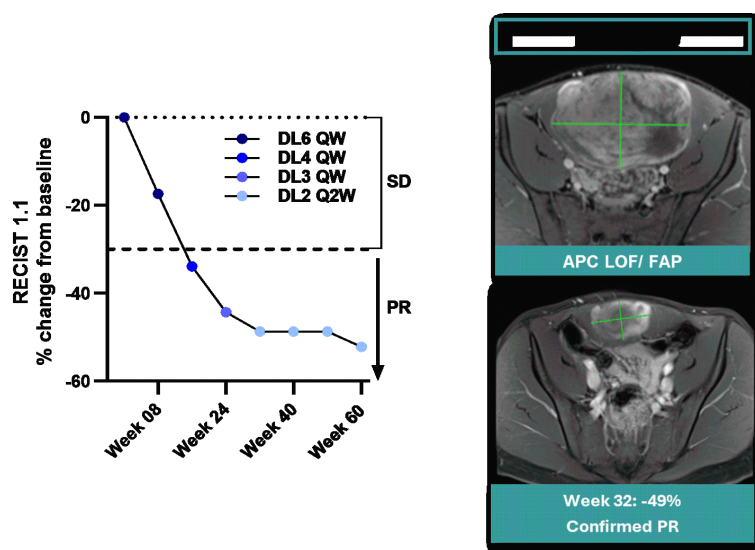
We are currently enrolling desmoid tumor patients who have FAP in our ongoing clinical trial. In the desmoid tumor cohort of our ongoing clinical trial, we have two patients with responses further detailed in this section. With the first patient, we observed significant improvement in duodenal polyposis burden at 60 weeks following initiation of treatment in one patient who had both FAP and an associated desmoid tumor and was treated with zolucetide. Substantial reductions in polyp number and size compared with a pre-treatment evaluation nearly two years prior were also observed, consistent with downstaging from Spigelman Stage 2 to Stage 1.

Figure 18: Endoscopy showed improvement in duodenal polyp burden in the first patient with desmoid tumor and FAP following treatment with zolucetide.



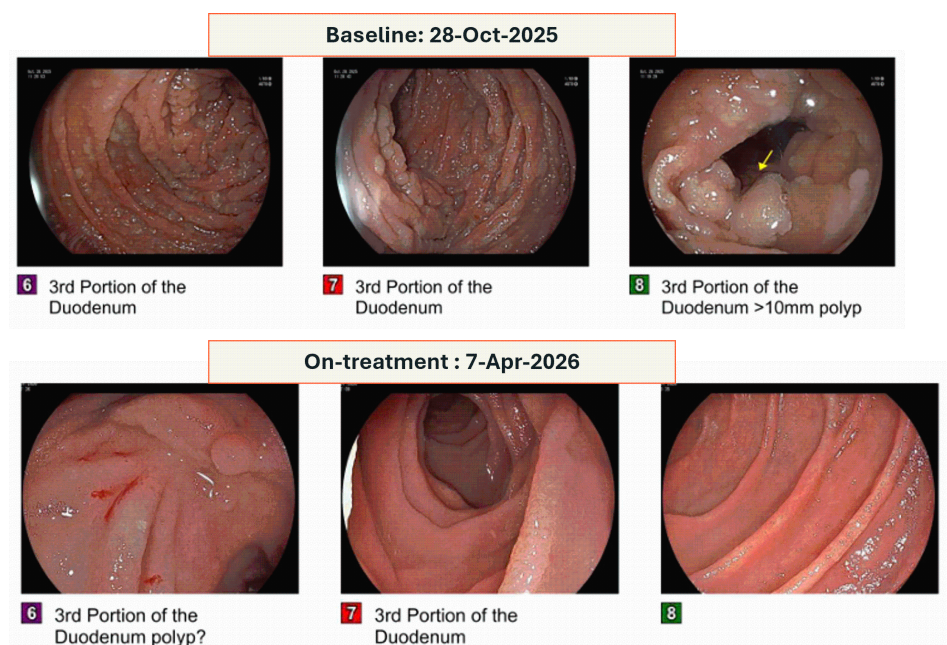
As shown on the right side of Figure 19, the patient was also observed to show tumor reduction of 49% at week 32 and continued to have a partial response (-52.2%) at week 60 in his desmoid tumor. No treatment-related serious adverse events have been reported.

Figure 19: Observed best percentage change from baseline for RECIST1.1 (desmoid) (left) and associated scans in the same patient with desmoid tumor and FAP (right).



In our ongoing Phase 1/2 clinical trial, a second desmoid tumor patient with a history of FAP received a preventive colectomy associated with a multifocal desmoid tumor. The patient, who harbors an APC mutation, was enrolled and began dosing at DL4 (450 mg) weekly on January 22, 2026, consistent with the induction dosing regimen in Part 1D of the trial. The patient subsequently transitioned to DL4 (450 mg) every two weeks maintenance dosing per protocol and remains on treatment as of the date of this prospectus. As part of routine clinical monitoring, this patient underwent endoscopy at approximately 10 weeks of treatment with zolucetide, where we observed a significant reduction in duodenal polyp burden, with improvement from Spigelman Stage 4 to findings consistent with an almost normal duodenum.

Figure 20: Endoscopy showed improvement in duodenal polyp burden in second patient with desmoid tumor and FAP following treatment with zolucetide.



Both FAP patients described above remain on trial as of the date of this prospectus. As of May 18, 2026, we have enrolled 12 desmoid tumor patients with FAP (inclusive of the two patients described above) in our ongoing Phase 1/2 trial and we expect potential further endoscopies over the course of this year and into next year, but do not have a pre-planned schedule for these endoscopies per the Phase 1/2 trial. We are also planning to enroll a separate dedicated cohort of patients with FAP, including pre-planned endoscopies, beginning in the second half of 2026.

Given the near-certain cancer risk without surgery, the morbidity of colectomy, the lifelong disease and monitoring burden, and the absence of approved disease-modifying treatments, we believe there remains a significant unmet medical need for targeted therapies for patients with FAP that zolucetide could address. These patients typically require chronic lifetime care, as their underlying genetic condition is not curable.

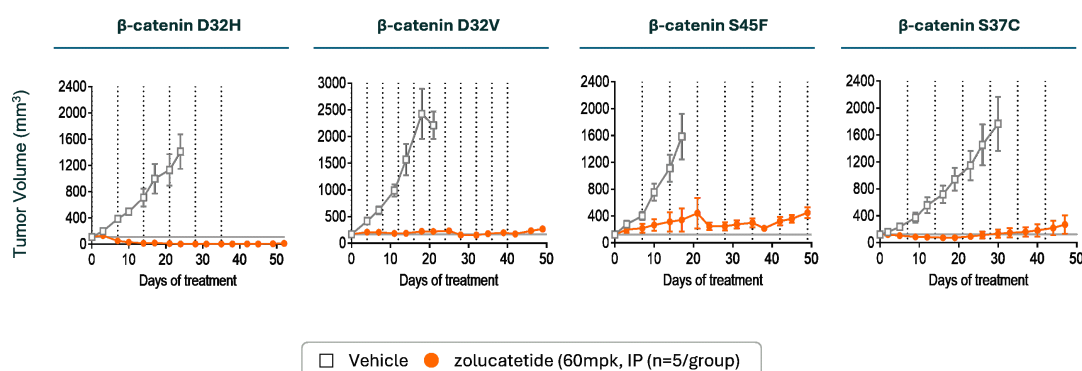
Hepatocellular Carcinoma (“HCC”)

A third indication for zolucetide is HCC, accounting for approximately 80-90% of liver cancer cases globally, with an estimated 38,000 new cases of HCC annually in the United States and 700,000-800,000 cases worldwide, with the highest burden in Asia, particularly China, which accounts for nearly half of global cases. Approximately 30% of HCC tumors have β -catenin mutations, defining a biologically distinct and substantial patient subset. There is an existing treatment paradigm of immune checkpoint inhibitor-based combinations and VEGF-targeted therapies, however most patients nonetheless ultimately experience disease progression. Notably, Wnt/ β -catenin-altered tumors may be particularly refractory to checkpoint inhibitors, reinforcing the potential unmet need in this patient population that lacks approved therapies directly targeting β -catenin-dependent signaling. Consistent with underlying biology, in our preclinical studies, β -catenin–mutant HCC PDX models showed marked sensitivity to zolucetide.

As detailed in Figure 21, we have observed what we believe to be promising preclinical antitumor activity with zolucetide across multiple oncogenic β -catenin point mutations occurring in patient-derived tumor xenografts. In preclinical studies evaluating tumor growth inhibition *in vivo*, zolucetide showed robust and durable suppression of tumor volume compared to vehicle-treated controls across all four β -catenin mutant models evaluated.

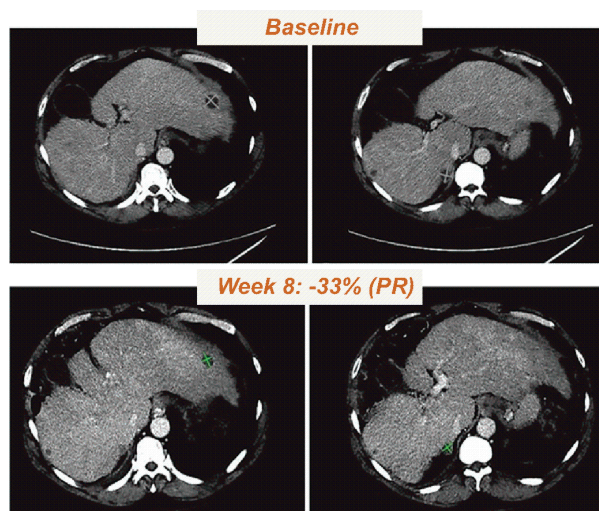
In each model, zolucetide-treated animals maintained near-baseline tumor volumes or experienced tumor regression throughout the study duration relative to vehicle-treated animals. The treatment effect observed was consistent across the distinct cohort of mutations in β -catenin — representing hotspot residues that are recurrently altered in a range of solid tumor types, including HCC, desmoid tumors and endometrial cancer.

Figure 21: Zolucetide sensitivity in β -catenin–mutant HCC PDX models



In dose escalation of our ongoing clinical trial, we observed a confirmed partial response in a heavily pre-treated patient with CTNNB1-mutant HCC who was administered zolucetide. This patient has been on treatment since July 2025 and remains on treatment as of February 16, 2026. Based on this observation, we have started enrolling an HCC specific cohort in our ongoing trial to further evaluate and better characterize the opportunity in this compelling indication.

Figure 22: Scans in one patient with HCC

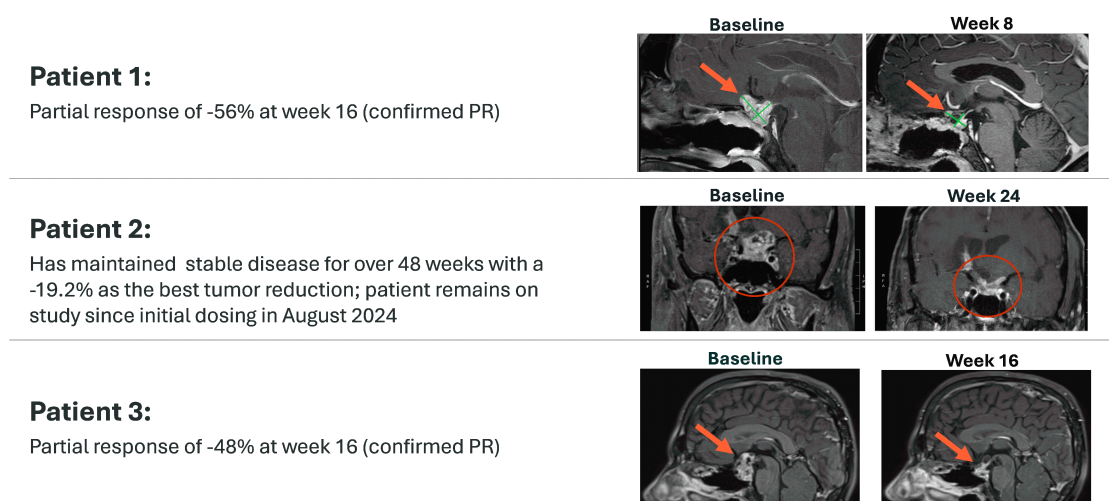


Additional Rare Indications

Beyond desmoid tumors, FAP, and HCC, we have observed partial responses in four additional indications featuring Wnt/ β -catenin pathway involvement:

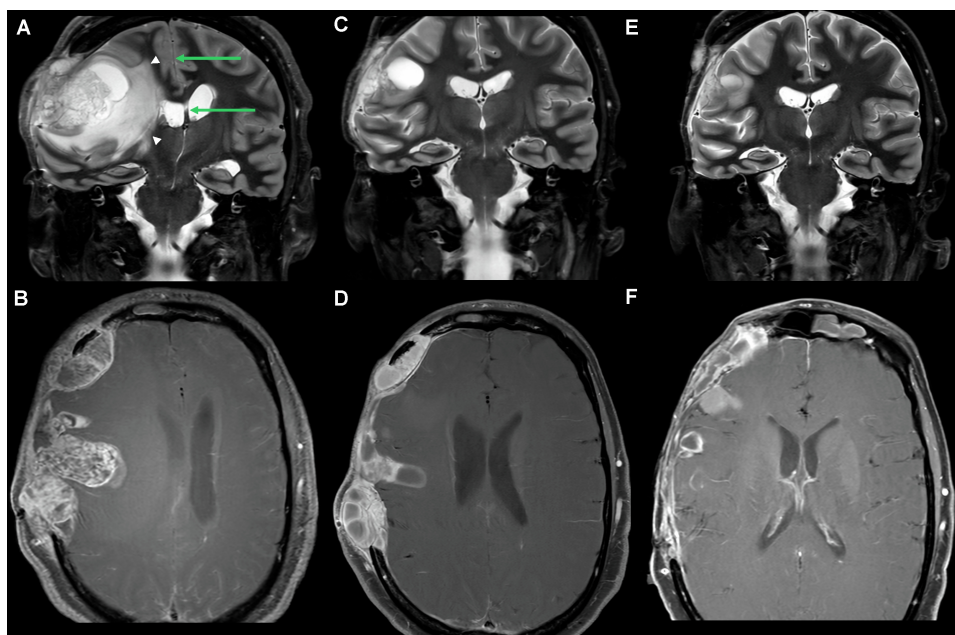
- **Adamantinomatous craniopharyngioma (“ACP”)** is a rare and chronic condition characterized by locally aggressive tumor arising near the pituitary gland, with onset typically in childhood or middle adulthood. We estimate the 15-year prevalence of ACP in the United States to be approximately 5,000-9,000 patients. Due to the tumor’s location at the base of the brain, beneath the hypothalamus, patients often experience hypothalamic dysfunction leading to severe obesity, as well as hypopituitarism requiring lifelong hormone replacement. Visual impairment is also common and clinically significant, resulting from tumor compression or invasion of the optic nerves and optic chiasm. Cognitive deficits affecting memory, attention, and executive function also contribute to significant long-term disease burden, particularly in pediatric patients. There is currently no approved drug therapy for ACP. Surgery and radiotherapy remain the primary treatment options; however, tumors are often difficult to fully resect given the location, and radiotherapies are frequently associated with limited durability and disease recurrence. We believe that patients with ACP could benefit from long-term systemic treatment. We have seen tumor shrinkage in all three of the observable ACP patients treated with zolucetide, including two confirmed partial responses.

Figure 23: Tumor reductions observed in three patients with ACP.



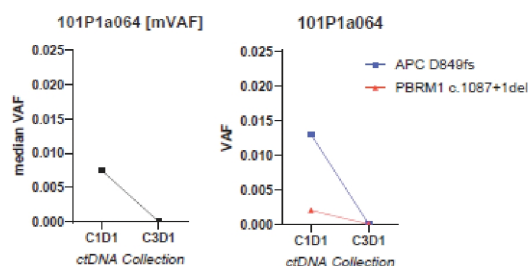
- **Solid pseudopapillary neoplasm (“SPN”)** of the pancreas is a rare, low-grade malignant tumor that predominantly affects young women. It represents a small fraction of pancreatic neoplasms, generally reported as <3% of exocrine pancreatic tumors. This patient achieved a confirmed partial response of -77% at week 16.
- **Salivary gland tumors** are rare neoplasms arising from the major or minor salivary glands and encompass a diverse group of histologies with numerous subtypes. They account for approximately 3-6% of head and neck cancers overall. This patient achieved a confirmed partial response of -48.3% at week 16.
- **Ameloblastoma** is a rare and locally aggressive jaw tumor and one of the most common benign neoplasms of the mandible. Calculated 15-year prevalence is approximately 5,000 patients in the United States, with higher reported rates in parts of Africa and Asia. In our ongoing Phase 1/2 trial, we treated a heavily pre-treated patient with recurrent right mandible ameloblastoma harboring a pathogenic APC frameshift mutation, low tumor mutation burden, strong nuclear β-catenin staining, and absence of BRAF alterations, for whom further surgery was no longer feasible. Following treatment with zolucetide, an investigator reported a softening of tumor masses after one cycle and at week 8, the investigator noted cerebral edema had resolved, with marked improvement in mass effect as well as reduced pain. At week 8, the patient achieved a -26.4% tumor reduction with clearance of ctDNA. The patient subsequently achieved a confirmed partial response of -33.9% at week 16, with ongoing partial response confirmed at 40 weeks and more than nine months of treatment without evidence of disease progression. The patient experienced only Grade 1 or 2 increases in aminotransferase and bilirubin levels, and had a complete resolution of the solid tumor component at week 40. This case was recently published in *The New England Journal of Medicine*.

Figure 24: Scans in one patient with ameloblastoma.



Shown is magnetic resonance imaging of recurrent right mandible ameloblastoma in the 29-year old study patient before treatment with zolucetide (Panels A and B) and throughout the course of treatment (Panels C through F). In Panel A (coronal view), the white arrows indicate cerebral edema, and the green arrows indicate midline shift; Panel B shows the axial view. Increasing resolution of the tumor mass, vasogenic edema, and midline shift are visible at 8 weeks (Panels C and D) and at 32 weeks (Panels E and F).

Figure 25: ctDNA collection in one patient with ameloblastoma.



VAF = variant allele frequency represents the ratio of mutant gene copy versus wild type

Summary of Zolucetide Data in Genomically Simple Tumors

As described further below, we are evaluating a range of solid tumors in our ongoing clinical trial, including those that are genomically simple and genomically complex. Genomically simple in this case refers to tumors that carry relatively few, if any, well-validated and otherwise prevalent oncogenic drives, like KRAS, PIK3CA or PTEN, but do, by definition, carry CTNNB1 or APC gene mutations. Conversely, genomically complex tumors, like those often observed in colorectal cancer, carry multiple such oncogenic drivers including but not limited to CTNNB1 or APC.

As of February 16, 2026, we evaluated patients with tumors of low genomic complexity at dose levels of DL2 or greater (n=54). Of those who are efficacy evaluable (n=39), we have observed 20 objective responses, including one complete response, across six different tumor types which qualitatively fit the description of genomically simple tumors, including desmoid tumors, ACP and ameloblastoma. We observed a 51% objective response rate and 87% DCR. We also have observed meaningful duration of response (>6 months) across multiple tumor types.

We intend to identify an appropriate regulatory pathway for the numerous tumors that prove to be responsive to zolucetide. We plan to explore accelerated approvals, randomized trials and basket (tumor-agnostic) trials with FDA and global regulators.

Figure 26: Observed best percentage change from baseline and overall response for patients with genomically simple tumors receiving zolucateride, as of February 16, 2026.

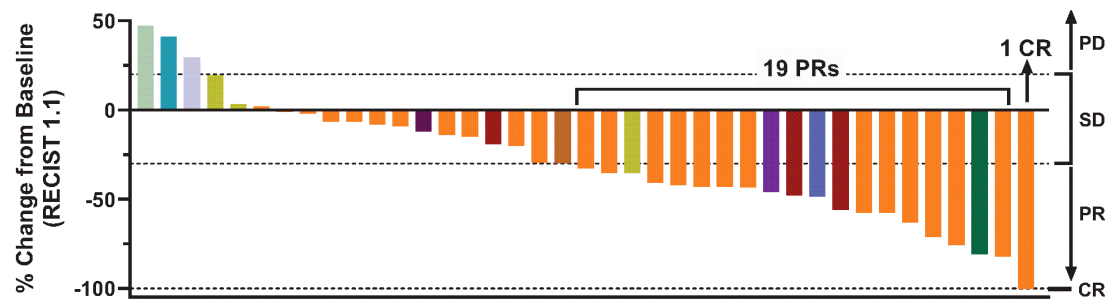
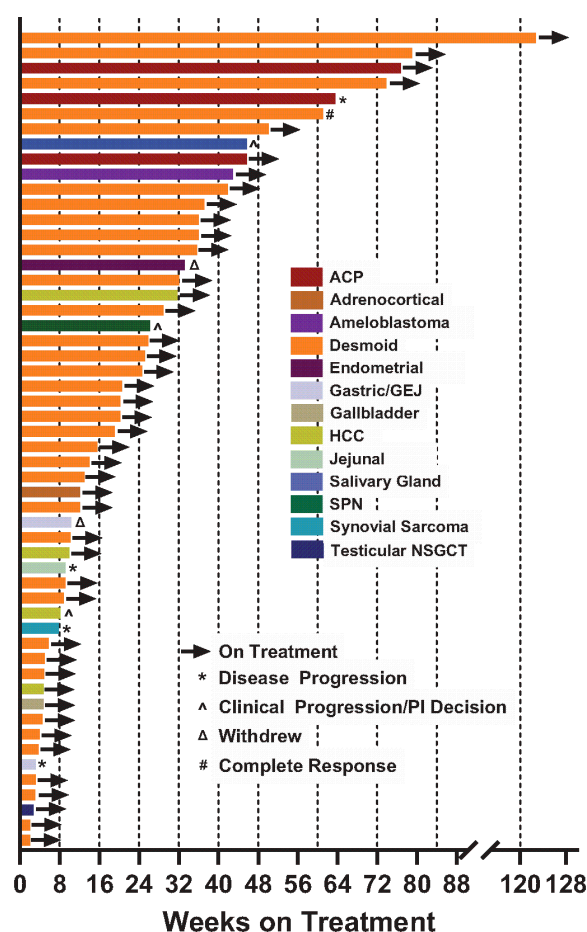


Figure 27: Observed time on study treatment per patient in the Phase 1/2 trial of zolucetide as of February 16, 2026.



Patient achieved a complete response and voluntarily discontinued treatment due to relocation away from study center.
GEJ: gastroesophageal junction; NSGCT: nonseminomatous germ cell tumors

Genomically Complex Tumors

While primarily focused on genomically simple tumors, we are also evaluating the potential of zolucetide to treat genomically complex tumors. We consider genomically complex tumors to be those in which Wnt/ β -catenin pathway alterations are present but are not the sole driver of disease, with additional oncogenic mutations implicated in driving tumor biology. This complexity often necessitates a combination treatment approach.

Colorectal Cancer

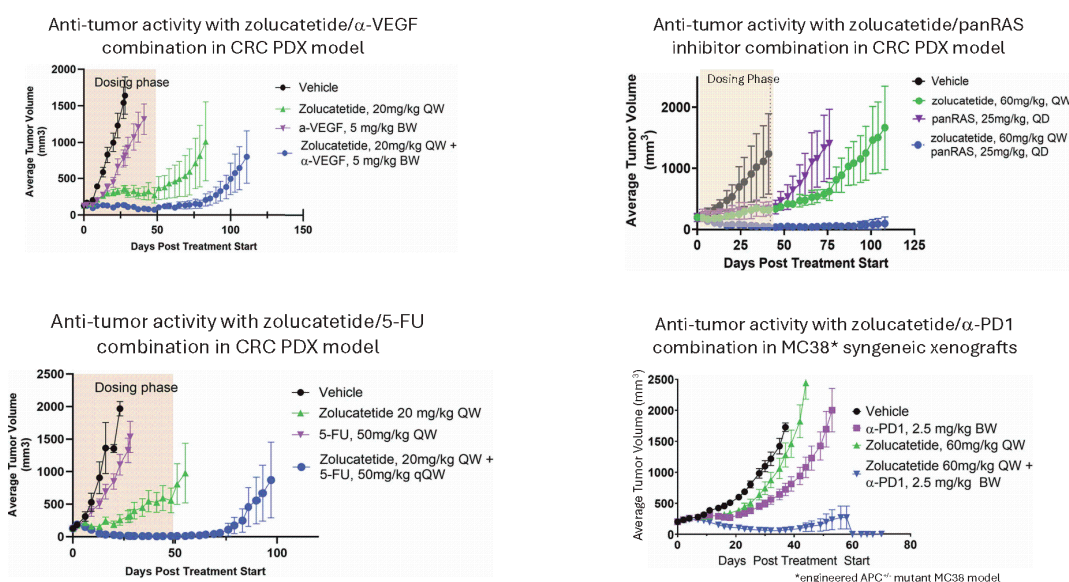
CRC is the third most commonly diagnosed cancer and the second leading cause of cancer-related death globally, with approximately two million new cases and nearly one million deaths each year. Despite advances in treatment, outcomes remain poor for patients with advanced disease, with five-year survival rates of approximately 16% in the metastatic setting, highlighting the need for more effective and broadly applicable therapeutic approaches.

For more than 30 years it has been appreciated that loss-of-function mutation in the APC gene is the key initiating mutational event in the evolution of CRC. Seminal studies elucidating the biology of these tumors have shown that the downstream consequence of APC mutation is the aberrant activation of β -catenin in complex with TCF proteins, which in turn drives proliferation and a stem cell-like phenotype in the tumor. β -catenin is aberrantly amplified in the context of tumor cells that have acquired APC mutations. These mutations in APC occur in more than 80% of microsatellite stable CRC patients, representing by far, the most prevalent mutations observed in this tumor type. In our preclinical studies we observed that treatment of human tumors in mouse models led to the inhibition of CRC tumor growth (see Figure 28). These data give us confidence in the potential utility of zolucetide for the treatment of CRC patients.

Although we have seen disease stabilization, tumor shrinkage and ctDNA reductions in a subset of CRC patients treated with zolucetide as monotherapy, we have not observed any objective responses. As such, we do not currently plan to advance zolucetide as a monotherapy for CRC patients. Since CRC is a genetically complex tumor type, with many additional oncogenic (KRAS, PI3K, BRAF) and tumor suppressor (p53) mutations that can co-occur alongside APC mutation, we believe it is likely that these tumors have adapted multiple mechanisms of growth and survival that are best addressed with combination drug approaches. Importantly, CRC patient tumor biopsy samples collected at baseline and after zolucetide treatment were used to interrogate transcriptional signatures that were modulated by drug treatment. These studies led to the hypotheses that via β -catenin inhibition, zolucetide coupled with - VEGF, chemotherapeutic agents like 5-FU/FOLFOX and immune checkpoint inhibitors like nivolumab could be beneficial.

Current treatment paradigms for CRC include combinations of chemotherapy, targeted agents, and immunotherapy. While biomarker-directed therapies have improved outcomes for select molecular subsets (e.g., BRAF V600E, HER2+, KRAS G12C), the majority of patients lack access to precision therapies that meaningfully alter disease trajectory. Early translational analyses from our ongoing Phase 1/2 trial, along with patient-derived xenograft studies (as outlined in Figure 28 below), further reinforce potential for multiple combinations such as anti-VEGF + 5-FU, chemotherapy + anti-VEGF, and anti-PD-1, which we are currently evaluating in combination with zolucetide in the dose escalation phase of our ongoing clinical trial. We may explore additional combinations in future development, including with inhibitors targeting the RAS/MAPK pathway, as multiple academic and industrial research teams have recently published data illustrating biological cross-talk between the RAS and Wnt signaling pathways. We believe data suggest that when one of the two pathways is inhibited the other appears to be upregulated to compensate for the loss of signaling in the first. This compensatory cross-talk appears to be bi-directional. Since APC and KRAS mutations represent two of the most prevalent driver mutations in CRC, we believe the concept of combination therapy to inhibit these two pathways simultaneously is compelling. Our own combination data using CRC PDX tumor models indicates that combination of zolucetide with a panRAS inhibitor can drive deeper and more durable anti-tumor activity in a preclinical setting, as shown in the figure below.

Figure 28: Data showing significant anti-tumor activity of zolucetide in combination with various agents.



Our Preclinical Data

Zolucetide has generated evidence of direct β -catenin inhibition with compelling on-target anti-tumor activity in multiple preclinical models. Biochemically, zolucetide was observed to bind directly to β -catenin with a dissociation constant of 500 picomolar by surface plasmon resonance and inhibit β -catenin:TCF interaction with a half-maximal inhibitory concentration (IC₅₀) below 5 nM as measured with competition fluorescence polarization assays. In cell-based assays, zolucetide was observed to effectively inhibit β -catenin:TCF interaction with an IC₅₀ of 1.2 μ M and zolucetide blocked β -catenin:TCF transcriptional activity with an IC₅₀ of 0.7 μ M in a cell-based TCF reporter assay. Zolucetide was observed to inhibit endogenous Wnt/ β -catenin target gene expression (such as AXIN2, SP5, and NOTUM) with IC₅₀ values ranging from 0.5 to 7 μ M in multiple cancer cell lines carrying APC and CTNNB1 mutations. This inhibition of transcriptional activity was shown to be β -catenin dependent in an isogenic cell line pair that shows a lack of zolucetide activity in the absence of β -catenin protein.

In proliferation assays, zolucetide displayed IC₅₀ values between 0.2 and 2 μ M in a set of sensitive cancer cell lines derived from colorectal, gastric, ovarian, and non-small cell lung tumors carrying mutations in APC or β -catenin.

In vivo, we have observed zolucetide to exhibit a pharmacokinetic profile that drives strong Wnt/ β -catenin pathway inhibition and antitumor activity in both colorectal and hepatocellular PDX tumor models driven by documented Wnt-pathway-activating mutations in APC or β -catenin. A single dose of zolucetide at 20 mg/kg significantly downregulated the Wnt/ β -catenin pathway in PDX tumor models carrying pathway mutations, as measured with RNAseq analyses. Zolucetide was observed to exhibit dose dependent inhibition of the expression of β -catenin:TCF target genes such as AXIN2 and C-MYC at both messenger RNA and protein levels in PDX tumors. AXIN2 and C-MYC are both relevant pharmacodynamic (PD) biomarkers since inhibition of these biomarkers is on target, dose dependent, correlated with efficacy and, in the case of C-MYC, likely to be relevant for the antitumor activity of zolucetide downstream of β -catenin inhibition. Significant inhibition of AXIN2 and C-MYC was observed in tumors starting at 20 mg/kg and maximal inhibition is achieved at 60 mg/kg. Repeat dosing at 20 to 60 mg/kg of zolucetide was observed to lead to tumor regression or stasis in multiple colorectal PDX models and regression or stasis in four hepatocellular PDX models harboring APC and β -catenin mutations, respectively.

Based on the aggregate of preclinical *in vivo* pharmacology data, we defined the 20 mg/kg dose level as having strong activity, resulting in strong tumor growth inhibition (“TGI”) or regressions in some models and defined 60 mg/kg as having maximal activity, resulting in complete, durable regressions in several models. As a result, the target exposure for efficacy in humans is based on the equivalent exposure in mice over a dose range of 20 to 60 mg/kg. We believe the evidence that zolucetide tumor exposure levels remain higher than that observed in plasma over time, and resulted in prolonged PD effects in tumors, supports dosing with less frequency than predicted from plasma exposure, in this case using a once every 7 days schedule.

We are currently enrolling three CRC combination cohorts: (1) zolucetide + FOLFOX/bevacizumab in 1L, (2) 3L combination of zolucetide + nivolumab, and (3) zolucetide + Lonsurf/bevacizumab. These combination cohorts are currently in dose escalation with potential for additional biologically rational CRC combinations including RAS in the future.

Prostate Franchise

Our Helicon platform enables the discovery of multiple product candidates against traditionally undruggable protein targets, supporting a repeatable approach across indications, including prostate cancer. In addition to inhibition, we have leveraged Helicons for targeted protein degradation, highlighting the multimodal potential of the platform. We are advancing two prostate cancer programs that exemplify these capabilities: an ERG degrader and an allosteric AR^{ON} degrader.

Prostate cancer is the fourth most commonly diagnosed cancer (second among men) and the eighth leading cause of cancer deaths (fifth among men) worldwide. Approximately 1.5 million new cases are diagnosed globally each year, and prostate cancer accounts for almost 400,000 deaths annually. The overall five-year survival rate for metastatic prostate cancer is approximately 38%, highlighting the significant clinical burden of advanced disease.

Advanced prostate cancer evolves along a well-characterized continuum beginning with metastatic hormone-sensitive prostate cancer (mHSPC), where tumors remain driven by androgen receptor signaling and are initially responsive to androgen deprivation therapy in combination with androgen receptor pathway inhibitors. Despite meaningful improvements in outcomes in this setting, most patients ultimately progress to mCRPC, a more aggressive and heterogeneous stage defined by continued disease progression despite castrate levels of testosterone. It is estimated that approximately 40,000 men in the United States are living with mCRPC. These patients continue to receive a backbone of AR-directed therapy.

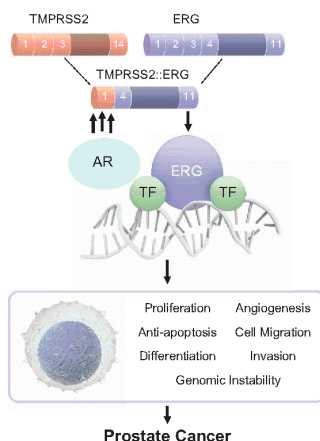
While multiple therapies are approved across mHSPC and mCRPC, including next-generation hormonal agents, taxane chemotherapies, radioligand therapies, and targeted agents, these treatments are not designed to fully address the underlying drivers of disease progression and therapeutic resistance, particularly in the mCRPC setting. There remains a clear unmet medical need for novel approaches that can more fundamentally alter disease biology.

Our ERG and AR^{ON} programs represent two distinct opportunities to address a large unmet need in the prostate cancer population. The ERG degrader is designed to target a previously undrugged oncogenic driver found in almost half of all prostate tumors, analogous to the paradigm addressed by our β -catenin program and zolucetide, which represents another previously undrugged and critical oncogene. In contrast, our AR^{ON} degrader program is designed to address a clinically validated target in prostate cancer that has been inadequately drugged multiple times with existing approaches, as previously approved drugs in the AR space have all shown transient activity and subsequent resistance driven by continued elevated AR activity. We believe both our ERG and AR^{ON} programs offer monotherapy and combination therapy opportunities in the clinic.

ERG Degradar

ERG is a transcription factor overexpressed in approximately 40-50% of prostate cancers via a TMPRSS2-ERG fusion, linking androgen signaling directly to oncogenic transcription factor activation. This ERG gene fusion event leads to aberrant expression of the ERG protein in prostate-derived cells where it is not normally expressed. As a result of this aberrant expression, ERG drives a transcriptional program that regulates multiple critical tumor functions, including proliferation and angiogenesis (see Figure 29). There are more than 15,000 newly diagnosed ERG-positive mCRPC patients annually in the United States based on reported prevalence estimates to date, and there are currently no approved therapies that directly target ERG. The prevalence of ERG fusions in prostate cancer, coupled with prior publications describing ERG's function in modulating the biology of prostate cancer cells, provides compelling reason to drug this target; however, to our knowledge, it has never been successfully drugged due to the absence of conventional small molecule binding sites.

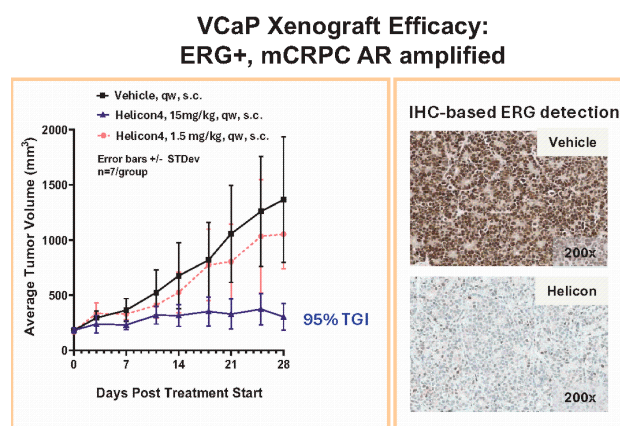
Figure 29: ERG degrader blocks TMPRSS2-ERG-driven transcription.



Using our Helicon discovery platform to identify novel peptide binding sites on ERG, we have identified bifunctional degraders that have been observed to achieve potent and selective ERG degradation in cells and in preclinical prostate tumor models. These Helicon degraders have enabled us to test for the first time the pharmacological consequence of ERG degradation and subsequent inhibition of activity in a number of preclinical *in vivo* models. We have observed that ERG degradation led to inhibition of a distinct transcriptional profile driven by ERG and resulted in robust dose-dependent prostate TGI of 60-95% in both cell line-derived xenografts (see Figure 30) and PDX models (see Figure 31) in preclinical studies. We also observed inhibition of tumor growth in the PDX context that exceeds that seen with enzalutamide, and we have combined these two agents (ERG Helicon degrader and enzalutamide) with positive anti-tumor activity of the combination. This single agent anti-tumor activity of ERG degrader exceeds that of single agent enzalutamide in our study. Furthermore, a recent report on the activity of an AR degrader in an independent study indicates that ERG degrader activity is at least equivalent to that of the AR degrader in the VCaP xenograft model run in eugonadal mice. Importantly, we have also shown the specificity of our ERG degraders using unbiased proteomics analyses from cells treated with ERG degraders. We have observed that our degraders are specific for ERG versus all detected and unrelated proteins in the cell and with predictable, tunable selectivity against closely related paralogues, like the FLI1 transcription factor which is in the same family of ETS transcription factors as ERG. In the exemplar seen in Figure 33 below, ERG protein is the only protein degraded >4-fold relative to control with a p-value of < 0.05 after treatment with a degrader concentration at 10x the cell-based DC₉₀ for ERG degradation.

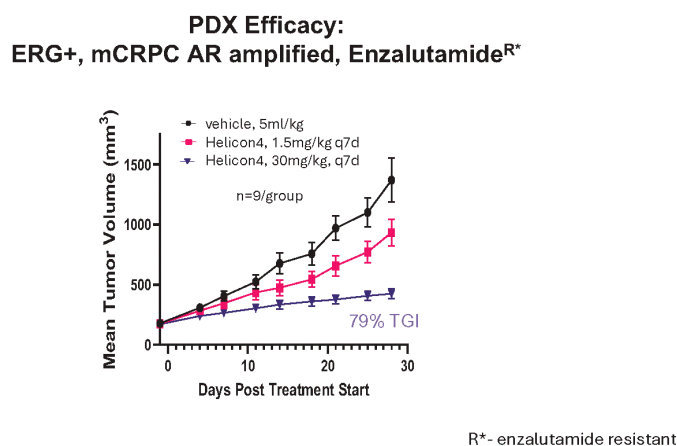
The following figure illustrates the dose dependent anti-tumor activity of ERG Helicon degrader in a cell-line derived xenograft model with ERG-fusion, and the ability of that degrader to clear ERG protein from the tumor using immunohistochemistry ("IHC").

Figure 30: Preclinical antitumor activity and target engagement of ERG degrader in a VCaP xenograft model.



The following figure illustrates the dose dependent anti-tumor activity of ERG Helicon degrader in a patient-derived xenograft model with ERG-fusion.

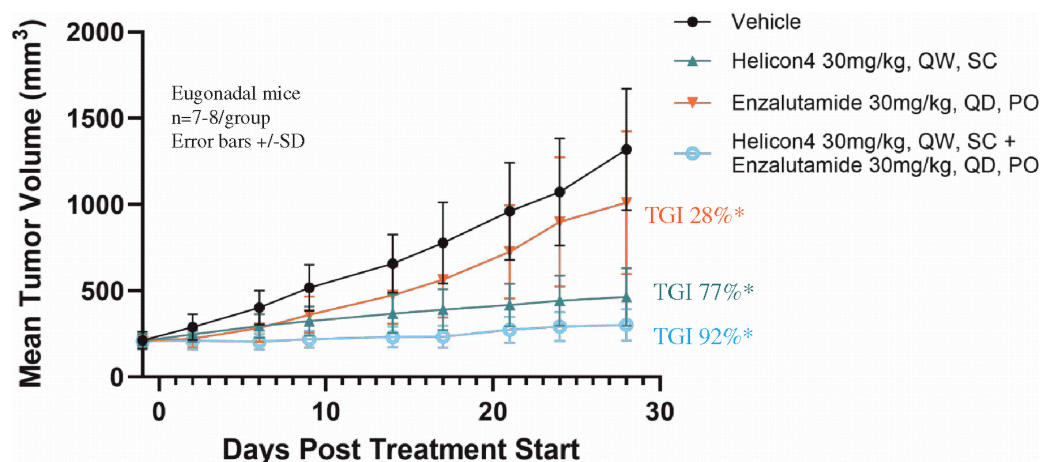
Figure 31: Preclinical antitumor activity of ERG degrader in an ERG-positive, enzalutamide-resistant PDX model.



The following figure illustrates the anti-tumor activity of ERG Helicon degrader as a single agent (green curve) in a patient-derived xenograft model with ERG-fusion, compared to the activity of enzalutamide as a single agent (orange curve), and the ability of the ERG degrader and enzalutamide to be combined (blue curve) for effective anti-tumor activity.

Figure 32: Anti-tumor activity of ERG degrader in PDX as single agent and in combination with enzalutamide

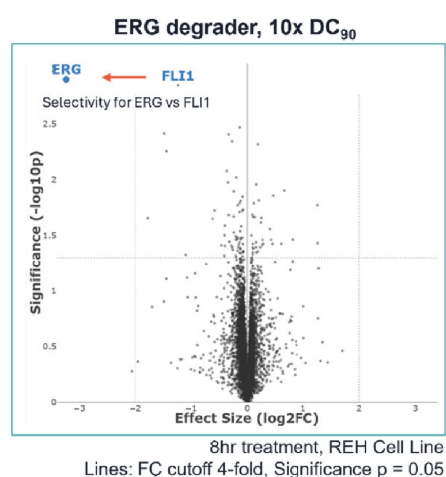
PDX Model: ERG-fusion⁺, AR amplified, AR mutant H875Y)



*Adjusted p-values relative to vehicle: 0.029, 0.012, 0.002

The following figure illustrates the unbiased proteomics profile of all detectable proteins in a cell line (REH) after treatment with ERG Helicon degrader for eight hours at high dose, indicating that the Helicon degrader specifically degrades ERG protein (upper left quadrant) versus all other proteins in the cell.

Figure 33: Proteomic evaluation of protein-level changes following treatment with ERG degrader.



AR^{ON} Degradation

While AR directed therapies are the backbone of and provide significant anti-tumor activity in prostate cancer treatment paradigms, the majority of patients ultimately develop resistance. Resistance to AR-directed therapies in approximately 80% of patients is associated with amplification of the AR gene and point mutations at the drug binding site of AR. All approved AR antagonists and clinical-stage AR degraders that we are aware of target the same ligand binding pocket, making them non-combinable and vulnerable to the same resistance mechanisms. We have identified four main limitations of current AR antagonists and AR degraders, including:

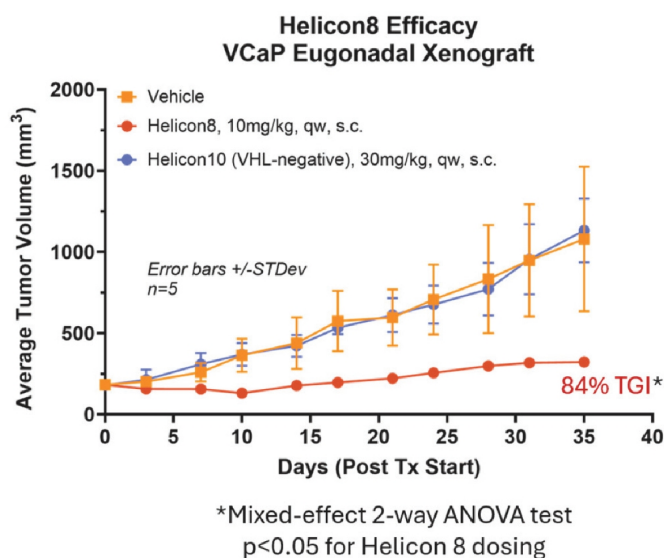
1. **Amplifications in AR.** Existing therapies do not consistently achieve broad efficacy in patients with AR^{AMP}. As such, clinical outcomes are variable, reflecting substantial heterogeneity in patient responses.

2. **Mutations in AR LBD.** All approved AR antagonists and clinical-stage AR degraders currently target the same ligand binding domain within the androgen binding pocket. This pocket is frequently mutated, and such mutations can significantly impair drug binding, reducing the ability of these agents to function optimally.
3. **AR Splice Variants.** The prevalence and expression of AR splice variants increase as disease progresses. AR-V7 is the most prominent variant and results in a truncated receptor that lacks the ligand binding domain, rendering LBD-targeted therapies ineffective.
4. **Combinability.** Because current AR antagonists and degraders bind to the same androgen binding pocket, they cannot be co-administered in combination regimens, limiting therapeutic flexibility and potential synergistic effects.

To overcome these challenges, we have identified a novel Helicon binding site, the AF2 co-activator binding site on AR, accessible only when AR is in its active state (*i.e.* when the receptor is bound to androgen). This site is distinct from and not competitive with the binding site of all approved AR antagonists including enzalutamide. Critically, we believe targeting the AR^{ON} conformation has the potential to (i) enable combination with approved AR-directed therapies for additive effects, (ii) lead to activity in tumors with AR resistance point mutations that compromise existing drug activity at the ligand binding pocket and (iii) provide preferential target engagement of the active AR pool in AR-amplified settings for maximal anti-tumor effects. Data supporting the combination potential of AR^{ON} Helicons with existing AR^{OFF} antagonists that engage the androgen binding pocket in an AR-amplified cell line (“VCaP”) is seen in Figure 36. In this experiment each single agent provided significant anti-proliferative activity and the combination of the two provided an additive benefit. We envision that this combination benefit in the clinical context will provide the ability to more completely inhibit AR activity in patient tumors, including AR amplified tumors, and ultimately lead to deeper and more durable suppression of tumor growth.

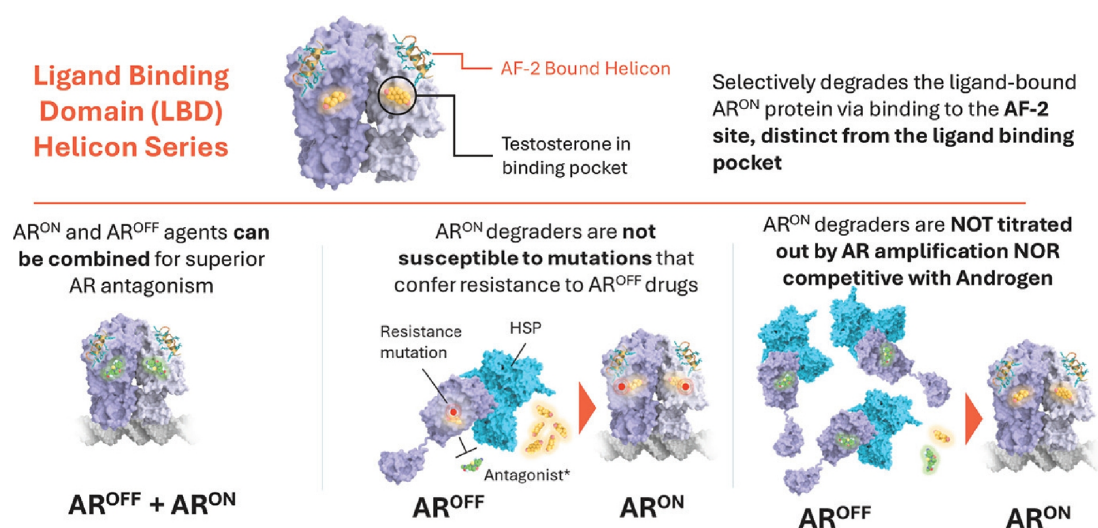
The figure below illustrates the anti-tumor activity of AR^{ON} Helicon degrader (Helicon8) in the VCaP cell-line derived xenograft model which is AR amplified, and for comparison, shows that a negative control helicon (Helicon10) that can bind to AR but lacks the ability to recruit E3 ligase, does not have activity.

Figure 34: Preclinical in vivo efficacy data using our AR^{ON} degrader.



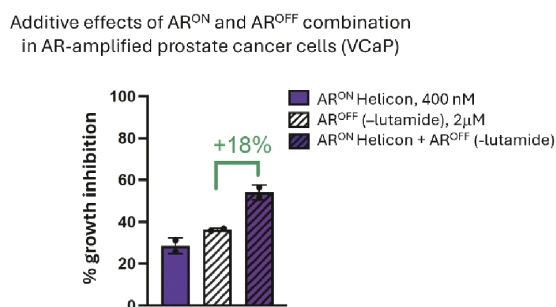
The following figure highlights three key features of our AR^{ON} Helicon degraders that are designed to improve on existing therapies: combinability, activity in tumors with resistance point mutations in AR, and activity in tumors with amplified AR.

Figure 35: Ligand binding domain Helicon series.



The following figure illustrates the improved anti-proliferative activity achieved by combining AR^{ON} Helicon degrader with enzalutamide versus either single agent treatment alone. We plan to conduct additional experiments to confirm the combination strategy described in VCaP cells using *in vivo* xenograft models.

Figure 36: Combination additivity in VCaP AR amplified prostate cancer cells.

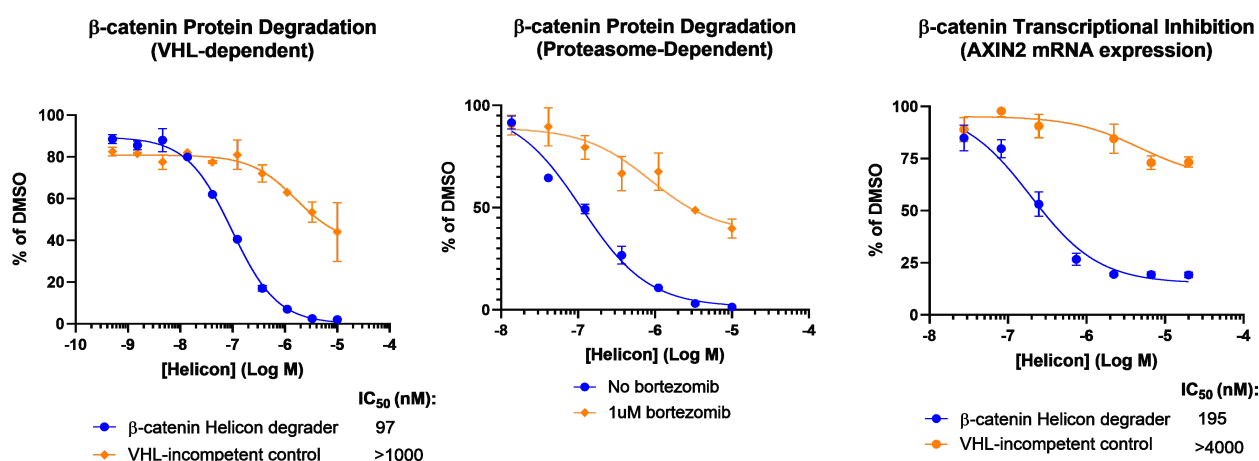


In addition, heterobifunctional Helicon degraders binding to the AR^{ON} conformation achieve potent and selective *in vivo* degradation of active AR, with anti-tumor activity equivalent to or exceeding approved AR antagonists in AR-amplified xenograft models. As shown below, we have observed robust tumor growth inhibition in preclinical models using our AR^{ON} degrader, and are in late lead-optimization progressing toward IND-enabling studies. In the representative *in vivo* experiment illustrated above in Figure 34, we observed 84% tumor growth inhibition of the AR amplified VCaP cell-line derived xenograft model when dosing Helicon8 at 10mg/kg on once weekly schedule with a subcutaneous dosing route. Importantly, when we dose the same tumor model with a negative control helicon (Helicon10) that is derived from active Helicon8 with a conservative chemical modification that retains AR binding ability but abrogates the ability of the Helicon to bind to VHL E3 ligase, anti-tumor activity of the Helicon is lost, demonstrating that the degrader functionality is critical for antitumor activity.

β-catenin Candidates Utilizing Our Helicon Discovery Platform

In addition to pursuing ERG and AR^{ON} degraders, we are continuing to develop novel approaches to target β-catenin, building on the foundational biology established through zolucetide. We have identified multiple binding sites on β-catenin beyond the one leveraged by zolucetide and are exploring the application of our degrader technology to develop a β-catenin targeted degrader. Data highlighting cell-based degradation of β-catenin protein using a bifunctional Helicon degrader is set forth in Figure 37. This Helicon degrader exhibited a potent DC₅₀ of ~100nM, which was dependent on engagement of the VHL E3 ligase (illustrated with a VHL incompetent negative control Helicon), and dependent on the proteasome (illustrated by rescue with the proteasome inhibitor, bortezomib). Finally, in the same Figure, the degradation of β-catenin protein led to a dose-dependent and VHL E3 ligase-dependent inhibition of β-catenin:TCF transcriptional activity as measured by monitoring AXIN2 gene expression.

Figure 37. Cell-based validation of a bifunctional Helicon degrader of β-catenin using the COLO320DM colorectal cell line as a model system.



The finding that β-catenin has at least five Helisites allows us to explore the biological impact of modulating β-catenin activity and levels in multiple ways. We believe the combination of a degrader approach and the exploration of additional Helisites may enable us to create new product candidates targeting the Wnt/ β-catenin pathway and further expand the opportunity of our β-catenin franchise.

Other Discovery Candidates Utilizing Our Helicon Discovery Platform

We believe zolucetide, our β-catenin and ERG degraders, and our allosteric AR^{ON} degrader program provide strong evidence of the potential of our Helicon discovery platform to repeatedly generate therapeutic candidates with the potential to selectively bind historically undruggable intracellular targets and exert desired biological activity. We are also actively working to broaden our platform's reach across additional historically undruggable high-value targets such as cyclin D1 and p53, among others. These targets have been specifically selected to align with our focus on genetically validated, historically undruggable proteins where we believe Helicon peptides offer a meaningful advantage over existing modalities. We apply a rigorous framework to evaluate and prioritize programs, assessing each against genetic validation, Helicon feasibility, safety, clinical path, and potential for value creation before committing substantial resources to advancement.

We are also exploring modality expansion, building our toolkit of Helicon functionalities to include protein-protein interaction inhibitors, protein-DNA inhibitors, bifunctional degraders, target-induced cell killing, and radioligand therapeutics. We believe our modality also has the potential to implement additional mechanisms of action with high precision by incorporating functional payloads or recruiting domains into the core Helicon scaffold. This modularity allows us to leverage continued advances across biotechnology to potentially extend the reach of the platform across multiple mechanisms.

We intend to advance multiple discovery-stage programs beyond our current clinical and preclinical pipeline, reflecting our goal to build a multi-therapeutic company that leverages the distinct strengths of the Helicon platform to create differentiated medicines.

Strategic Partnerships

In addition to advancing wholly-owned programs, we intend to pursue selective strategic partnerships to maximize the impact of the Helicon platform. In oncology, where we maintain deep internal expertise in target biology, clinical development, and regulatory strategy, we expect to develop programs through regulatory approvals and commercialize the products ourselves in the United States. Outside of the United States, we may seek partnerships with global pharmaceutical companies or distributors to expand our reach to patients globally. For certain oncology indications where scaled manufacturing, broad commercial infrastructure, or other capabilities would be required to fully realize a program's potential, we may choose to advance a program to an appropriate value inflection point and then partner with organizations that bring these capabilities. In such cases, where we believe a partnership could accelerate patient access and expand the clinical and commercial impact of a program beyond what we could achieve independently, we would seek to structure collaborations that both enable that broader reach and allow us to achieve meaningful near-term and downstream value creation.

We also intend to evaluate strategic research collaborations to advance Helicon-based programs against new targets and indications largely outside of oncology. In these partnerships, we expect to leverage our Helicon discovery platform to generate molecules against undruggable targets, while partners contribute disease-area biology, translational insight, and development and commercialization capabilities specific to their therapeutic focus. We believe this strategy allows us to expand the reach of the Helicon platform into high-value indications that we would not otherwise pursue independently, generating additional value and optionality for our company and for patients.

Consistent with this strategy, we recently entered into a License and Collaboration Agreement with Regeneron Pharmaceuticals, Inc. ("Regeneron") pursuant to which we plan to discover and develop multiple therapeutic candidates based on our Helicon platform, with a particular focus on Antibody-Helicon Conjugates ("AHCs") directed to historically undruggable and challenging intracellular targets. The collaboration will focus primarily on indications outside of oncology. Additional information regarding our collaboration with Regeneron is set forth in the section titled "*License and Collaboration Agreements*" below.

Manufacturing

We believe that Helicons can be reliably and efficiently manufactured, and that our team possesses the expertise and technical capabilities required to produce zolucetide, as well as Helicons more broadly, at commercial scale. To date, our focused efforts have enabled us to: (1) develop manufacturing processes that we believe are scalable for commercial production; (2) establish a network of contract manufacturers capable of reliably and efficiently supplying zolucetide for clinical trials and, ultimately, commercialization; (3) significantly reduce cost of goods sold through optimization and scale-up of our solid-phase process, as well as development of a liquid-phase process; and (4) advance the development of a self-administered injectable formulation of zolucetide for commercial use. Looking ahead, we intend to continue innovating to support further improvements, including transitioning to our liquid-phase manufacturing process. In parallel, we are advancing a formulation development to enable convenient self-administered injectable dosing, which we expect will be used for zolucetide at the commercial stage and may be applied across other programs. Under the oversight of our experienced manufacturing team, we intend to continue to enhance our end-to-end manufacturing capabilities.

With respect to our supply chain, we rely on third parties for the GMP manufacture of our product candidates for certain preclinical studies and clinical trial materials, including active pharmaceutical ingredients, as well as the raw materials and consumables required for their production. We expect to continue this outsourcing strategy in the future, including for commercial manufacturing, if our product candidates receive marketing approval. We do not own or operate GMP manufacturing facilities and do not currently plan to build internal GMP manufacturing capabilities for clinical or commercial production. However, our team includes personnel with extensive manufacturing experience who provide oversight of our contract manufacturing partners. In the future, we may also engage collaboration partners, in addition to contract manufacturers, to support the manufacture of our product candidates or any approved products.

We believe that zolucetide can be manufactured using reliable and reproducible synthetic process from readily available raw materials, followed by purification and packaging suitable for clinical use. We further believe that the chemistry is amenable to scale-up, and that our continued focus on innovation will allow us to maintain robust manufacturing expertise.

Competition

The pharmaceutical industry is characterized by rapid technological evolution and intense competition. We face and will continue to face competition from pharmaceutical and biotechnology companies of all sizes, academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for the research, development, manufacturing, and commercialization of new products.

Any product candidates that we successfully develop and commercialize will compete with existing approved therapies, off-label treatments, and/or new therapies that may become available in the future. We believe that the key competitive factors affecting the success of zolucetide and any future product candidates, if approved, will include efficacy, durability of response, time to response, safety and tolerability, route of administration, cost and reimbursement coverage, and the strength of our intellectual property protection.

We are developing our lead product candidate, zolucetide, initially for the treatment of desmoid tumors. The competitive landscape for desmoid tumors has evolved in recent years with the emergence of one approved targeted therapy and others in development, and we expect this landscape to continue to evolve as additional agents advance through clinical development.

We consider our most direct competitors to be companies developing γ -secretase inhibitors, including nirogacestat (Ogsiveo), an approved drug for desmoid tumors commercialized by Merck KGaA (acquired from SpringWorks Therapeutics), and varegacestat, being developed by Immunome, Inc., has completed a Phase 3 clinical trial in desmoid tumors. Varegacestat targets the same mechanistic pathway as Ogsiveo and, if approved, would represent an additional source of direct competition.

There may be additional agents in early clinical development by other companies targeting this indication through tumor-agnostic or basket studies that may enroll patients with desmoid tumors. We cannot predict whether varegacestat or other clinical-stage agents will receive regulatory approval, or on what timeline, but the potential entry of additional approved therapies could intensify the competitive environment and make it more difficult to achieve and maintain market share for zolucetide, if approved.

Furthermore, we are aware of several therapies used off-label for the treatment of desmoid tumors, including chemotherapeutic agents such as liposomal doxorubicin and vinblastine/methotrexate, non-steroidal anti-inflammatory drugs, anti-hormonal therapies, and tyrosine kinase inhibitors such as sorafenib, imatinib, and pazopanib. These therapies, some of which are available generically and at lower cost, may continue to be used by treating physicians and could limit the addressable market for zolucetide.

For our zolucetide program in FAP, where there are no therapies currently approved by the FDA, we are aware of clinical-stage product candidates being evaluated. These include: eRapa (encapsulated rapamycin), an oral mTOR inhibitor being developed by Emtora Biosciences, and REC-4881, an allosteric MEK1/2 inhibitor being developed by Recursion Pharmaceuticals, as well as TPST-1495 (Tempest Therapeutics) and ONC201 (Jazz Pharmaceuticals). We are also aware of therapies being evaluated in tumor-agnostic or related gastrointestinal indications that may include FAP patients. All of these and other potential entrants could create competition for our program.

Many of our current and potential competitors have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals, obtaining reimbursement, and marketing approved products. Mergers and acquisitions in the biopharmaceutical industry may result in even greater resources being concentrated among a smaller number of well-capitalized competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with larger and more established companies.

Our competitors also compete with us in recruiting and retaining qualified scientific, clinical, and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, and acquiring technologies complementary to or necessary for our programs. If our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, or are less expensive than zolucetide or any future product candidates we may develop, our commercial opportunity could be reduced or eliminated. Our competitors may also obtain FDA or other regulatory approvals for their products more rapidly than we may obtain approval for ours, which could allow them to establish a strong market position before we are able to enter the market.

The availability of reimbursement from government and private payors will also significantly affect the pricing and competitiveness of our products. Even if zolucetide or any future product candidates achieve regulatory approval, they may be priced at a significant premium over competitive products if any have been approved by then, which could result in reduced competitiveness or limited market adoption.

Intellectual Property

We pursue a layered intellectual property strategy to protect our Helicon discovery platform, our development programs, our product candidates and other technologies. One focus of our intellectual property strategy is to provide protection for our Helicon discovery platform and product candidates currently in development. We also pursue intellectual property protection for assets that may be used in future development programs or that may be of interest to future collaborators or otherwise may prove valuable in the field.

Various aspects of our Helicon discovery platform and our product candidates are covered by claims in patent filings. We also pursue other modalities of protection, including trademark and trade secret protection, as appropriate. Many of our intellectual property assets were developed and are owned solely by us, some have been developed via collaboration and are jointly owned, and some have been licensed from third parties. We intend to continue filing additional patent applications, and to pursue opportunities to acquire and/or license additional intellectual property assets and technologies, for example, from collaborations, as developments arise or are identified.

Our commercial success depends, in large part, on our ability to obtain and maintain patents, trademarks, and other proprietary protections for commercially important technologies, including inventions, trade secrets and know-how, related to our business including our Helicon discovery platform and our product candidates; to defend and enforce our patents and other intellectual property rights; to preserve the confidentiality of our trade secrets; and to operate without infringing, misappropriating or violating patents and other intellectual property rights of third parties. See “*Risk Factors—Risks Related to Our Intellectual Property*” for a more comprehensive description of risks related to our intellectual property.

As of March 23, 2026, our overall owned and in-licensed patent portfolio included at least 17 patent families, each of which includes at least an application filed under the Patent Cooperation Treaty (a “PCT application”) or a filing in the United States, and several of which are pending or granted in multiple jurisdictions. The patent families include at least 12 patent families that are solely owned by us, and the rest that we have licensed from third parties.

An issued patent typically provides its owner (or possibly its exclusive licensee) with a right to exclude others from making, using, offering to sell, or selling that which is claimed in the patent, for a specified period of time (the “term” of the patent), in the jurisdiction in which the patent is issued. In the United States, a patent has a presumptive term of 20 years from its patent term filing date (which is the filing date of the patent, or if the patent claims the benefit of the filing date of another non-provisional application, the filing date of the earliest non-provisional application whose filing date the patent claims the benefit of) depending upon timely payments of maintenance fees. Many other jurisdictions provide a similar presumptive 20-year patent term. Many jurisdictions, including the United States, require the payment of periodic maintenance fees in order for patents to remain in force for the full 20-year term. The United States also has provisions that require the term of a patent to be shortened if its claims are too similar to another patent that is owned by the same party and/or shares a common inventor therewith that has a shorter term, and also permits patentees to disclaim term. The United States and certain other jurisdictions also have provisions that permit extension of patent term for patents that cover a product that is subject to regulatory approval, such as drugs and certain medical devices, approved uses thereof, or methods of manufacturing them, under certain circumstances. In the United States, such extension is called a Patent Term Extension (“PTE”), and it is limited to a period of not more than five years, and the total patent term including the PTE cannot exceed 14 years after the date of regulatory approval; only one patent can be extended per product approval. There are analogous rules for extending patents in certain other jurisdictions, such as EU Member States, Japan, South Korea, and Canada. The United States also offers a different form of patent term extension, known as Patent Term Adjustment (“PTA”), whereby a particular patent’s term is extended beyond the 20-year date if the United States Patent and Trademark Office (“USPTO”), caused delay during its examination; however, potentially available PTA is reduced by any amount of any delay caused by the patent applicant.

Below, we provide a summary of our current patent portfolio as of March 23, 2026, as it relates to different aspects of our Helicon discovery platform and product candidates. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO and its foreign equivalents can be significantly narrowed or otherwise altered by the time they issue, if they issue at all. We expect this could be the case with respect to some or all of our pending patent applications referred to below. Particularly given our clinical stage of development, we cannot be certain that any of the patent filings in our portfolio will provide meaningful protection for any product we ultimately attempt to commercialize.

Helicon Discovery Platform

Our patent portfolio includes patent filings directed to various features of our Helicon discovery platform, some of which are utilized in our development programs. For example, certain patent families in-licensed from the President and Fellow of Harvard College (“Harvard”) describe various amino acids and stapling technologies that can be useful for certain Helicons, Helicons comprising such amino acids and stapling technologies, and methods for manufacturing such Helicons. These families include issued patents and/or pending applications in multiple jurisdictions including major market jurisdictions such as the United States, Europe and/or Japan, and their presumptive 20-year terms extend to 2028-2034.

We own certain patent filings that describe certain amino acids, staples or patterns thereof, the presumptive 20-year terms of which range from 2038 to at least 2041.

Certain patent families in our portfolio describe technologies useful for identifying Helicons that can bind various targets, and Helicons identified thereby. Some of these families offer presumptive 20-year terms that extend to at least 2039.

Helicon Product Candidates

As of March 23, 2026, our most advanced product candidate is zolucetide. Our patent portfolio includes patent families that are owned by us and may protect the composition of matter of zolucetide. The presumptive 20-year term of such patent families extends to at least 2042. Certain patent families owned by us may provide protection of certain formulations and/or uses of zolucetide; their presumptive 20-year expiration dates range from 2042 to at least 2044. Together, these patent families include pending patent applications in the United States and various other jurisdictions such as Brazil, Canada, China, Eurasia, Europe, Israel, India, Japan, South Korea, Mexico, and Singapore. No patents have issued from these patent families yet.

We maintain a thoughtful program for developing and protecting additional intellectual property including platform and program technologies. We also intend to prepare and submit patent filings specifically directed to protecting individual product candidates and their uses as our programs progress.

License and Collaboration Agreements

License Agreement with President and Fellows of Harvard College

On August 30, 2017, we entered into a License Agreement with President and Fellows of Harvard College, as amended on January 12, 2018, June 20, 2019 and July 16, 2020 (as amended, the “Harvard License”), pursuant to which we received an exclusive, royalty-bearing license under certain Harvard intellectual property to develop and commercialize products incorporating certain polypeptide technologies (the “Licensed Product”) solely in the field of prevention and treatment of disease in humans, worldwide. Harvard retains the right to use the licensed intellectual property for research, educational, and scholarly purposes (excluding clinical trials). The Licensed Products are further categorized as Type I Licensed Products and Type II Licensed Products based on whether such Licensed Product is covered by a valid claim licensed from Harvard. We believe that zolucetide is a Type I Licensed Product because pending or issued claims in the licensed families cover zolucetide. Because our earlier-stage pipeline is still under development it is not yet clear that any licensed families would cover those products. We own any improvements that we create to technology that we licensed under the Harvard License.

As partial consideration for the rights granted to us under the Harvard License, we entered into a stock subscription agreement with Harvard pursuant to which we issued shares of our common stock to Harvard. As additional consideration for the license, we are required to pay Harvard: (i) annual license maintenance fees in the low six-figures; (ii) up to an aggregate of \$18.3 million in development, regulatory and sales milestone payments for each Licensed Product; (iii) royalties with a rate based on aggregate net sales per calendar year of each of Type I Licensed Products and Type II Licensed Products, ranging in the low single digits based on the type of Licensed Product; and (iv) a percentage of non-royalty income received under sublicenses or strategic partnerships with third parties based on what stage of development the first Licensed Product at the time we enter into such agreement (*i.e.*, before or after enrollment of first patient in a Phase 2 clinical study of a Licensed Product), ranging in the low to mid-teens. The royalties due for Type I Licensed Products are subject to a potential reduction related to certain third party license fees. The royalty term for Type I Licensed Products will expire on a Licensed Product-by-Licensed Product and country-by-country basis upon the expiration or termination of the last valid claim within the Harvard licensed patents covering or claiming the composition, manufacture, sale or use of such Licensed Product in such country. The royalty term for Type II Licensed Products will expire on a Licensed Product-by-Licensed Product and country-by-country basis on the 12 year anniversary of the first commercial sale of such Licensed Product in such country.

Under the Harvard License, we have certain diligence obligations to perform certain development and commercialization activities in accordance with a development plan and timelines therein (“Development Milestones”). We may request extensions to the timelines for achieving Development Milestones subject to Harvard’s approval and an amendment to the development plan. Harvard may terminate for our failure to negotiate Development Milestones or failure to achieve a Development Milestone, subject to a cure period.

We may terminate the Harvard License for convenience upon prior written notice, and Harvard may terminate for our failure to negotiate Development Milestones or failure to achieve a Development Milestone, subject to a cure period, as described above. Either party may terminate for uncured material breach or insolvency.

Upon termination of the Harvard License for any reason, all licenses granted by Harvard will terminate and revert to Harvard and we will retain the right to sell off existing inventory and complete work-in-progress, subject to ongoing insurance, royalty and reporting obligations. Following termination, we may not have all of the rights necessary to continue our research and development and commercialization efforts for zolucetide or any other product candidates covered by the license. Any sublicensees who obtained sublicenses from us will have a right to obtain a direct license with Harvard.

License and Collaboration Agreement with Regeneron Pharmaceuticals, Inc.

On May 15, 2026, we entered into a License and Collaboration Agreement (the “Regeneron Agreement”) with Regeneron Pharmaceuticals, Inc. (“Regeneron”) to discover, develop, and commercialize Helicons, with a particular focus on Antibody-Helicon Conjugates (“AHCs”), directed to a set of specified targets (each, a “Collaboration Target”).

Under the terms of the Regeneron Agreement and during the research term for each Collaboration Target, we will collaborate with Regeneron to perform certain research and preclinical development activities, including screening, generating, testing and evaluating new Helicons and AHCs directed to such Collaboration Target (each, a “Product”). Under the Regeneron Agreement, there are five initial Collaboration Targets, with Regeneron having the right to replace up to two targets and the option to nominate up to five additional Collaboration Targets, subject to an additional option payment from Regeneron. For one initial Collaboration Target, Regeneron may add one or more additional programs with respect to such Collaboration Target, subject to payment of additional program fees.

Following Regeneron's nomination of a Product to be a “Licensed Product” during the research term for the applicable Collaboration Target (including additional Collaboration Targets), Regeneron has the sole right to advance through development, manufacturing and worldwide commercialization of Licensed Products, including clinical and regulatory strategy, pricing, and promotion.

Under the terms of the Regeneron Agreement, Regeneron has agreed to make a \$50.0 million upfront payment and invest \$75.0 million in our next equity financing, subject to certain conditions, which investment is expected to be the concurrent private placement described in this prospectus. For the initial Collaboration Targets, we are eligible to receive: (i) up to \$470.0 million in development milestone payments; (ii) up to \$575.0 million in regulatory milestone payments; (iii) up to \$1.15 billion in commercial milestone payments; and (iv) tiered royalty payments, ranging in the high single digits to low double digits during the period commencing upon the first commercial sale of such Licensed Product in a given country and expiring on the latest of: (a) expiration of the last valid claim of a royalty term-extending patent right of such Licensed Product in such country, (b) 12 years after the first commercial sale of such Licensed Product in such country, and (c) loss of regulatory exclusivity for such Licensed Product in such country, subject to customary reductions.

Under the terms of the Regeneron Agreement, we are subject to an exclusivity obligation for each Collaboration Target until the last to expire royalty term for Licensed Products directed to such Collaboration Target, which restrict us from, directly or indirectly, licensing, developing, manufacturing, commercializing, or otherwise exploiting any competing product directed to such Collaboration Target outside of activities conducted under the Regeneron Agreement, subject to customary exceptions for our acquisition of a competing product and change of control.

Unless earlier terminated pursuant to its terms, the Regeneron Agreement will remain in effect until the expiration of the last royalty term for the last Licensed Product under the Regeneron Agreement. Regeneron has the right to terminate the Regeneron Agreement for convenience and for certain violations of our exclusivity covenants. Each party may terminate the Regeneron Agreement for material breach, subject to a cure period. We may terminate the Regeneron Agreement for certain patent challenges by Regeneron or any of its affiliates on our patent rights and failure to withdraw such challenge within a certain time period, subject to certain exceptions.

Upon termination of the Regeneron Agreement for any reason, all licenses granted to Regeneron will terminate and revert to us. Any sublicensees who obtained sublicenses from Regeneron will have a right to obtain a direct license from us, provided such sublicensee was in compliance with the applicable sublicense agreement and such sublicense agreement was entered in accordance with the Regeneron Agreement.

The Regeneron Agreement includes various representations, warranties, covenants, dispute escalation and resolution mechanisms, indemnities and other provisions customary for transactions of this nature.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union (“EU”), extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates drugs under the U.S. Federal Food, Drug, and Cosmetic Act (“FDCA”) and its implementing regulations. The failure to comply with applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the U.S. Department of Justice or other governmental entities. In addition, an applicant may need to recall a product.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of nonclinical, or preclinical, laboratory tests, animal studies and formulation studies in compliance with the FDA’s good laboratory practice (“GLP”) regulations;
- submission to the FDA of an investigational new drug application (“IND”) which must take effect before human clinical trials may begin;
- approval by an institutional review board (“IRB”) representing each clinical site before each clinical trial may be initiated at that site;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices (“GCPs”) to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a New Drug Application (“NDA”) and payment of user fees;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices (“cGMP”) requirements and to assure that the facilities, methods and controls are adequate to preserve the product’s identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- FDA review and approval of the NDA; and
- compliance with any post-approval requirements, any post-approval studies required by the FDA.

Preclinical Studies

Before an applicant begins testing a compound in humans, the drug candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient (“API”) and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. Some long-term preclinical testing, such as animal tests of reproductive adverse effects and carcinogenicity, may continue after the IND is submitted.

The IND and IRB Processes

An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of the investigational drug. In an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments. In addition, the results of the preclinical tests, manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. The FDA also may impose a clinical hold or partial clinical hold after commencement of a clinical trial under an IND. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation (or full investigation in the case of a partial clinical hold) may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical trial is not conducted under an IND, the sponsor must ensure that the study is conducted in accordance with GCP, including review and approval by an independent ethics committee (“IEC”) and informed consent from subjects. The GCP requirements are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. FDA must also be able to validate the data from the study through an on-site inspection if necessary.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review of the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health (“NIH”) for public dissemination on its ClinicalTrials.gov website. Sponsors also must disclose certain results of these clinical trials, although disclosure of results may be delayed until after the new product or new indication has been approved by the FDA. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to public notifications of noncompliance, civil monetary penalties, and also prevent the non-compliant party from receiving future grant funds from the federal government.

Human Clinical Trials in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects, or their legal representative, provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- *Phase 1.* The drug is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine maximal dosage.
- *Phase 2.* The drug is administered to a limited patient population to identify possible Adverse Effects (“AEs”) and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- *Phase 3.* The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Post-approval studies, often referred to as Phase 4 studies, may be conducted after initial regulatory approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. In addition, within 15 calendar days after the sponsor determines that the information qualifies for reporting, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor’s initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the applicant must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Review of an NDA by the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product’s chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to a significant application user fee as well as annual prescription drug product program fees. These fees are typically increased annually. Certain exceptions and waivers are available for some of these fees.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt, before accepting the NDA for filing, to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Applications for drugs containing new molecular entities have a “goal date” for a decision by the FDA of 10 months from the date of filing, and applications for “priority review” products containing new molecular entities have a goal date of six months from the date of filing. A goal date does not create an enforceable right to a decision by that date, and FDA does not always meet its goal dates. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

During its review of an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA, including drug component manufacturing (such as APIs), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an NDA unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

In addition, as a condition of approval, the FDA may require an applicant to develop risk evaluation and mitigations strategies (“REMS”). REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS program is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential AEs, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use (“ETASU”). ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug product intended to treat a rare disease or condition, which is generally a disease or condition that affects either (i) fewer than 200,000 individuals in the U.S. or (ii) more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. for this type of disease or condition will be recovered from sales of the product. A company must request orphan drug designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the use or indication for which it has such designation, the product is entitled to orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications to market the same product for the same approved indication for seven years, except in certain limited circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan use or indication as long as the products contain different active ingredients. Moreover, competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan drug has exclusivity. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Fast Track, Breakthrough Therapy, and Priority Review

The FDA has a number of programs intended to facilitate and expedite development and review of new drugs if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. Three of these programs are referred to as Fast Track Designation, Breakthrough Therapy Designation, and priority review designation.

Specifically, the FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the

FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track Designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate an NDA review for a priority review if it is for a product that treats a serious or life-threatening disease or condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from 10 months to six months.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Fast Track designation, Breakthrough Therapy designation, and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM"), and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly.

The accelerated approval pathway is contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Sponsors are also required to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. Under

FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the sponsor fails to conduct such studies in a timely manner and send the necessary updates to the FDA, or if a confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, unless otherwise informed by the agency, pre-approval of promotional materials for product candidates approved under accelerated regulations, which could adversely impact the timing of the commercial launch of the product.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities and select clinical trial sites, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application, and may cause significant delay and expense. If a complete response letter is issued, the applicant may resubmit the NDA to address all of the deficiencies identified in the letter, withdraw the application, or request a hearing. If the applicant resubmits the NDA, the FDA will issue an approval letter only when the deficiencies have been addressed to the FDA's satisfaction. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety or effectiveness after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. All of these limits may adversely affect the commercial success of the product.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, reporting of adverse experiences with the product and applicable product tracking and tracing requirements. After approval, many changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are annual prescription drug product program fee requirements for certain marketed products.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the NDA holder and any third-party manufacturers that the NDA holder may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or voluntary product recalls;
- fines, warning or untitled letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA"), which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Hatch-Waxman Amendments

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application ("ANDA"). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product, known as a reference listed drug ("RLD"). ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through *in vitro*, *in vivo*, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

Non-Patent Exclusivity

Under the Hatch-Waxman Amendments, the FDA may not approve (or in some cases accept) an ANDA or 505(b)(2) application until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity ("NCE"). For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, which states the proposed generic drug will not infringe one or more of the already approved product's listed patents or that such patents are invalid or unenforceable, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity for non-NCE drugs if the NDA or a supplement to the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application or supplement. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication, but it generally would not protect the original, unmodified product from generic competition. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; it only prevents FDA from approving such ANDAs.

A drug product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the active moiety and to patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection and patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

Hatch-Waxman Patent Certification and the 30-Month Stay

In seeking approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Upon approval, each of the patents listed by the NDA sponsor is published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Upon submission of an ANDA or 505(b)(2) NDA, an applicant is required to certify to the FDA concerning any patents listed for the RLD in the Orange Book that:

- no patent information on the drug product that is the subject of the application has been submitted to the FDA;
- such patent has expired;
- the date on which such patent expires; or
- such patent is invalid, unenforceable or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505(b)(2) NDA applicant has provided a paragraph IV certification the applicant must send notice of the paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation. If the drug has NCE exclusivity and the ANDA is submitted four years after approval, the 30-month stay is extended so that it expires seven and a half years after approval of the innovator drug, unless the patent expires or there is a decision in the infringement case that is favorable to the ANDA applicant before then.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Amendments, which permits a patent term restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date, provided the sponsor acted with diligence. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question and within 60 days of drug approval. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office ("USPTO") reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Review and Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the EU generally follows similar lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of a marketing authorization application ("MAA") and granting of a marketing authorization by these authorities before the product can be marketed and sold in the EU.

Clinical Trial Approval

In the EU, an applicant for authorization of a clinical trial must obtain prior approval from the national competent authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the relevant independent ethics committee has issued a favorable opinion. In April 2014, the Clinical Trials Regulation, (EU) No 536/2014 (the “Clinical Trials Regulation”) was adopted in the EU. The Clinical Trials Regulation is directly applicable in all the EU Member States and repealed the Clinical Trials Directive 2001/20/EC, as of January 31, 2022.

The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, known as the “Clinical Trials Information System”; a single set of documents to be prepared and submitted for the application, as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by an elected Reference Member State, with support of the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (the “Member States Concerned”). Part II is assessed separately by each Member State Concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure continues to be governed by the national law of the concerned EU Member State, however, overall related timelines are defined by the Clinical Trials Regulation.

Marketing Authorization

To obtain a marketing authorization for a product in the EU, an applicant must submit an MAA either under a centralized procedure administered by the European Medicines Agency (“EMA”) or one of the procedures administered by competent authorities in the EU Member States (decentralized procedure or mutual recognition procedure) for obtaining a marketing authorization in multiple EU Member States. A marketing authorization may be granted only to an applicant established in the European Economic Area (“EEA”) (which is comprised of the EU Member States plus Norway, Iceland and Liechtenstein).

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid throughout the EEA. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene therapy, somatic cell therapy and tissue-engineered products) and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of HIV, AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

Under the centralized procedure, the Committee for Medicinal Products for Human Use (“CHMP”) established at the EMA is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from a public health perspective and in particular from the point of view of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150 days, excluding clock stops, but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. At the end of this period, the CHMP provides a scientific opinion on whether or not a marketing authorization should be granted in relation to a medicinal product. Within 67 days from the date of the CHMP opinion, the European Commission will adopt its final decision on the MAA.

Now that the United Kingdom (which comprises Great Britain and Northern Ireland) (“UK”) has left the EU, Great Britain is no longer covered by centralized marketing authorizations (under the Northern Ireland Protocol, centralized marketing authorizations currently continue to be recognized in Northern Ireland). On January 1, 2024, a new international recognition framework was put in place by the Medicines and Healthcare products Regulatory Agency (“MHRA”), the UK medicines and medical devices regulator, under which the MHRA may have regard to decisions on the approval of marketing authorizations made by the EMA and certain other regulators when determining an application for the grant of a UK or Great Britain marketing authorization. The MHRA also has the power to have regard to marketing authorizations approved in EU Member States through decentralized or mutual recognition procedures with a view to more quickly granting a marketing authorization in the UK or Great Britain. For additional information related to the regulatory framework in the UK, please refer to the discussion below under the section titled “—*Brexit and the Regulatory Framework in the United Kingdom.*”

The decentralized marketing authorization procedure allows an applicant to apply for simultaneous authorization in more than one EU Member State of medicinal products that have not yet been authorized in any EU Member State and that do not fall within the mandatory scope of the centralized procedure. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The Reference Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the Concerned Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a Concerned Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all Member States.

The mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of another EU Member State. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

Pediatric Development

Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the EU, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan (“PIP”) covering all subsets of the pediatric population, unless the EMA has granted (1) a product-specific waiver, (2) a class waiver or (3) a deferral for one or more of the measures included in the PIP. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the product for which a marketing authorization is being sought. Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (“SPC”) provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to two years before the SPC expires, even where the trial results are negative. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Data and Market Exclusivity

In the EU, innovative medicinal products approved on the basis of a complete and independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. Data exclusivity prevents applicants for authorization of generics or biosimilars of these innovative products from referencing the innovator’s preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar (abbreviated) marketing authorization, for a period of eight years from the date on which the reference product was first authorized in the EU. During an additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator’s data may be referenced, but no generic or biosimilar medicinal product can be placed on the EU market until the expiration of the market exclusivity. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained a marketing authorization based on an MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Orphan Designation and Exclusivity

Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition, (2) either (i) such condition affects no more than five in ten thousand persons in the EU when the application is made, or (ii) without the benefits derived from orphan status, it is unlikely that the marketing of the product in the EU would generate sufficient return to justify the necessary investment in its development; (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the product would be of significant benefit to those affected by that condition.

An orphan designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized EU marketing authorization. Marketing authorization for an orphan medicinal product leads to a ten-year period of market exclusivity being granted following marketing approval of the orphan product. During this market exclusivity period, the EMA, the European Commission or the competent authorities of the EU Member States may only grant marketing authorization to a

“similar medicinal product” for the same therapeutic indication if: (i) a second applicant can establish that its product, although similar to the authorized product, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the authorized product consents to a second orphan medicinal product application; or (iii) the marketing authorization holder for the authorized product cannot supply enough orphan medicinal product. A “similar medicinal product” is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation because, for example, the product is sufficiently profitable not to justify market exclusivity. Orphan designation must be requested before submitting an application for marketing approval. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Periods of Authorization and Renewals

A marketing authorization has an initial validity of five years. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the relevant EU Member State for a nationally authorized product. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authorities of the relevant Member States decide, on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for centrally-authorized products) or on the market of the authorizing EU Member State (for nationally-authorized products) within three years after authorization ceases to be valid (the so-called “sunset clause”).

Regulatory Requirements after a Marketing Authorization has been Obtained

Where an authorization for a medicinal product in the EU is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the EU’s stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.
- The manufacturing of authorized medicinal products, for which a separate manufacturer’s license is mandatory, must also be conducted in strict compliance with the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive (EU) 2017/1572, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and APIs, including the manufacture of APIs outside of the EU with the intention to import the APIs into the EU.
- The marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products and/or the general public, are strictly regulated in the EU notably under Directive 2001/83/EC, as amended, and EU Member State laws.

The aforementioned EU rules are generally applicable in the EEA.

Reform of the Regulatory Framework in the European Union

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval. In October 2023, the European Parliament published draft reports proposing amendments to the legislative proposals, which will be debated by the European Parliament. Once the European Commission’s legislative proposals are approved (with or without amendment), they will be adopted into EU law.

Brexit and the Regulatory Framework in the United Kingdom

The UK ceased being a Member State of the EU on January 31, 2020, and the EU and the UK have concluded a trade and cooperation agreement (“TCA”), which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP,

inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented previous EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework continues to apply in Northern Ireland). Except in respect of the EU Clinical Trials Regulation, the regulatory regime in Great Britain therefore aligns in many ways with current EU medicines regulations, however it is possible that these regimes will diverge more significantly in the future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. However, notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, under a new international recognition framework which was put in place by the MHRA on January 1, 2024, the MHRA may take into account decisions on the approval of marketing authorizations from the EMA (and certain other regulators) when considering an application for a Great Britain or UK marketing authorization.

On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework." This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (*i.e.*, Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide marketing authorization will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, so the UK government and the EU will enact legislative measures to bring it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025.

Other Healthcare Laws

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs;
- federal civil and criminal false claims laws, including the False Claims Act ("FCA"), which can be enforced through civil "qui tam" or "whistleblower" actions, and civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (*e.g.*, public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating these statutes without actual knowledge of the statutes or specific intent to violate them in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), imposes requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- Even when HIPAA does not apply, according to the Federal Trade Commission (“FTC”), failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a). The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards;
- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the “ACA”) and its implementing regulations, which requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the Department of Health and Human Services (“HHS”) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed healthcare professionals (*i.e.*, physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales, and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and responsible individuals may be subject to imprisonment.

Privacy and Data Security

In the ordinary course of business, we process sensitive data. Accordingly, we are, or may be become, subject to numerous privacy and data security obligations, including global, federal, state, and local laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations related to privacy and data security.

These privacy and data security laws are evolving and may impose potentially conflicting obligations. Such obligations may include, without limitation, federal health information privacy laws, state information security and data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (*e.g.*, the Federal Trade Commission Act). In addition, in the past few years, numerous U.S. states have passed, or are in the process of enacting comprehensive privacy laws, rules, and regulations that impose certain obligations on covered businesses, and similar laws are being considered in several other states, as well as at the federal and state levels. While these states exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing, as more fully discussed in the section titled “*Risk Factors*” appearing elsewhere in this prospectus.

Additionally, to the extent we collect personal data from individuals outside of the United States, through clinical trials or otherwise, we are, or may become, subject to foreign data and data security laws, such as the European Union’s General Data Protection Regulation 2016/679 (“EU GDPR”) and other national data protection legislation in force in relevant EEA Member States, and the EU GDPR as it forms part UK law by virtue of section 3 of the European Union (Withdrawal) Act 2018 (“UK GDPR”). Foreign privacy and data security laws impose significant and complex compliance obligations on entities that are subject to those laws, as more fully discussed in the section titled “*Risk Factors*” appearing elsewhere in this prospectus.

Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. Factors payors consider in determining coverage and reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a third-party payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price (“ASP”) and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare

programs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Even if we do receive a favorable coverage determination for approved products by third-party payors, coverage policies and third-party payor reimbursement rates may change at any time.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the U.S. Centers for Medicare & Medicaid Services ("CMS") may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several U.S. Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the EU Member States have the option to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States, and parallel trade, *i.e.*, arbitrage between low-priced and high-priced EU Member States, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Current and Future U.S. Healthcare Reform

In the U.S., there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably.

There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the Inflation Reduction Act of 2022 ("IRA"), among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions started taking effect progressively in fiscal year 2023. HHS has announced and negotiated final prices for two rounds of drugs; and HHS has also announced the third round of 15 drugs to be negotiated. The Medicare drug price negotiation program is currently subject to several constitutional challenges. It is unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry.

Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The IRA delayed implementation of this rule to January 1, 2032.

Other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- The U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, and, due to subsequent legislative amendments to the statute, will remain in effect until 2032.
- The U.S. American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers.
- The American Rescue Plan Act of 2021 eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.
- The IRA also includes several other provisions that may impact our business to varying degrees, including provisions that create a \$2,000 out-of-pocket cap for Medicare Part D beneficiaries (effectively eliminating the Medicare Part D "donut hole" as described above), and impose new manufacturer financial liability on all drugs in Medicare Part D.
- The One Big Beautiful Bill Act of 2025 imposed significant reductions in Medicaid funding, additional work requirements for certain Medicaid beneficiaries and more frequent eligibility redeterminations. These changes are expected to place increased pressure on state Medicaid budgets and could reduce enrollment, utilization and reimbursement levels for prescription drugs, including our products, which could adversely affect our business.

The costs of drugs have also been the subject of considerable discussion in the United States. To date, there have been several recent U.S. congressional inquiries, as well as proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. The Trump Administration has issued executive orders and supported proposed regulatory initiatives in 2025 that could have a significant impact on the prices that we, or any collaborators, may receive for any approved products.

On May 12, 2025, President Trump signed an executive order directing the Secretary of HHS to set and communicate most-favored-nation ("MFN") price targets to manufacturers and propose a rulemaking plan to impose MFN pricing if "significant progress" is not made, and also directing the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. The executive order further states that the Administration will take additional action (for example, examining whether marketing approvals should be modified or rescinded or considering individual drug importation waiver authorities) should manufacturers fail to offer American consumers the MFN lowest price. In July 2025, President Trump sent letters to certain pharmaceutical companies demanding that these companies extend MFN pricing to Medicaid and newly launched drugs as well as move to direct-to-consumer models priced at MFN pricing, and soliciting binding commitments by September 29, 2025. Since this time, multiple drug manufacturers have announced plans to, for certain of their drugs, lower prices to reflect similar pricing around the world, and to sell these reduced-price drugs on a direct-to-consumer purchasing platform developed by the federal government; however, it is not known what results will occur to the extent the recipients of these letters do not reduce their U.S. prices.

On December 19, 2025, CMS released two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs. The first proposal, the Global Benchmark for Efficient Drug Pricing Model ("GLOBE") for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GLOBE would begin a five year performance period on October 1, 2026 and GUARD would begin its performance period in 2027. These proposals will likely be subject to legal challenges that could delay their implementation or modify their impact on manufacturer pricing and revenue. Additionally, in November 2025, CMS introduced the GENERating cost Reductions for U.S. Medicaid ("GENEROUS") Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers.

Individual states have also been increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and

other health care programs. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare products and services.

Facilities

Our corporate headquarters are located in Cambridge, Massachusetts, where we lease approximately 122,000 square feet of office, laboratory and manufacturing space. Our Cambridge lease expires in February 2031, and includes two five-year renewal options.

We believe our existing facilities in Cambridge are sufficient for our needs for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

Employees and Human Capital Resources

As of April 1, 2026, we had 145 full-time employees and 31 full-time consultants, and 69 of our employees have M.D. or Ph.D. degrees. Within our workforce, 122 employees are engaged in research and development and 23 are engaged in business development, finance, legal, and general management and administration. Our human capital resources objectives include identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors as of June 1, 2026:

Name	Age	Position
<i>Executive Officers:</i>		
Mathai Mammen, M.D., Ph.D.	58	Chairman, Chief Executive Officer and President
Fawzi Benzaghrou, M.D.	50	Chief Medical Officer
Helen Ho, Ph.D.	47	Chief Business and Strategy Officer
Thomas Kotarakos	44	Chief Financial Officer
Rohin Mhatre, Ph.D.	61	Chief Technical Operations Officer
Teresa Jurgensen, J.D.	48	General Counsel
<i>Non-Employee Directors:</i>		
Alexis Borisy ⁽²⁾	54	Director
Edward Fitzgerald ⁽³⁾	71	Director
Rick Klausner, M.D. ⁽¹⁾	74	Director
Alan M. Sebulsky ⁽²⁾⁽³⁾	67	Director
Jake Simson, Ph.D. ⁽²⁾	40	Director
Barbara Weber, M.D. ⁽¹⁾⁽³⁾	69	Director
Krishna Yeshwant, M.D. ⁽¹⁾	48	Director

(1) Member of the compensation committee.

(2) Member of the nominating and corporate governance committee.

(3) Member of the audit committee.

Executive Officers

Mathai Mammen, M.D., Ph.D. has served as our Chief Executive Officer and Chairman of our board of directors since June 2023. Dr. Mammen served as the Global Head of R&D, Pharmaceuticals at Johnson & Johnson (NYSE: JNJ) from June 2017 to August 2022. Prior to joining Janssen Pharmaceutical Companies, Dr. Mammen was Senior Vice President at Merck Research Laboratories from March 2016 to June 2017. Prior to Merck, Dr. Mammen led research and development at Theravance, a company he co-founded in 1997 until March 2016. In 2014, he and the Theravance Leadership Team separated Theravance into two publicly traded companies: Innoviva (NASDAQ: INVA) and Theravance Biopharma (NASDAQ GS: TBPH). Through his career, Dr. Mammen was responsible for leading teams in discovery and development that led to the approval and global commercialization of 19 medicines, many of them medical practice changing. Dr. Mammen is an author or inventor on over 100 peer reviewed papers and patents. Dr. Mammen has served on the board of directors of Sandoz Group, AG, a Swiss public company (SWX: SDZ), since May 2024 and previously served on the board of directors of 10X Genomics (NASDAQ: TXG) from August 2017 to October 2024. Dr. Mammen received his M.D. from Harvard Medical School/Massachusetts Institute of Technology (Health Sciences and Technology program) and his Ph.D. in Chemistry from Harvard University's Department of Chemistry. He received his B.Sc. in Chemistry and Biochemistry from Dalhousie University in Halifax, Nova Scotia. We believe Dr. Mammen is qualified to serve as a member of our board of directors because of his significant academic training and current and previous experience serving as a director and co-founder of another life sciences company, as well as his operating experience with several life sciences companies.

Fawzi Benzaghrou, M.D. has served as our Chief Medical Officer since September 2025. Previously, Dr. Benzaghrou served as Senior Vice President, Global Head of Oncology R&D at Ipsen (XPAR: IPN.PA), a publicly traded biopharmaceutical company where he spent nine years in several senior roles in the oncology area. During this time, he led and secured six global approvals. Prior to his roles at Ipsen, Dr. Fawzi was Head of Development at Steba Biotech. Dr. Benzaghrou is a board-certified pediatric surgeon and a graduate from Algiers University and then from Paris Cité University, where he practiced for several years, including at Necker Children's Hospital. He obtained several certificates in oncology and clinical research. He also holds a Master's Degree in strategy and management in health industries from ESSEC Business School and is a graduate of an executive education program at Harvard Business School. Dr. Benzaghrou is a member of several scientific societies including the American Society of Clinical Oncology and the European Society for Medical Oncology and is a co-author of several peer-reviewed publications.

Helen Ho, Ph.D. has served as our Chief Business and Strategy Officer since April 2026. Prior to joining us, Dr. Ho served as Chief Business Officer of Blueprint Medicines Corporation (formerly NASDAQ: BPMC) from January 2022 to January 2025. Dr. Ho previously served as Blueprint's Senior Vice President, Head of Corporate Development from January 2021 to January 2022, and as Blueprint's Vice President, Head of Corporate Development from April 2018 to January 2021. Prior to joining Blueprint, Dr. Ho was Head of Corporate Development at TCR2 Therapeutics (formerly NASDAQ: TCRR) from 2016 to 2018 and held various business development and operations roles at Agios Pharmaceuticals (NASDAQ GS: AGIO) from 2011 to 2016. Prior to her time at Agios, Dr. Ho worked as a Management Consultant at L.E.K. Consulting from 2007 to 2011. Dr. Ho holds a Ph.D. in Cell Biology from Yale University and a B.S. in Biochemistry from the University of California, Los Angeles.

Thomas Kotarakos has served as our Chief Financial Officer since February 2026 and previously was our Executive Vice President of Finance from March 2023 to February 2026 and Senior Vice President of Finance from December 2021 to March 2023. Prior to joining us, Mr. Kotarakos was the Senior Vice President of Finance and Business Operations at Codiak BioSciences (formerly NASDAQ: CDAK), from December 2018 to December 2021. Mr. Kotarakos previously served as the Corporate Controller at Seres Therapeutics (NASDAQ GS: MCRB) from December 2014 to December 2018. Before his time at Seres, Mr. Kotarakos held various management positions at GT Advanced Technologies and served as an audit manager at PricewaterhouseCoopers. Mr. Kotarakos is a certified public accountant and received his M.S. and B.S. degrees in Accounting from Bentley University.

Rohin Mhatre, Ph.D. has served as our Chief Technical Operations Officer since October 2023. Prior to joining us, Dr. Mhatre served as Biogen Inc.'s ("Biogen") (NASDAQ: BIIB) Senior Vice President, Pharmaceutical Development, Engineering and Technology from January 2017 to August 2023. Dr. Mhatre previously held several other roles at Biogen, including Vice President, Global Regulatory Affairs from October 2015 to January 2017, Vice President, Biopharmaceutical Development, Senior Director, CMC Management, and Director, Biopharmaceutical Development. Dr. Mhatre has also served as a member of the board of directors of Repligen Corp. (NASDAQ: RGEN) since March 2020. Dr. Mhatre has a Ph.D. in Chemistry from Northeastern University.

Teresa Jurgensen, J.D. has served as our General Counsel since August 2024. Prior to joining us, Ms. Jurgensen served as the Senior Vice President, General Counsel and Head of Enabling Functions at 2seventy bio (formerly NASDAQ: TSVT), a spin-out of bluebird bio, from November 2021 to August 2024. Ms. Jurgensen previously served as Vice President, General Counsel, Oncology at bluebird bio (formerly NASDAQ: BLUE) from January 2021 to November 2021 and as bluebird bio's Senior Director, Business Development and Alliance Management Counsel from December 2018 to January 2021. Prior to her time at bluebird bio, Ms. Jurgensen served as Associate General Counsel at Teva Pharmaceutical Industries Ltd. (NYSE: TEVA) from October 2016 to November 2018, as Teva's Director, Executive Counsel from September 2015 to October 2016, and as Teva's Transactional Counsel from October 2014 to September 2015. Prior to her time at Teva, Ms. Jurgensen worked as an Associate at Saul Ewing LLP and as Corporate Counsel at Synthes, Inc. Ms. Jurgensen holds a B.S. in Marketing from Penn State University and a J.D. from Widener University School of Law.

Non-Executive Directors

Alexis Borisy has served as a member of our board of directors since February 2024. Mr. Borisy is the co-founder and operating chairman of Curie.Bio, a new model for venture in biotech. In 2022, Mr. Borisy co-founded IDRx, Inc., a biopharmaceutical company. Also in July 2022, Mr. Borisy became a director of Nextech Invest, a Swiss-based venture firm, where he also serves as Chairman. Prior to its acquisition by Revolution Medicines, Inc. (NASDAQ: RVMD) in November 2023, Mr. Borisy served as Chief Executive Officer and Chairman of EQRx, Inc., (formerly NASDAQ: EQRX), a biotechnology company, from August 2019 to November 2023. From 2010 to June 2019, Mr. Borisy was a partner at Third Rock Ventures, a series of venture capital funds investing in life science companies. Mr. Borisy co-founded Blueprint Medicines Corporation (formerly NASDAQ: BPMC), a biopharmaceutical company, and served as its Interim Chief Executive Officer from 2013 to 2014 and served as a member of its board of directors from 2011 until its acquisition by Sanofi in July 2025. Mr. Borisy co-founded Foundation Medicine, Inc. and served as its Interim Chief Executive Officer from 2009 to 2011 and served as a member of its board of directors from 2009 to July 2018, until its acquisition by Roche. In addition, Mr. Borisy serves as a member of the board of directors of Relay Therapeutics, Inc. (NASDAQ: RLAY) and Revolution Medicines, Inc. (NASDAQ: RVMD). During the past five years, Mr. Borisy also served as a member of the board of directors of Magenta Therapeutics, Inc. (formerly NASDAQ: MGTA), Editas Medicine, Inc. (NASDAQ: EDIT), OPKO Health, Inc. (NASDAQ: OPK), and Tango Therapeutics, Inc. (NASDAQ: TNGX). Mr. Borisy received an A.B. in Chemistry from the University of Chicago and an A.M. in Chemistry and Chemical Biology from Harvard University. We believe Mr. Borisy's extensive experience as an executive of, and working with and serving on the boards of directors of, multiple biopharmaceutical and life sciences companies, his educational background and his experience working in the venture capital industry provide him with the qualifications and skills necessary to serve as a member of our board of directors.

Edward Fitzgerald has served as a member of our board of directors since July 2017. Mr. Fitzgerald has worked as an independent business advisor since 2016, and previously served as a member of the board of directors of Akcea Therapeutics, Inc. (formerly NASDAQ GS: AKCA) from May 2017 to April 2020 and a member of the advisory board of Analgesic Solutions, LLC from May 2016 to April 2019. Mr. Fitzgerald previously served as Chief Financial Officer and Treasurer of ARIAD Pharmaceuticals, Inc. (NASDAQ: ARIA) and Senior Vice President, Chief Financial Officer and Secretary at AltaRex, Inc. (formerly NYSE: AYY). Mr. Fitzgerald also held management roles at BankBoston Corporation and served as a Partner at Arthur Anderson & Co. Mr. Fitzgerald received a B.S. and an M.B.A. from Babson College and served on the college's board of trustees from 1997 to 2006, chairing its finance committee. We believe Mr. Fitzgerald is qualified to serve on our board of directors due to his extensive executive, financial and management experience, including his tenure as Chief Financial Officer of ARIAD Pharmaceuticals, Inc.

Rick Klausner, M.D. has served as a member of our board of directors since November 2022. Dr. Klausner is the founder and current Board Chair of Lyell Immunopharma, Inc. (NASDAQ GS: LYEL) and was previously its Chief Executive Officer from September 2018 to July 2020 and Executive Chairman from August 2020 to October 2021. Dr. Klausner is the founder and co-chair of Altos Labs, Inc. a private life sciences company. He is the President of the Milky Way Research Foundation and founder and Managing Partner of Milky Way Investments. He was the founder and Director of Juno Therapeutics Inc. (formerly NASDAQ: JUNO) and the founder and Director of GRAIL LLC (NASDAQ GS: GRAL). He is the Chairman of Sonoma Biotherapeutics, Co-Founder and Chairman of LifeMine Therapeutics Inc. and Board member of Ohalo Genetics Inc. He is the former Senior Vice President, Chief Medical Officer, and Chief Opportunity Officer of Illumina Inc. (NASDAQ: ILMN). Previously, he was Executive Director for Global Health of the Bill and Melinda Gates Foundation. Dr. Klausner was appointed by Presidents Clinton and Bush as the eleventh Director of the U.S. National Cancer Institute between 1995 and 2001. Dr. Klausner served as chief of the Cell Biology and Metabolism Branch of the National Institute of Child Health and Human Development and a past president of the American Society of Clinical Investigation. Dr. Klausner earned an M.D. from Duke Medical School and a B.S. from Yale University. We believe that Dr. Klausner's scientific and medical expertise, particularly in cell biology, molecular biology and cancer, as well as his industry, academic and public service leadership roles, make him an appropriate member of our board of directors.

Alan M. Sebulsky has served as a member of our board of directors since May 2026. Mr. Sebulsky has served as the Managing Member of Apothecary Capital LLC since its reestablishment in April 2026. Mr. Sebulsky previously served as a Partner and Portfolio Manager at Adage Capital Management, LP. from July 2012 to April 2026, where he was responsible for managing a biopharmaceutical portfolio. Prior to that Mr. Sebulsky served as a Portfolio Manager at BBT Capital Management Advisory LLC from April 2003 to March 2012, through his role as the Managing Partner of Apothecary Capital LLC over the same period. From 1994 to 2002, Mr. Sebulsky held various positions, most recently as a Managing Director, at Lincoln Capital Management, a private investment management firm, where he was responsible for investments in the healthcare industry. Mr. Sebulsky previously served as a director of Jazz Pharmaceuticals PLC (NASDAQ: JAZZ) and Arrow International, Inc. (formerly NASDAQ: ARRO). Mr. Sebulsky received a B.B.A. and an M.S. from the University of Wisconsin, Madison. We believe Mr. Sebulsky is qualified to serve on our board of directors due to his experience and perspective as a former Wall Street healthcare stock analyst and an investor who actively follows the healthcare industry and previously managed a dedicated healthcare investment fund.

Jake Simson, Ph.D., has served as a member of our board of directors since January 2026. Since December 2020, Dr. Simson has served as a Partner of RA Capital Management, L.P., a life sciences investment advisor. Dr. Simson previously served as an associate, analyst and principal at RA Capital Management, L.P. from July 2013 to December 2020. Dr. Simson serves as a member of the board of directors of Tyra Biosciences Inc, a public biotechnology company (NASDAQ GS: TYRA), Janux Therapeutics, Inc, a public biopharmaceutical company (NASDAQ: JANX), Septerna, Inc., a public biotechnology company (NASDAQ: SEPN), and Bicara Therapeutics Inc., a public biotechnology company (NASDAQ: BCAX). Dr. Simson also served on the board of directors of DICE Therapeutics, Inc., a biotechnology company (NASDAQ: DICE), from December 2020 until it was acquired by Eli Lilly and Company (NYSE: LLY) in August 2023. Dr. Simson also serves on the boards of directors of various private companies. Dr. Simson received his Ph.D. in Biomedical Engineering from Johns Hopkins University and his S.B. in Materials Science and Engineering from Massachusetts Institute of Technology. We believe Dr. Simson is qualified to serve on our board of directors due to his experience serving as a director for several private and public life science companies and his experience in the life sciences investment industry.

Barbara Weber, M.D. has served as a member of our board of directors since October 2018. Dr. Weber has served as Executive Chairman of Tango Therapeutics, Inc. (NASDAQ: TNGX) since January 2026, and was previously President and Chief Executive Officer and a member of the board of directors of Tango Therapeutics, Inc. from March 2017 to January 2026. Dr. Weber was a Venture Partner at Third Rock Ventures from March 2015 until June 2022. Previously, Dr. Weber served as Senior Vice President, Oncology Translational Medicine, Novartis (SIX: NVS) from 2009 to 2015, Vice President, Oncology at GSK Plc (LSE: GSK) from 2005 to 2009 and Professor, Medicine and Genetics at the University of Pennsylvania from 1994 to 2005. Dr. Weber served on the board of directors of Revolution Medicines, Inc. (NASDAQ: RVMD), a biotechnology company, from April 2018 until June 2025. Dr. Weber previously served as a director of OPY Acquisition Corp. I (NASDAQ: OHAA), a special purpose acquisition company. Dr. Weber received a B.S. in Chemistry and an M.D. from the University of Washington, was a resident in internal medicine at Yale University and a fellow in medical oncology at the Dana Farber Cancer Institute. We believe Dr. Weber is qualified to serve on our board based on her position as President and Chief Executive Officer of Tango Therapeutics, Inc. and her extensive leadership experience in the biopharmaceutical industry.

Krishna Yeshwant, M.D. has served as a member of our board of directors since April 2018. Dr. Yeshwant has served as a general partner at GV Management Co. LLC, a venture capital firm, since June 2009 and has been working with GV since June 2008. Dr. Yeshwant was previously employed by Partners Healthcare, a not-for-profit health care system, as an internal medicine physician at The Brigham and Women's Hospital from 2009 to 2021. Before joining GV, Dr. Yeshwant helped start Stanford Students Consulting, an electronic data interchange company that was acquired by The Hewlett-Packard Company in 2000. In 2000, he was part of the early team at Recourse Technologies, Inc., a network security company that was acquired by Symantec Corporation in 2002. Dr. Yeshwant previously served on the board of directors of Foundation Medicine, Inc. (formerly NASDAQ: FMI), a molecular information company, from 2011 to July 2018, on the board of directors of EQRx, Inc. (formerly NASDAQ: EQRX), a biotechnology company that was acquired by Revolution Medicines, Inc. in 2023, from January 2020 to November 2023, and on the board of directors of Verve Therapeutics, Inc. (formerly NASDAQ: VERV), a biotechnology company that was acquired by Eli Lilly and Company in 2025, from August 2018 to July 2025. Dr. Yeshwant received a B.S. in computer science from Stanford University, an M.D. from Harvard Medical School and an M.B.A. from Harvard Business School. We believe Dr. Yeshwant is qualified to serve on our board of directors because of his medical experience as a physician, his experience working with and serving on the boards of directors of life sciences companies and his experience working in the venture capital industry.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Composition of Our Board of Directors

Our business and affairs are managed under the direction of our board of directors, which currently consists of eight members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Certain members of our board of directors were elected under the provisions of our sixth amended and restated certificate of incorporation and agreements with our stockholders, which agreements are described under the section of this prospectus entitled "*Certain Relationships and Related Person Transactions*." Subject to and under the terms of our sixth amended and restated certificate of incorporation and our fifth amended and restated voting agreement, the stockholders who are party to our fifth amended and restated voting agreement agreed to vote their respective shares to elect: (i) one person designated by the holders of at least 75% of our Series A preferred stock then outstanding, currently vacant, (ii) one person designated by GV 2017, L.P., currently Krishna Yeshwant, M.D., (iii) one person designated by venBio Global Strategic Fund III, L.P., currently vacant, (iv) one person designated by Milky Way Investments Group Limited, currently Rick Klausner, M.D., (v) one person designated by Nextech VIII Oncology SCSp, currently Alexis Borisy, (vi) one person designated by RA Capital Healthcare Fund, L.P. and RA Capital Nexus Fund III, L.P., currently Jake Simson, Ph.D. (vii) our Chief Executive Officer, currently Mathai Mammen, M.D., Ph.D., and (viii) up to three individuals to serve as independent directors, currently Edward Fitzgerald, Alan M. Sebulsky and Barbara Weber, M.D. These board composition provisions will terminate upon the closing of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance committee's and our board of directors' priority in selecting board members is the identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, professional and personal experiences, and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our seventh amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, and our amended and restated bylaws, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Staggered Board

Our seventh amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, and our amended and restated bylaws, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, will permit our board of directors to establish the authorized number of directors from time to time by resolution. Each director serves until the expiration of the term for which such director was elected or appointed, or until such director's earlier death, resignation or removal. In accordance with our seventh amended and restated certificate of incorporation, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be Edward Fitzgerald, Rick Klausner and Barbara Weber, and their terms will expire at our first annual meeting of stockholders following this offering, to be held in 2027;
- the Class II directors will be Jake Simson and Krishna Yeshwant, and their terms will expire at our second annual meeting of stockholders following this offering, to be held in 2028; and
- the Class III directors will be Alexis Borisy, Mathai Mammen and Alan Sebulsky, and their terms will expire at our third annual meeting of stockholders following this offering, to be held in 2029.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

This classification of our board of directors may have the effect of delaying or preventing changes in control of our company.

Director Independence

Under the listing standards, requirements and rules of The Nasdaq Stock Market LLC ("Nasdaq Listing Rules"), independent directors must comprise a majority of our board of directors as a listed company within one year of the listing date.

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning her or his background, employment, and affiliations, including family relationships, our board of directors has determined that Alexis Borisy, Edward Fitzgerald, Rick Klausner, Alan Sebulsky, Jake Simson, Barbara Weber and Krishna Yeshwant do not have relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Nasdaq Listing Rules. Our board of directors has determined that Dr. Mammen, by virtue of his employment relationship with us, is not independent under applicable rules and regulations of the SEC and the Nasdaq Listing Rules. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director and the transactions described in the section titled "*Certain Relationships and Related Person Transactions*." Upon the completion of this offering, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of Nasdaq and the rules and regulations of the SEC.

Board Policies

In connection with this offering, we have adopted policies and procedures for director candidates for our nominating and corporate governance committee, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, which will provide for factors, such as a candidate's character, judgment, skills, education, expertise, and absence of conflicts of interest, that should be considered in determining director candidates. Our priority in selection of board members will be identification of members who will further the interests of our stockholders through their established records of professional accomplishment, their ability to contribute positively to the collaborative culture among board members, and their knowledge of our business and understanding of the competitive landscape in which we operate and adherence to high ethical standards.

Board Leadership Structure

Our board of directors recognizes that one of its key responsibilities is to evaluate and determine its optimal leadership structure so as to provide effective oversight of management. Our bylaws and corporate governance guidelines will provide our board of directors with flexibility to combine or separate the positions of Chairman of our board of directors and Chief Executive Officer. Our board of directors currently believes that our Chief Executive Officer is best situated to serve as Chairman because he is the director who is most familiar with our business and industry and possesses detailed and in-depth knowledge of the issues, opportunities and challenges facing us and is therefore best positioned to ensure that our board of directors' time and attention are focused on the most critical matters. Our independent directors bring experience, oversight and expertise from outside the Company and industry, while the Chief Executive Officer brings Company-specific experience and expertise. Our board of directors believes that the combined role of Chairman and Chief Executive Officer facilitates information flow between management and the board of directors, which is essential to effective governance.

On May 28, 2026, Alexis Borisy was appointed, effective upon the effectiveness of the registration statement of which this prospectus forms a part, as our Lead Independent Director. The duties of our Lead Independent Director include (i) presiding at all meetings of our board of directors at which the Chairman of our board of directors is not present and leading executive sessions of the independent directors; (ii) providing input on board of directors agendas and materials in advance of meetings of our board of directors; (iii) if requested by stockholders, ensuring that our Lead Independent Director is available for consultation and direct communication; and (iv) performing such other functions as our board of directors may delegate to our Lead Independent Director from time to time. Our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Board's Role in Risk Oversight

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our financial condition, development and commercialization activities, operations, strategic direction, and intellectual property as more fully discussed in the section titled "*Risk Factors*" appearing elsewhere in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees below and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairperson of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Committees of Our Board of Directors

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Our board of directors has adopted written charters for each committee, which will be effective upon the closing of this offering, that satisfy the applicable rules and regulation of the SEC, the Sarbanes-Oxley Act and the Nasdaq Listing Rules.

Our board of directors has also established a science and technology committee of the board of directors that will operate under a charter duly adopted by the board of directors.

We will post the written charters to our website at www.parabilismed.com upon the completion of this offering. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

Our audit committee consists of Edward Fitzgerald, Alan M. Sebulsky and Barbara Weber, and the chair of our audit committee is Edward Fitzgerald. Our board of directors has determined that each member of the audit committee is independent under Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Exchange Act and can read and understand fundamental financial statements in accordance with applicable requirements. Our board of directors has also determined that Edward Fitzgerald is an “audit committee financial expert” within the meaning of SEC regulations. In arriving at these determinations, our board of directors has examined each audit committee member’s scope of experience and the nature of their employment in the corporate finance sector. Both our independent registered public accounting firm and management will periodically meet privately with our audit committee.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our corporate accounting and financial reporting processes, systems of internal control and financial-statement audits, and to oversee our independent registered public accounting firm. Specific responsibilities of our audit committee include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending based upon the audit committee’s review and discussions with management and our independent registered public accounting firm whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

Compensation Committee

Our compensation committee consists of Rick Klausner, Barbara Weber and Krishna Yeshwant, and the chair of our compensation committee is Krishna Yeshwant. Our board of directors has determined that each member of the compensation committee is independent under the Nasdaq Listing Rules and is a “non-employee director” as defined in Rule 16b-3 under the Exchange Act.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors in overseeing our compensation policies, plans, and programs and to review and determine the compensation to be paid to our executive officers, directors, and other senior management, as appropriate. Specific responsibilities of our compensation committee include:

- annually reviewing and recommending to the board of directors the corporate goals and objectives relevant to the compensation of our Chief Executive Officer;
- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and based on such evaluation (i) reviewing and determining the cash compensation of our Chief Executive Officer and (ii) reviewing and approving grants and awards to our Chief Executive Officer under equity-based plans;
- reviewing and approving the compensation of our other executive officers;

- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq listing rules;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors;
- preparing our compensation committee report if and when required by SEC rules;
- reviewing and discussing annually with management our “Compensation Discussion and Analysis,” if and when required, to be included in our annual proxy statement; and
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Alexis Borisy, Alan M. Sebulsky and Jake Simson, and the chair of our nominating and corporate governance committee is Alexis Borisy. Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the Nasdaq Listing Rules, a non-employee director, and free from any relationship that would interfere with the exercise of his or her independent judgment.

The primary purpose of the nominating and corporate governance committee is to discharge the responsibilities of our board of directors with respect to our corporate governance functions and to identify, communicate with, evaluate and recommend candidates for our board of directors. Specific responsibilities of our nominating and corporate governance committee include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board’s committees;
- developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines; and
- overseeing the evaluation of our board of directors and management.

Science and Technology Committee

The science and technology committee, which consists of Alexis Borisy, Rick Klausner, Barbara Weber and Krishna Yeshwant, and is chaired by Rick Klausner, supports board oversight of our research and development, and manufacturing and supply activities, by providing a forum for review of strategic considerations and issues in such areas, as well as to evaluate relevant emerging technology and advances in our field.

Code of Business Conduct and Ethics

In connection with this offering, we have adopted an amended written code of business conduct and ethics, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, that will apply to all our employees, officers, and directors. This includes our principal executive officer, principal financial officer, and principal accounting officer or controller, or persons performing similar functions. The full text of our code of business conduct and ethics will be posted on our website at www.parabilismed.com. We intend to disclose on our website any future amendments of our code of business conduct and ethics or waivers that exempt any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions, or our directors from provisions in the code of business conduct and ethics. The

information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our officers or employees. None of our officers currently serve, or have served during the last calendar year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Limitations on Liability and Indemnification Agreements

As permitted by Delaware law, provisions in our seventh amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, and our amended and restated bylaws which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, limit or eliminate the personal liability of directors and officers for a breach of their fiduciary duty of care as a director or officer. The duty of care generally requires that, when acting on behalf of the corporation, a director and or officer exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, a director or officer will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director or officer, except for liability for:

- any breach of the director or officer's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- for our directors, unlawful payments of dividends or unlawful stock repurchases, or redemptions as provided in Section 174 of the Delaware General Corporation Law ("DGCL");
- for our officers, any derivative action by or in the right of the corporation; or
- any transaction from which the director or officer derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions do not alter a director or officer's liability under other laws, such as the federal securities laws or other state or federal laws. Our seventh amended and restated certificate of incorporation that will become effective upon the closing of this offering also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated bylaws will also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our amended and restated bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification that will be provided for in our seventh amended and restated certificate of incorporation and amended and restated bylaws, we have entered into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification provisions contained in the DGCL. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our seventh amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

EXECUTIVE COMPENSATION

The following discussion contains forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. The actual amount and form of compensation and the compensation policies and practices that we adopt in the future may differ materially from currently planned programs as summarized in this discussion.

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to “smaller reporting companies” as such term is defined in the rules promulgated under the Securities Act. Our named executive officers (“NEOs”) for the year ended December 31, 2025 consist of (i) our principal executive officer; (ii) our two most highly compensated executive officers (other than our Chief Executive Officer) who were serving as our executive officers on December 31, 2025 and (iii) our former Chief Medical Officer, who would have been one of our two most highly compensated executive officers (other than our Chief Executive Officer) but for the fact that he was no longer serving as an executive officer on December 31, 2025. Our former Chief Medical Officer resigned as our Chief Medical Officer effective April 11, 2025, and our current Chief Medical Officer commenced employment as our Chief Medical Officer effective September 2, 2025. Accordingly, our NEOs for the fiscal year ended December 31, 2025 are:

- Mathai Mammen, M.D., Ph.D., our President, and Chief Executive Officer;
- Fawzi Benzaghrou, M.D., our Chief Medical Officer;
- Teresa Jurgensen, J.D., our General Counsel; and
- Keith Orford, M.D., Ph.D., our former Chief Medical Officer.

To date, the compensation of our NEOs has primarily consisted of a combination of base salary, annual cash incentive compensation, and long-term incentive compensation, as described in more detail below. Our executive officers, like all full-time employees, are eligible to participate in our health, welfare and retirement benefit plans. As we transition from a private company to a publicly traded company, we intend to evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require.

2025 Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by, or paid to our NEOs for services rendered to us in all capacities during the fiscal year ended December 31, 2025.

Name and principal position	Year	Salary (\$)	Bonus (\$)(1)	Option awards (\$)(2)	Non-equity incentive plan compensation (\$)	All other compensation (\$)	Total (\$)
Mathai Mammen, M.D., Ph.D. <i>President & Chief Executive Officer</i>	2025	784,840	496,411	—	—	14,000 ⁽³⁾	1,295,251
Fawzi Benzaghrou, M.D. <i>Chief Medical Officer</i> ⁽⁴⁾	2025	198,904	206,496 ⁽⁵⁾	671,354	—	2,769 ⁽³⁾	1,079,523
Teresa Jurgensen, J.D. <i>General Counsel</i>	2025	464,100	213,486	—	—	14,000 ⁽³⁾	691,586
Keith Orford, M.D., Ph.D. <i>Former Chief Medical Officer</i> ⁽⁶⁾	2025	168,566	—	1,486 ⁽⁷⁾	—	613,688 ⁽⁸⁾	783,740

(1) The amounts reported represent the annual discretionary bonuses each NEO earned during the applicable fiscal year based on achievement of company performance, which were paid in the first quarter of the following fiscal year.

(2) Except as set forth below, the amounts reported in this column represent the aggregate grant date fair value of stock options awarded to our NEOs in the applicable fiscal year, calculated in accordance with the Financial Accounting Standards Board Accounting Standards Codification Topic 718, or FASB ASC Topic 718, disregarding estimated forfeitures related to service-based vesting. The assumptions used in calculating the grant date fair values are set forth in Note 8 of our consolidated audited financial statements for fiscal year 2025, included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for the options and do not correspond to the actual economic value that may be received by our NEOs upon the exercise of the options or any sale of the underlying shares.

- (3) The amounts reported reflect matching contributions under our 401(k) plan for the applicable NEO.
- (4) Dr. Benzaghoughou commenced employment with the Company on September 2, 2025 and his annual base salary and annual bonus for fiscal year 2025 were pro-rated accordingly.
- (5) The amount reported includes a \$115,000 sign-on bonus paid to Dr. Benzaghoughou pursuant to his sign-on bonus agreement in connection with his commencement of employment, as further described under the section titled “Employment Arrangements in Place Prior to the Offering with our NEOs” below.
- (6) Dr. Orford resigned as our Chief Medical Officer effective April 11, 2025 and his annual base salary for fiscal year 2025 was pro-rated accordingly. Dr. Orford’s salary for fiscal year 2025 includes \$19,353 in accrued paid time off paid in connection with Dr. Orford’s separation from the Company.
- (7) The amount reported represents the incremental fair value, calculated in accordance with FASB ASC Topic 718, related to the acceleration of vesting of certain equity awards held by Dr. Orford in connection with his separation from the Company, as further described under the section titled “Employment Arrangements in Place Prior to the Offering with our NEOs” below.
- (8) The amount reported includes matching contributions under our 401(k) plan (\$12,233) and severance payments (\$601,455) payable to Dr. Orford in connection with his separation from the Company, as further described under the section titled “Employment Arrangements in Place Prior to the Offering with our NEOs” below.

Narrative Disclosure to the 2025 Summary Compensation Table

Elements of Compensation

The compensation of our NEOs generally consists of three key elements: (i) base salary; (ii) annual cash bonus opportunities; and (iii) long term incentive compensation in the form of equity awards.

Annual Base Salaries

The annual base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive’s skill set, experience, role, responsibilities, and contributions. Each NEO’s initial annual base salary was specified in their offer letter or employment agreement, as described below, and is reviewed (and, if applicable, adjusted) from time to time by our board of directors or compensation committee thereof.

For the fiscal year ended December 31, 2025, the annual base salaries for Dr. Mammen, Dr. Benzaghoughou, Ms. Jurgensen and Dr. Orford were \$784,840, \$600,000, \$464,100 and \$539,235 respectively. Dr. Orford resigned as our Chief Medical Officer effective April 11, 2025 and Dr. Benzaghoughou commenced employment as our Chief Medical Officer effective September 2, 2025. As a result, their base salaries for fiscal year 2025 were pro-rated accordingly.

2025 Bonuses

Annual Discretionary Cash Bonus Opportunities

For the fiscal year ended December 31, 2025, each of our NEOs was eligible to earn an annual discretionary bonus based on the Company’s achievement of certain performance objectives. The 2025 target annual bonuses for Dr. Mammen, Dr. Benzaghoughou, Ms. Jurgensen and Dr. Orford were 55%, 40%, 40% and 40% of their annual base salaries, respectively. Dr. Benzaghoughou’s 2025 bonus was prorated based on his partial year of employment with us in 2025.

Pursuant to our bonus program, each NEO’s annual cash bonus for 2025 was determined by reference to the Company’s achievement of certain performance milestones relating to pre-determined clinical, financial, organizational, and pipeline goals. Following a review of our 2025 performance, our board of directors determined that we had achieved our 2025 goals at 115% and approved 2025 annual discretionary cash bonuses to Dr. Mammen, Dr. Benzaghoughou and Ms. Jurgensen equal to 115% of their respective target annual bonuses.

Dr. Orford was not paid an annual discretionary cash bonus for fiscal year 2025 because his employment with the Company ended in April 2025.

Other Bonuses

In connection with Dr. Benzaghoul's commencement of employment, he was entitled to a one-time sign-on bonus equal to \$100,000 multiplied by our 2025 corporate bonus multiplier, payable in a lump sum at the same time that 2025 annual discretionary cash bonuses are paid to other executives. Dr. Benzaghoul received his sign-on bonus payment of \$115,000 on March 6, 2026. Dr. Benzaghoul's sign-on bonus is subject to full repayment if he voluntarily terminates employment for any reason within 12 months following his start date. If Dr. Benzaghoul voluntarily terminates his employment for any reason within months 13 to 24 following his start date, he is required to repay a monthly pro-rated portion of this sign-on bonus.

Equity-based Compensation

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants promote executive retention because they incentivize our executive officers to remain in our employment during the vesting period.

Accordingly, our board of directors or our compensation committee, as applicable, periodically reviews the equity incentive compensation of our NEOs and may grant equity incentive awards to them from time to time. See "—Outstanding Equity Awards at 2025 Fiscal Year-End" for more information regarding equity awards made to our NEOs.

Perquisites/Personal Benefits

Perquisites or other personal benefits are not a significant component of our executive compensation program. Accordingly, we do not provide significant perquisites or other personal benefits to our executive officers, including our NEOs.

401(k) Plan

We currently maintain a tax-qualified 401(k) retirement savings plan for our employees, including our NEOs, who satisfy certain eligibility requirements. Our NEOs are eligible to participate in the 401(k) plan on the same terms as other full-time employees. Our 401(k) plan is intended to qualify for favorable tax treatment under Section 401(a) of the Internal Revenue Code of 1986, as amended (the "Code"), and contains a cash or deferred feature that is intended to meet the requirements of Section 401(k) of the Code. We make matching contributions equal to 100% of employee deferrals of up to 4% of eligible compensation.

Compensation Recovery Policy

In accordance with the requirements of the SEC and Nasdaq Listing Rules, our board of directors adopted a compensation recovery policy, which became effective upon the date on which the registration statement of which this prospectus is part was declared effective by the SEC. The compensation recovery policy will provide that in the event we are required to prepare a restatement of financial statements due to material noncompliance with any financial reporting requirement under securities laws, we will seek to recover any incentive-based compensation that was based upon the attainment of a financial reporting measure and that was received by any current or former executive officer during the three-year period preceding the date that the restatement was required if such compensation exceeds the amount that the executive officers would have received based on the restated financial statements.

Outstanding Equity Awards at 2025 Fiscal Year-End

The following table provides information regarding the outstanding equity awards held by our NEOs as of December 31, 2025. All awards were granted pursuant to the 2016 Employee, Director and Consultant Incentive Plan, as amended from time to time (the “2016 Plan”). See “—Equity Incentive Plans—2016 Plan” below for additional information.

Name	Option Awards						
	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date
Mathai Mammen, M.D. Ph.D.	4/21/2023	—	—	—	419,506 ⁽¹⁾	3.43	4/20/2033
	4/21/2023	3/16/2023	1,634,325 ⁽²⁾	742,876 ⁽²⁾		3.43	4/20/2033
	3/28/2024	3/28/2024	259,202 ⁽³⁾	333,260 ⁽³⁾		1.48	3/27/2034
	3/28/2024	3/28/2024	258,536 ⁽⁴⁾	332,403 ⁽⁴⁾		1.48	3/27/2034
Fawzi Benzaghrou, M.D.	9/11/2025	9/2/2025	—	357,398 ⁽²⁾		2.42	9/10/2035
Teresa Jurgensen, J.D.	9/5/2024	8/1/2024	71,479 ⁽²⁾	142,959 ⁽²⁾		1.88	9/4/2034
Keith Orford, M.D., Ph.D. ⁽⁵⁾	—	—	—	—		—	—

- (1) This award vests on the effective date of the sale and issuance of the Company’s capital stock in one or more related financings primarily for equity financing purposes in which an aggregate of at least \$100,000,000 worth of capital stock is issued and sold by the Company at a price per share of at least \$33.1267 per share or other financial transaction that generates equivalent value for the Company as determined by our board of directors, or other sufficient value for which vesting is deemed appropriate by our board of directors (a “Qualified Financing”), provided that Dr. Mammen remains employed by the Company as the Chief Executive Officer on the effective date of a such Qualified Financing; provided further that, in the event that a change in control (as defined in Dr. Mammen’s offer letter, further described below) occurs while he is employed by the Company as the Chief Executive Officer, all unvested shares shall vest in full on the date of consummation of such change in control. Dr. Mammen’s award is also subject to certain acceleration of vesting rights as set forth in his Amended Employment Agreement (as defined below) and the Severance Plan (as defined below), as described below.
- (2) The shares underlying this award vest as follows: 25% on the first anniversary of the Vesting Commencement Date, with the remainder vesting in 36 equal monthly installments over the following three years, subject to the applicable NEO’s continued service through the applicable vesting date. The award is also subject to certain acceleration of vesting rights as set forth in the applicable NEO’s Amended Employment Agreement and the Severance Plan, as described below.
- (3) The shares underlying this award vest in equal monthly installments over four years from the Vesting Commencement Date, subject to the applicable NEO’s continued service through the applicable vesting date. The award is also subject to certain acceleration of vesting rights as set forth in the applicable NEO’s Amended Employment Agreement and the Severance Plan, as described below.
- (4) The shares underlying this award are subject to both performance- and time-vesting conditions. The performance-vesting condition, which was met on January 22, 2025, required the Company to close the second tranche of its Series E preferred stock financing. After satisfaction of this condition, the award vests in equal monthly installments over four years from the Vesting Commencement Date, subject to Dr. Mammen’s continued service through the applicable vesting date. The award is also subject to certain acceleration of vesting rights as set forth in Dr. Mammen’s Amended Employment Agreement and the Severance Plan, as described below.
- (5) All unvested options held by Dr. Orford upon his termination of employment on April 11, 2025 were forfeited at such time for no consideration. All of Dr. Orford’s vested options subsequently expired on July 10, 2025 without being exercised.

Employment Arrangements in Place Prior to the Offering with our NEOs

Mathai Mammen, M.D., Ph.D.

On March 12, 2023, we entered into an employment agreement with Dr. Mammen (the “Mammen Offer Letter”), for the position of our President and Chief Executive Officer. The Mammen Offer Letter provides for Dr. Mammen’s at-will employment and sets forth his initial annual base salary, an initial target annual bonus opportunity, and an initial equity incentive award in the form of stock options.

The Mammen Offer Letter provides for severance benefits upon a termination of Dr. Mammen’s employment by us without cause or his resignation for good reason (each, a “Qualifying Termination”), subject to Dr. Mammen’s execution and delivery of an irrevocable separation agreement, including a general release of claims in the Company’s favor, consisting of: (i) continuation of base salary for 12 months, payable in substantially equal installments over 12 months (or, in the event of a Qualifying Termination occurring on or within 12 months following a change in control (as defined in the Mammen Offer Letter), a lump sum payment equal to 1.5 times the sum of Dr. Mammen’s annual base salary plus target bonus); (ii) payment of COBRA premiums for up to 18 months following such termination, and if Dr. Mammen remains eligible for COBRA at the end of such 18-month period and he is still not eligible for health benefits under another employer’s group medical plan, he is entitled to an additional lump sum payment equal to six months of employer health insurance contributions the Company would have made if he had remained employed by the Company; (iii) 12 months of accelerated vesting of outstanding time-based equity awards; and (iv) any earned but unpaid prior-year bonus and a pro rata bonus for the year of termination based on actual Company performance. In addition, the Mammen Offer Letter provides that, upon any termination of employment other than for cause, the post-termination exercise period for Dr. Mammen’s vested stock options will continue until the earlier of 24 months following termination or the original 10-year expiration date. The Mammen Offer Letter also provides that (i) all unvested shares subject to Dr. Mammen’s initial option grant and the option that would vest upon a Qualified Financing (as defined in the Mammen Offer Letter) will fully vest upon a change in control occurring within three months following a termination of Dr. Mammen’s employment without cause, and (ii) the options which would vest upon a Qualified Financing will fully vest in the event such Qualified Financing occurs within three months following a termination of Dr. Mammen’s employment without cause. Finally, in the event Dr. Mammen’s employment by the Company is terminated due to death or disability, he will be entitled to any unpaid bonus earned for the previous performance year and a prorated bonus for the year in which such termination occurs based on the Company’s actual performance with any individual performance goals deemed fully satisfied.

The payments and benefits provided to Dr. Mammen in connection with a change in control may not be eligible for a federal income tax deduction for the company pursuant to Section 280G of the Code, and may subject Dr. Mammen to an excise tax under Section 4999 of the Code. If the payments or benefits payable to Dr. Mammen in connection with a change in control would be subject to the excise tax on golden parachutes imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to Dr. Mammen.

Fawzi Benzaghrou, M.D.

On July 7, 2025, we entered into an employment agreement with Dr. Benzaghrou (the “Benzaghrou Offer Letter”), for our position of our Chief Medical Officer. The Benzaghrou Offer Letter provides for Dr. Benzaghrou’s at will employment and sets forth his initial annual base salary, an initial target annual bonus opportunity, and an initial equity incentive award in the form of stock options. In addition, we entered into a sign-on bonus agreement in connection with Dr. Benzaghrou’s commencement of employment, dated as of July 7, 2025, that provides a one-time sign-on bonus equal to \$100,000, multiplied by our 2025 corporate bonus multiplier and payable in a lump-sum at the same time that 2025 annual discretionary cash bonuses are paid to other executives. Dr. Benzaghrou received his sign-on bonus payment of \$115,000 on March 6, 2026. The sign-on bonus is subject to full repayment if Dr. Benzaghrou voluntarily terminates employment for any reason within 12 months following his start date. If Dr. Benzaghrou voluntarily terminates his employment for any reason within months 13 to 24 following his start date, he is required to repay a monthly pro-rated portion of this sign-on bonus.

The Benzaghrou Offer Letter provides for severance benefits upon a termination of Dr. Benzaghrou’s employment by us without cause or his resignation for good reason, subject to his execution of a separation agreement and general release of claims in a form satisfactory to the Company, consisting of: (i) continuation of base salary for 12 months, paid in accordance with the Company’s customary payroll practices and (ii) payment of the portion of COBRA premiums equal to the employer portion of premiums the Company pays for coverage of active and similarly situated employees who receive the same type of coverage for up to 12 months, subject to earlier cessation upon his eligibility for other substantially equivalent health coverage in connection with new employment or self-employment. In addition, the Benzaghrou Offer Letter provides for full acceleration of vesting of the unvested portion of his initial equity incentive award in the event of a termination by the Company without cause or by Dr. Benzaghrou for good reason, in each case occurring on or within 12 months following a change in control.

Teresa Jurgensen, J.D.

On June 11, 2024, we entered into an employment agreement with Ms. Jurgensen (the “Jurgensen Offer Letter”). The Jurgensen Offer Letter provides for Ms. Jurgensen’s at-will employment and sets forth her initial annual base salary, an initial target annual bonus opportunity, and an initial equity incentive award in the form of stock options.

The Jurgensen Offer Letter provides for severance benefits upon a termination of Ms. Jurgensen’s employment by us without cause or her resignation for good reason, subject to her execution of a separation agreement and general release of claims in a form satisfactory to the Company, consisting of: (i) continuation of base salary for 12 months, paid in accordance with the Company’s customary payroll practices; (ii) payment of the portion of COBRA premiums equal to the employer portion of premiums the Company pays for coverage of active and similarly situated employees who receive the same type of coverage for up to 12 months, subject to earlier cessation upon her eligibility for other substantially equivalent health coverage in connection with new employment or self-employment; and (iii) any earned but unpaid prior-year bonus and the target bonus for the year of termination prorated to the period of full-time service provide to the Company in the year of termination, with such bonus payments to be paid on the first date of payment of the severance base salary described in (i) of this sentence. In addition, the Jurgensen Offer Letter provides for full acceleration of vesting of the unvested portion of time-vesting options held by Ms. Jurgensen in the event of a termination by the Company without cause or by Ms. Jurgensen for good reason, in each case occurring on or within 12 months following a change in control.

Keith Orford, M.D., Ph.D.

On June 2, 2021, we entered into an offer letter with Dr. Orford, which was superseded by a new offer letter entered into on March 28, 2024 (the “2024 Orford Offer Letter”). The 2024 Orford Offer Letter provides for Dr. Orford’s at will employment and sets forth his then-current annual base salary, then-current target annual bonus opportunity, and eligibility for equity incentive awards in the form of stock options.

The 2024 Orford Offer Letter provides for severance benefits upon a termination of Dr. Orford’s employment by us without cause or his resignation for good reason, subject to his execution of a separation agreement and general release of claims in a form satisfactory to the Company, consisting of: (i) continuation of base salary for 12 months, paid in accordance with the Company’s customary payroll practices; (ii) payment of the portion of COBRA premiums equal to the employer portion of premiums the Company pays for coverage of active and similarly situated employees who receive the same type of coverage for up to 12 months, subject to earlier cessation upon his eligibility for other substantially equivalent health coverage in connection with new employment or self-employment; and (iii) any earned but unpaid prior-year bonus and the target bonus for the year of termination prorated to the period of full-time service provide to the Company in the year of termination, with such bonus payments to be paid on the first date of payment of the severance base salary described in (i) of this sentence. In addition, the 2024 Orford Offer Letter provides for full acceleration of vesting of the unvested portion of time-vesting options held by Dr. Orford in the event of a termination by the Company without cause or by Dr. Orford for good reason, in each case occurring on or within 12 months following a change in control.

On February 26, 2025, we entered into a separation and release agreement with Dr. Orford in connection with his departure from the Company in his role as Chief Medical Officer (the “Orford Separation Agreement”). Pursuant to the Orford Separation Agreement, Dr. Orford received (i) 12 months of his base salary to be paid in substantially equal installments in accordance with our payroll practice over 12 months, (ii) subject to Dr. Orford’s copayment of premium amounts at the applicable active employees’ rate and proper election to continue COBRA health coverage, payment of the portion of the premium equal to the amount that the Company would have paid to provide health insurance to Dr. Orford had he remained employed with the Company until the earliest of: (x) the first anniversary of the date of termination; (y) Dr. Orford’s eligibility for group medical plan benefits under any other employer’s group medical plan or otherwise through other employment; or (z) the cessation of Dr. Orford’s continuation coverage rights under COBRA; and (iii) a payment in an amount equal to Dr. Orford’s target bonus for 2025, prorated based upon his date of termination and his earned, but not yet paid, 2024 target bonus, which will be payable on the date the of the first severance payment described above. In addition, the Orford Separation Agreement provides that Dr. Orford’s unvested equity awards granted on December 19, 2021 shall accelerate in vesting and become vested as of the later of (x) of Dr. Orford’s date of termination and (y) the effective date of the Orford Separation Agreement. The Orford Separation Agreement also contains a reaffirmation of Dr. Orford’s confidentiality and nonsolicitation obligations to the Company and a general release of claims by Dr. Orford.

Amended and Restated Employment Agreements

We have entered into new employment agreements with Dr. Mammen, Dr. Benzaghoul, and Ms. Jurgensen, effective as of and subject to the closing of this offering, (each, an “Amended Employment Agreement,” and collectively, the “Amended Employment Agreements”). The Amended Employment Agreements will supersede, in all respects, all prior employment arrangements and offer letters between each of Dr. Mammen, Dr. Benzaghoul, and Ms. Jurgensen and the Company.

Under the Amended Employment Agreements, each of Dr. Mammen, Dr. Benzaghoul, and Ms. Jurgensen will continue to serve in their respective roles on an at-will basis. The Amended Employment Agreements will provide for each of Dr. Mammen, Dr. Benzaghoul, and Ms. Jurgensen’s base salary, target annual bonus eligibility, and continued compliance with their applicable restrictive covenants agreements. In addition, though each such NEO will be eligible to participate in our Executive Severance Plan, as further described below, such NEO’s existing severance benefits, as described above in the applicable prior offer letters, will also continue to apply; provided, that each NEO is entitled to full acceleration of vesting of the unvested portion of time-vesting awards in the event of a termination by the Company without cause or by the applicable NEO for good reason, in each case occurring within the period beginning three months prior to and ending on the one-year anniversary following a change in control.

Executive Severance Plan

Our board of directors has adopted an Executive Severance Plan (the “Severance Plan”), subject to the effectiveness of this offering, in which our NEOs, and certain other executives, will participate. The benefits provided in the Severance Plan will not replace any severance arrangements for which our NEOs may be eligible under their Amended Employment Agreements or prior offer letters.

The Severance Plan will provide that upon a termination by us for any reason other than for “cause,” as defined in the Severance Plan, death or “disability,” as defined in the Severance Plan, or resignation for “good reason,” as defined in the Severance Plan, in each case outside of the change in control period (i.e., the period beginning three months before and ending one year after a “change in control,” as defined in the Severance Plan), an eligible participant will be entitled to receive, subject to the execution and delivery of an effective release of claims in favor of the Company and continued compliance with all applicable restrictive covenants, (i) 12 months of “base salary” (i.e., the annual base salary in effect immediately prior to the date of termination unless the eligible participant has resigned for good reason following a material diminution of the eligible participant’s annual base salary, in which case the “base salary” shall mean the annual base salary immediately prior to such diminution) for our Chief Executive Officer, 12 months for Tier 2 executives (which is determined by the plan administrator and includes the NEOs other than the Chief Executive Officer) and six months for Tier 3 executives (which is determined by the plan administrator) and (ii) an amount equal to the monthly employer contribution, based on the premiums as of the date of termination, that we would have made to provide health insurance for the eligible participant if he or she had remained employed by us until the earlier of (x) 12 months for our Chief Executive Officer, 12 months for Tier 2 executives and six months for Tier 3 executives, (y) the date that the eligible participant becomes eligible for group medical plan benefits under any other employer’s group medical plan, or (z) the cessation of the eligible participant’s health continuation rights under COBRA. The payments under (i) and (ii) will be paid in substantially equal installments in accordance with our payroll practice over 12 months for our Chief Executive Officer, 12 months for Tier 2 executives and six months for Tier 3 executives.

The Severance Plan will also provide that upon a (A) termination by us other than for cause, death or disability or (B) resignation for good reason, in each case within the change in control period, an eligible participant will be entitled to receive, in lieu of the payments and benefits above and subject to the execution and delivery of an effective release of claims in favor of the Company and continued compliance with all applicable restrictive covenants, (I) a lump sum amount equal to 18 months of the base salary and 1.5x of the “target bonus” (i.e., the higher of the target annual bonus in effect immediately prior to the date of termination or the target annual bonus in effect immediately prior to the change in control) for our Chief Executive Officer, 12 months of the base salary and 1.0x of the target bonus for our Tier 2 executives and nine months of the base salary and 0.75x target bonus for our Tier 3 executives, (II) a monthly cash payment in an amount equal to the monthly employer contribution, based on the premiums as of the date of termination, that we would have made to provide health insurance for the eligible participant if he or she had remained employed by us until (x) 18 months for our Chief Executive Officer, 12 months for our Tier 2 executives and nine months for our Tier 3 executives, (y) the date that the eligible participant becomes eligible for group medical plan benefits under any other employer’s group medical plan, or (z) the cessation of the eligible participant’s health continuation rights under the Consolidated Omnibus Budget Reconciliation Act of 1985 (“COBRA”), and (III) for all outstanding and unvested equity awards of the Company that are subject to time-based vesting held by the participant, full accelerated vesting of such awards; provided, that the performance conditions applicable to any outstanding and unvested equity awards subject to performance-based vesting will be subject to the terms of the applicable award agreement.

The payments and benefits provided under the Severance Plan in connection with a change in control may not be eligible for a federal income tax deduction by us pursuant to Section 280G of the Code. These payments and benefits may also subject an eligible participant, including the NEOs, to an excise tax under Section 4999 of the Code. If the payments or benefits payable in connection with a change in control would be subject to the excise tax imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to the participant.

Equity Incentive Plans

2016 Employee, Director and Consultant Incentive Plan

Our 2016 Plan, as amended, was originally adopted by our board of directors and approved by our stockholders on May 25, 2016 to enable the issuance of stock options, stock grants, and other stock-based awards to our employees, directors, and consultants. As of March 31, 2026, options to purchase 8,823,077 shares of our common stock were outstanding under the 2016 Plan. Our board of directors determined not to make any further awards under the 2016 Plan following the adoption of the January 2026 Plan (as described below), but all outstanding awards under the 2016 Plan will continue to be governed by the 2016 Plan. The following summary describes the material terms of the 2016 Plan. This summary is not a complete description of all provisions of the 2016 Plan.

Under the terms of the January 2026 Plan, if an award under the 2016 Plan is forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of stock or otherwise terminated (other than by exercise), the unissued or reacquired shares that were subject to such award and any shares that were withheld upon exercise of an option or settlement of an award to cover the exercise price or tax withholding will become available for issuance under the January 2026 Plan.

The 2016 Plan provided for the grant of both incentive stock options (“ISOs”) and non-qualified stock options to purchase shares of our common stock at a stated exercise price. The 2016 Plan required the exercise price of non-qualified stock options granted under the 2016 Plan to be at least equal to the fair market value of our common stock on the date of grant. For ISOs, the exercise price was required to be at least 100% of fair market value (or 110% for participants owning more than 10% of the total combined voting power of all classes of our stock) on the date of grant. The maximum term of options granted under the 2016 Plan is ten years (or five years for ISOs granted to participants owning more than 10% of the total combined voting power of all classes of our stock).

The 2016 Plan provided for the grant of stock-based grants and stock awards. The purchase price per share, if any, of shares covered by a stock grant was required to be determined by the plan administrator but could not be less than the minimum consideration required by the DGCL. The plan administrator also had the right to grant other stock-based awards based upon our common stock, including the grant of shares based upon certain conditions, securities convertible into shares, stock appreciation rights, phantom stock awards or stock units, on such terms and conditions as the plan administrator determined.

If we are to be consolidated with or acquired by another entity in a merger, consolidation, or sale of all or substantially all of our assets (a “Corporate Transaction”), the plan administrator or the board of directors of any successor entity may, with respect to outstanding options, either (i) make appropriate provision for the continuation of such options by substituting equivalent consideration, (ii) upon written notice to participants, provide that such options must be exercised within a specified period, at the end of which period such options will terminate, or (iii) terminate such options in exchange for a cash payment equal to the consideration payable in the Corporate Transaction less the aggregate exercise price. With respect to outstanding stock grants, the plan administrator or the successor board will make appropriate provision for the continuation of such stock grants or, in lieu thereof, may terminate each outstanding stock grant in exchange for a cash payment equal to the consideration payable in the Corporate Transaction.

In the event that shares of our common stock are subdivided or combined into a greater or smaller number of shares, or if we issue any shares of common stock as a stock dividend on our outstanding common stock, or if additional shares or new or different shares or other securities or other non-cash assets are distributed with respect to such shares, each stock right and the number of shares deliverable thereunder will be appropriately increased or decreased proportionately, and appropriate adjustments will be made to the exercise or purchase price per share, to reflect such events.

Unless otherwise approved by the plan administrator and set forth in the applicable agreement, 2016 Plan stock rights generally may not be transferred by a participant other than by will or by the laws of descent and distribution, and no stock right may be transferred by a participant for value. During a participant’s lifetime, a stock right may only be exercised by or issued to such participant (or his or her legal representative) and may not be assigned, pledged or hypothecated in any way or be subject to execution, attachment or similar process.

2026 Stock Option and Grant Plan

Our 2026 Stock Option and Grant Plan (the “January 2026 Plan”) was adopted by our board of directors and approved by our stockholders on January 6, 2026 to enable the issuance of stock options, restricted stock awards, stock grants, and restricted stock unit awards to our officers, employees, directors, consultants, and other key persons. As of March 31, 2026, options to purchase 5,986,341 shares of our common stock were outstanding under the January 2026 Plan. A summary of the material terms of the January 2026 Plan follows below.

The January 2026 Plan authorizes the award of equity-based awards, including: (i) stock options (both ISOs and nonqualified stock options), (ii) restricted stock awards (“RSAs”), (iii) unrestricted stock grants, and (iv) restricted stock units (“RSUs”). ISOs may be granted only to employees. All other types of awards may be issued to employees, directors, consultants and other service providers. No awards may be granted under the January 2026 Plan after the date that is ten years from the effective date of the January 2026 Plan.

We reserved 8,873,223 shares of our common stock for issuance under our January 2026 Plan. No more than 88,732,230 shares of our common stock may be issued under the January 2026 Plan through ISOs. Shares of our common stock issued by us through the assumption or substitution of awards in connection with a future acquisition of another entity will not reduce the shares available for issuance under the January 2026 Plan.

Our board of directors has acted as administrator of the January 2026 Plan. The administrator has full power to, among other things, select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, to accelerate at any time the exercisability or vesting of any award and to determine the specific terms and conditions of each award, subject to the provisions of the January 2026 Plan. Persons eligible to participate in the January 2026 Plan are those full or part-time officers, employees, non-employee directors, consultants and key persons as selected from time to time by the administrator in its discretion.

The January 2026 Plan permits the granting of both options to purchase common stock intended to qualify as ISOs under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by the administrator but may not be less than 100% of the fair market value of our common stock on the date of grant, or in the case of an ISO granted to an employee who holds more than 10% of the combined voting power of all classes of our stock (a “10% owner”), the exercise price shall not be less than 110% of the fair market value of our common stock on the date of grant. The term of each option will be fixed by the January 2026 Plan administrator and may not exceed ten years from the date of grant, or five years from the date of grant in the case of an ISO granted to a 10% owner. The January 2026 Plan administrator will determine at what time or times each option may be exercised.

An RSA is an issuance of shares of our common stock subject to forfeiture restrictions that lapse based on the satisfaction of service and/or performance conditions. The price, if any, of each share subject to an RSA will be determined by the January 2026 Plan administrator. During the vesting period, a participant will have the right to vote and receive any dividends with respect to restricted stock. RSUs represent the right to receive shares of our common stock (or cash equal to the value of such shares) at a specified time in the future, following the satisfaction of specified service and/or performance conditions.

Other stock-based awards (including awards to receive unrestricted shares of our common stock) may be granted to participants. The January 2026 Plan administrator will determine the terms and conditions of each such award, including, as applicable, the term, any exercise or purchase price, performance goals, vesting conditions and other terms and conditions. Payment in respect of other stock-based award may be made in cash, shares of our common stock, or a combination of both, at the discretion of the January 2026 Plan administrator.

Upon the effective time of a “sale event” (as defined in the January 2026 Plan), all outstanding option awards granted under the January 2026 Plan shall terminate unless assumed or continued by a successor entity. In the event of such termination, individuals holding options will be permitted to exercise such options within a specified period of time prior to the sale event. In the event of a sale event, all unvested restricted stock awards and restricted stock units (other than those that become vested as a result of the sale event) will be forfeited unless assumed or continued by a successor entity. With respect to individuals holding restricted stock that is forfeited upon a sale event, such restricted stock shall be repurchased by the Company at a price per share equal to the original per share purchase price paid by the holder for such shares of our restricted stock. In addition, in connection with a sale event, we may make or provide for a cash payment to participants in exchange for the cancellation of their options (to the extent then vested and exercisable, including by reason of acceleration in connection with such sale event) or outstanding restricted stock or restricted stock units, in an amount equal to the difference between (a) the per share consideration in the sale event times the number of shares subject to such awards being cancelled and (b) the aggregate exercise price of such outstanding vested and exercisable stock options. We may also make or provide for a cash payment to participants in exchange for the cancellation of their restricted stock or restricted stock

units, in an amount equal to the per share consideration in the sales event times the number of shares subject to such awards being cancelled, with any such cash payments in respect of restricted stock or restricted stock units to be paid at the time of the sale event or upon the later vesting of such awards.

Except for certain estate planning transfers authorized by the January 2026 Plan administrator, awards granted under the January 2026 Plan are generally nontransferable except by will or by the laws of descent and distribution.

Our board of directors may amend or discontinue the January 2026 Plan and the January 2026 Plan administrator may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under any outstanding award without the holder's consent. Certain amendments to the January 2026 Plan require the approval of our stockholders. The January 2026 Plan administrator may exercise its discretion to reduce the exercise price of outstanding stock options or to effect repricing through the cancellation of outstanding stock options and grant of replacement awards.

2026 Stock Option and Incentive Plan

Our 2026 Stock Option and Incentive Plan (the "2026 Plan") was adopted by our board of directors on May 28, 2026, approved by our stockholders on June 1, 2026, and became effective upon the date immediately preceding the date on which the registration statement of which this prospectus is part was declared effective by the SEC. The 2026 Plan replaced the January 2026 Plan as our board of directors has determined not to make additional awards under the January 2026 Plan following the completion of this offering. However, the January 2026 Plan and the 2016 Plan will continue to govern outstanding equity awards granted thereunder. The 2026 Plan allows us to make equity-based and cash-based incentive awards to our officers, employees, directors and consultants. The following summary describes the material terms of the 2026 Plan. This summary is not a complete description of all provisions of the 2026 Plan and is qualified in its entirety by reference to the 2026 Plan, which will be filed as an exhibit to the registration statement to which this prospectus is a part.

We have initially reserved 11,070,000 shares of our common stock for the issuance of awards under the 2026 Plan (the "Initial Limit"). The 2026 Plan provides that the number of shares reserved and available for issuance under the 2026 Plan will automatically increase on January 1, 2027 and each January 1 thereafter through January 1, 2036, by (i) 5% of the sum of (A) the number of shares of our common stock issued and outstanding on the immediately preceding December 31, (B) the number of shares underlying the Company's outstanding preferred stock (determined on an as-converted basis without regard to any limitations on such conversion) on the immediately preceding December 31, and (C) the number of shares of common stock issuable pursuant to the exercise of any outstanding pre-funded warrants to acquire such common stock for a nominal exercise price on the immediately preceding December 31 or (ii) such lesser number of shares as determined by our compensation committee (the "Annual Increase"). The number of shares reserved under the 2026 Plan is subject to adjustment in the event of a stock split, stock dividend, or other change in our capitalization.

The shares we issue under the 2026 Plan will be authorized but unissued shares or shares that we reacquire. The shares of our common stock underlying any awards under the 2026 Plan and the January 2026 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) will be added back to the shares of our common stock available for issuance under the 2026 Plan.

The maximum number of shares of our common stock that may be issued in the form of ISOs shall not exceed the Initial Limit, cumulatively increased on January 1, 2027 and on each January 1 thereafter by the lesser of the Annual Increase for such year or 11,070,000 shares of our common stock.

The grant date fair value of all awards made under our 2026 Plan and all other cash compensation paid by us to any non-employee director in any calendar year for services as a non-employee director shall not exceed \$750,000; provided, however, that such amount shall be \$1,000,000 for the calendar year in which the applicable non-employee director is initially elected or appointed to our board of directors.

The 2026 Plan is administered by our board of directors or our compensation committee. Our compensation committee has the full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted and the number of shares subject to such awards, to make any combination of awards to participants, to accelerate at any time the exercisability or vesting of any award and to determine the specific terms and conditions of each award, subject to the provisions of the 2026 Plan. Persons eligible to participate in the 2026 Plan will be those full or part-time officers, employees, non-employee directors and consultants as selected from time to time by our compensation committee in its discretion.

The 2026 Plan permits the granting of both options to purchase common stock intended to qualify as ISOs under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant (110% in the case of certain ISOs) unless the option (i) is granted pursuant to a transaction described in, and in a manner consistent with Section 424(a) of the Code, (ii) is granted to an individual who is not subject to U.S. income tax, or (iii) complies with or is exempt from Section 409A of the Code. The term of each option will be fixed by our compensation committee and may not exceed ten years from the date of grant (or five years in the case of certain ISOs). Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights under the 2026 Plan subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of our common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right generally may not be less than 100% of the fair market value of our common stock on the date of grant unless the share appreciation right (i) is granted pursuant to a transaction described in, and in a manner consistent with Section 424(a) of the Code, (ii) is granted to an individual who is not subject to U.S. income tax, or (iii) complies with or is exempt from Section 409A of the Code. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed 10 years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Our compensation committee may award restricted shares of our common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. Our compensation committee may also grant shares of our common stock that are free from any restrictions under the 2026 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of our common stock.

Our compensation committee may grant cash bonuses under the 2026 Plan to participants, subject to the achievement of certain performance goals.

The 2026 Plan provides that upon the effectiveness of a “sale event,” as defined in the 2026 Plan, an acquirer or successor entity may assume, continue or substitute outstanding awards under the 2026 Plan. To the extent that awards granted under the 2026 Plan are not assumed or continued or substituted by the successor entity, upon the effective time of the sale event, such awards shall terminate. In such case, except as may be otherwise provided in the relevant award agreement, all awards with time-based vesting, conditions or restrictions shall become fully vested and nonforfeitable as of the effective time of the sale event and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in connection with a sale event in the administrator’s discretion or to the extent specified in the relevant award agreement. In the event of such termination, (i) individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) within a specified period of time prior to the sale event or (ii) we may make or provide for a payment, in cash or in kind, to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share consideration payable to our stockholders in the sale event and the exercise price of the options or stock appreciation rights and we may make or provide for a payment, in cash or in kind, to participants holding other vested awards.

Our board of directors may amend or discontinue the 2026 Plan, and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder’s consent. Certain amendments to the 2026 Plan require the approval of our stockholders. The administrator of the 2026 Plan is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants without stockholder consent. No awards may be granted under the 2026 Plan after the date that is 10 years from the effective date of the 2026 Plan. No awards under the 2026 Plan have been made prior to the date of this prospectus.

Employee Stock Purchase Plan

Our 2026 Employee Stock Purchase Plan (the “ESPP”), was adopted by our board of directors on May 28, 2026, approved by our stockholders on June 1, 2026, and became effective on the date immediately preceding the date on which the registration statement of which this prospectus forms a part was declared effective by the SEC. The ESPP is intended to have two components: a component intended to qualify as an “employee stock purchase plan” within the meaning of Section 423 of the Code (the “423 Component”) and a component that is not intended to qualify (the “Non-423 Component”). Except as otherwise provided, the Non-423 Component will

be operated and administered in the same manner as the 423 Component, except where prohibited by law. The following summary describes the material terms of the ESPP. This summary is not a complete description of all provisions of the ESPP and is qualified in its entirety by reference to the ESPP, which will be filed as an exhibit to the registration statement to which this prospectus is a part.

The ESPP initially reserves and authorizes the issuance of up to a total of 1,110,000 shares of our common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2027 and each January 1 thereafter through January 1, 2036, by the least of (i) 1,110,000 shares of common stock, (ii) 1% of the sum of (A) the number of shares of our common stock issued and outstanding on the immediately preceding December 31, (B) the number of shares underlying the Company's outstanding preferred stock (determined on an as-converted basis without regard to any limitations on such conversion) on the immediately preceding December 31, and (C) the number of shares of common stock issuable pursuant to the exercise of any outstanding, pre-funded warrants to acquire such common stock for a nominal exercise price immediately preceding December 31, or (iii) such lesser number of shares of our common stock as determined by the administrator of the ESPP. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

All employees who are customarily employed by us or one of our designated subsidiaries for more than 20 hours per week and who have been employed for a number of days as determined by the administrator prior to each offering period are eligible to participate in the ESPP. However, any employee who owns 5% or more of the total combined voting power or value of all classes of our stock will not be eligible to purchase shares of our common stock under the ESPP.

We may make one or more offerings, consisting of one or more purchase periods, each year to our employees to purchase shares under the ESPP. The administrator may, in its discretion, determine when each offering will occur, including the duration of any offering; provided, that no offering will exceed 27 months in duration. Each eligible employee may elect to participate in any offering by submitting an enrollment form at least 15 business days before the applicable offering date.

Each employee who is a participant in the ESPP may purchase shares of our common stock by authorizing payroll deductions at a minimum of 1% up to 15% of his or her eligible compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares of our common stock on the last business day of the purchase period at a price equal to 85% of the closing price of the shares of our common stock on the first business day of the offering or the last business day of the purchase period, whichever is lower, provided that no more than a number of shares of common stock determined by dividing \$25,000 by the fair market value of our common stock on the offering date of such offering (or such other lesser maximum number of shares as may be established by the administrator) may be purchased by any one employee during any purchase period. Under applicable tax rules, an employee may purchase no more than \$25,000 worth of shares of our common stock, valued at the start of the offering period, under the ESPP for each calendar year during which any option granted to the employee is outstanding at any time.

In the case of and subject to the consummation of a "sale event," as defined in the ESPP, the administrator of the ESPP, in its discretion, and on such terms and conditions as it deems appropriate, is authorized to take any one or more of the following actions under the ESPP or with respect to any right under the ESPP or to facilitate such transactions or events: (i) provide for either (A) termination of any outstanding option in exchange for an amount of cash, if any, equal to the amount that would have been obtained upon the exercise of such option had such option been currently exercisable or (B) the replacement of such outstanding option with other options or property selected by the administrator of the ESPP in its sole discretion; (ii) provide that the outstanding options under the ESPP shall be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for similar options covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices; (iii) make adjustments in the number and type of shares of common stock (or other securities or property) subject to outstanding options under the ESPP and/or in terms and conditions of outstanding options and options that may be granted in the future; (iv) provide that the offering with respect to which an option relates will be shortened by setting a new exercise date on which such offering period will end; and (v) provide that all outstanding options shall terminate without being exercised and all amounts in the accounts of participants shall be promptly refunded.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

The ESPP may be terminated or amended by our board of directors at any time. An amendment that increases the number of shares of our common stock authorized under the ESPP and certain other amendments require the approval of our stockholders.

Senior Executive Cash Incentive Bonus Plan

Our board of directors has adopted the Senior Executive Cash Incentive Bonus Plan (the “Bonus Plan”). The Bonus Plan provides for cash bonus payments based upon Company and individual performance targets established by our compensation committee. The payment targets will be related to financial and operational measures or objectives with respect to our company (“corporate performance goals”), as well as individual performance objectives. The following summary describes the material terms of the Bonus Plan. This summary is not a complete description of all provisions of the Bonus Plan and is qualified in its entirety by reference to the Bonus Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

Our compensation committee may select corporate performance goals from among the following: developmental, publication, clinical or regulatory milestones; cash flow (including, but not limited to, operating cash flow and free cash flow); revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of our common stock; economic value-added; acquisitions, licenses, collaborations or strategic transactions; financing or other capital raising transactions; operating income (loss); return on capital, assets, equity, or investment; stockholder returns; return on sales; total stockholder return; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of the Company’s common stock; bookings, new bookings or renewals; sales or market shares; number of prescriptions or prescribing physicians; coverage decisions; leadership development, employee retention and recruiting and other human resources matters; operating income and/or net annual recurring revenue, or any other performance goal selected by our compensation committee, any of which may be (A) measured in absolute terms or compared to any incremental increase, (B) measured in terms of growth, (C) compared to another company or companies or to results of a peer group, (D) measured against the market as a whole and/or as compared to applicable market indices and/or (E) measured on a pre-tax or post-tax basis (if applicable).

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by our compensation committee and communicated to each executive. The corporate performance goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as our compensation committee determines. If the corporate performance goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period, but not later than 2.5 months after the end of the year in which such performance period ends. Subject to the rights contained in any agreement between the executive officer and us, an executive officer shall be required to be employed by us on the bonus payment date to be eligible to receive a bonus payment under the Bonus Plan. The Bonus Plan also permits our compensation committee to approve additional bonuses to executive officers in its sole discretion.

DIRECTOR COMPENSATION

The following table presents the compensation awarded to, earned by, or paid to each person who served as a non-employee member of our board of directors during the fiscal year ended December 31, 2025. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2025. During the year ended December 31, 2025, Mathai Mammen, M.D., Ph.D., who is our Chief Executive Officer, did not receive any additional compensation for his service as a director. The compensation received by Dr. Mammen, as an NEO, is presented in “2025 Summary Compensation Table” above.

2025 Director Compensation Table

Name(1)	Fees Earned or Paid in Cash\$(2)	All Other Compensation (\$)	Total (\$)
Alexis Borisy	—	—	—
Edward Fitzgerald	80,000	—	80,000
Corey Goodman, Ph.D. ⁽⁴⁾	—	—	—
Rick Klausner, M.D.	—	(3 20,000)	20,000
Jeffrey Leerink ⁽⁵⁾	50,000	—	50,000
Jake Simson	—	—	—
Barbara Weber, M.D.	80,000	—	80,000
Krishna Yeshwant, M.D.	—	—	—

- (1) As of December 31, 2025, Mr. Borisy, Dr. Goodman, Mr. Simson and Dr. Yeshwant did not hold any outstanding equity awards. As of December 31, 2025, Mr. Fitzgerald, Dr. Klausner, Mr. Leerink, and Dr. Weber held outstanding options to purchase an aggregate of 32,490; 70,009; 32,490; and 32,490 shares of our common stock, respectively.
- (2) The amounts reported represent the cash fees each director received for their services to our board of directors during the year ended December 31, 2025.
- (3) Amount reflects fees for scientific advisory board services.
- (4) Corey Goodman resigned from our board of directors on May 12, 2026.
- (5) Jeffrey Leerink resigned from our board of directors on May 14, 2026.

Non-Employee Director Compensation Policy

In connection with this offering, our board of directors has adopted a non-employee director compensation policy, which became effective as of the date on which the registration statement of which this prospectus forms a part was declared effective. The policy will be designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, our non-employee directors will be eligible to receive cash retainers (which will be payable quarterly in arrears and prorated for partial years of service) and equity awards as set forth below:

Annual Retainer for Board Membership:	
Members	\$ 40,000
Additional retainer for non-executive chair/lead independent director	\$30,000/\$25,000
Additional Annual Retainer for Committee Membership:	
Audit Committee:	
Members (other than chair)	\$ 10,000
Chair	\$ 20,000
Compensation Committee:	
Members (other than chair)	\$ 7,500
Chair	\$ 15,000
Nominating and Corporate Governance Committee:	
Members (other than chair)	\$ 5,000
Chair	\$ 10,000
Science and Technology Committee	
Members (other than chair)	\$ 7,500
Chair	\$ 15,000

In addition, the non-employee director compensation policy provides that, upon initial election or appointment to our board of directors, each non-employee director will be granted a one-time stock option award to purchase 71,479 shares of our common stock, up to a maximum Value (as defined in the non-employee director compensation policy) of \$600,000 (the “Director Initial Grant”). The Director Initial Grant will vest in equal monthly installments over three years following the grant date, subject to continued service through the applicable vesting date. The Director Initial Grant will expire ten years from the date of grant and have an exercise price per share equal to the fair market value of our common stock on the date of grant.

Furthermore, on the date of each annual meeting of stockholders following the completion of this offering, each non-employee director who continues as a non-employee director following such meeting (other than a non-employee director receiving a Director Initial Grant) will be granted an annual stock option award to purchase 35,739 shares of our common stock, up to a maximum Value of \$300,000 (the “Director Annual Grant”). The Director Annual Grant will vest in full upon the earlier of (i) the first anniversary of the date of grant or (ii) the date of the next annual meeting of our stockholders, subject to continued service through the applicable vesting date. If a non-employee director joins our board of directors on a date other than the date of the annual meeting of our stockholders, then in lieu of the Director Annual Grant, such non-employee director will be granted a prorated portion of the Director Annual Grant corresponding to such partial year of service at the next annual meeting of stockholders. The pro-rated Director Annual Grant will vest in full upon the earlier of (i) the first anniversary of the date of grant or (ii) the date of the next annual meeting of our stockholders, subject to continued service through the applicable vesting date. The Director Annual Grant (including any pro-rata portions thereof) will expire ten years from the date of grant and have an exercise price per share equal to the fair market value of our common stock on the date of grant.

The Director Initial Grant and the Director Annual Grant (including any pro-rata portions thereof) are subject to full accelerated vesting upon the sale of the company.

The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any non-employee director for service as a non-employee director in a calendar year period will not exceed \$1,000,000 in the first calendar year such individual becomes a non-employee director and \$750,000 in any other calendar year.

We will reimburse all reasonable out-of-pocket expenses incurred by directors for their attendance at meetings of our board of directors or any committee thereof.

Employee directors will receive no additional compensation for their service as a director.

2026 Stock Option Grants to Directors

In connection with this offering, we have granted each of our directors, other than Dr. Mammen and Alan M. Sebulsky, a non-statutory stock option to purchase 35,739 shares of our common stock, subject to a maximum value of \$300,000 contingent on, and effective immediately following, the time the registration statement of which this prospectus is a part is declared effective (the “IPO Effective Date”). If our initial public offering does not close within five business days after the IPO Effective Date, then the stock options will be forfeited at such time. The stock options have a per share exercise price equal to the initial public offering price per share in this offering, which is the fair market value of a share of our common stock on the grant date of the stock options. The stock options will vest in full on the earlier of (A) the one-year anniversary of the grant date or (B) the next annual meeting of stockholders, so long as the grantee continues to be a service provider through each applicable vesting date. The stock options will be subject to the terms and conditions of the 2026 Plan, and the applicable stock option agreements thereunder. Our board of directors has elected to make these stock option grants to recognize the services of our non-employee directors to date.

Director Appointment Grant

Mr. Sebulsky was appointed to our board of directors on May 7, 2026 and was granted a non-statutory stock option to purchase 71,479 shares of our common stock, subject to a maximum value of \$600,000 (the “Sebulsky Option”), contingent on, and effective as of the IPO Effective Date. If our initial public offering does not close within five business days after the IPO Effective Date, then the stock option will be forfeited at such time. The Sebulsky Option has a per share exercise price equal to the initial public offering price per share in this offering, which is the fair market value of a share of our common stock on the grant date of the stock option, and will vest in equal monthly installments over three years following the grant date, subject to continued service through the applicable vesting date.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

In addition to the compensation arrangements, including employment, termination of employment and change in control arrangements, and indemnification arrangements discussed, when required, in the sections titled “*Management*” and “*Executive Compensation*” and the registration rights described in the section titled “*Description of Capital Stock—Registration Rights*,” the following is a description of all transactions since January 1, 2023 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amounts involved exceeded or will exceed the lesser of \$120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years; and
- any of our directors, executive officers or holders of more than 5% or more of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities or affiliated entities, had or will have a direct or indirect material interest.

Series E Convertible Preferred Stock Financing

In February 2024, we issued and sold an aggregate of 12,445,024 shares of our Series E convertible preferred stock at a price per share of \$6.2281 to certain investors, for an aggregate purchase price of approximately \$77.5 million.

In January 2025, we issued and sold an additional aggregate of 10,836,539 shares of our Series E convertible preferred stock at a price per share of \$6.2281 to certain investors in a second closing, for an aggregate purchase price of approximately \$67.5 million.

The following table summarizes the shares of our Series E convertible preferred stock issued to our related parties:

Purchasers ⁽¹⁾	Series E Convertible Preferred Stock	Total Purchase Price
Arch Venture Fund XII, L.P. ⁽²⁾	1,605,626	\$ 10,000,000
Entities affiliated with Cormorant ⁽³⁾	1,093,259	\$ 6,808,926
Entities affiliated with Fidelity ⁽⁴⁾	1,600,441	\$ 9,967,707
GV 2017, L.P. ⁽⁵⁾	1,926,751	\$ 11,999,998
Jeffrey Leerink ⁽⁶⁾	44,154	\$ 274,996
Milky Way Investments Group Limited ⁽⁷⁾	80,281	\$ 499,998
Nextech VII Oncology SCSp ⁽⁸⁾	4,442,359	\$ 27,667,456
Entities affiliated with RA Capital ⁽⁹⁾	802,812	\$ 4,999,993
venBio Global Strategic Fund III, L.P. ⁽¹⁰⁾	642,250	\$ 3,999,997

- (1) Additional details regarding these stockholders and their equity holdings are included in the section titled “*Principal Stockholders*.”
- (2) Arch Venture Fund XII, L.P. beneficially owns more than 5% of our outstanding capital stock.
- (3) Cormorant collectively refers to Cormorant Global Healthcare Master Fund, LP, Cormorant Private Healthcare Fund IV, LP and Cormorant Private Healthcare Fund V, LP. Cormorant beneficially owns more than 5% of our outstanding capital stock.
- (4) Fidelity collectively refers to Fidelity Growth Company Commingled Pool By: Fidelity Management Trust Company, as Trustee; Fidelity Mount Vernon Street Trust: Fidelity Growth Company Fund; Fidelity Mt. Vernon Street Trust: Fidelity Growth Company K6 Fund; and Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund. Fidelity beneficially owns more than 5% of our outstanding capital stock.
- (5) GV 2017, L.P., together with its affiliates (collectively, “GV”), beneficially own more than 5% of our outstanding capital stock. Dr. Yeshwant, a member of our board of directors, was designated to our board of directors by GV and is a general partner at GV.
- (6) Reflects shares purchased by Healthcare Innovation Investment Fund LLC (“HIIF”), an investment fund associated with Leerink Partners LLC, and a trust for the benefit of Mr. Leerink’s family. Mr. Leerink, a former member of our board of directors, is the Chairman and CEO of Leerink Partners LLC.
- (7) Milky Way Investments Group Limited beneficially owns more than 5% of our outstanding capital stock. Dr. Klausner, a member of our board of directors, was designated to our board of directors by Milky Way Investments Group Limited and is the founder and managing partner of Milky Way Investments Group Limited.
- (8) Nextech VII Oncology SCSp beneficially owns more than 5% of our outstanding capital stock. Mr. Borisy a member of our board of directors, was designated to our board of directors by Nextech VII Oncology SCSp and is Chairman of Nextech Invest.

- (9) RA Capital collectively refers to RA Capital Healthcare Fund, L.P. and RA Capital Nexus Fund III, L.P. RA Capital beneficially owns more than 5% of our outstanding capital stock. Dr. Simson, a member of our board of directors, was designated to our board of directors by RA Capital and is a partner at RA Capital Management.
- (9) venBio Global Strategic Fund III, L.P., together with its affiliate, venBio Fund III SPV I, L.P. (together, “venBio”), beneficially owns more than 5% of our outstanding capital stock. Dr. Goodman, a member of our board of directors, was designated to our board of directors by venBio and is managing partner of venBio Partners.

Series F Convertible Preferred Stock Financing

In January 2026, we issued and sold an aggregate of 49,518,175 shares of our Series F convertible preferred stock at a price per share of \$6.1644 to certain investors, for an aggregate purchase price of approximately \$305.2 million.

The following table summarizes the shares of our Series F convertible preferred stock issued to our related parties:

Purchasers ⁽¹⁾	Series F Convertible Preferred Stock	Total Purchase Price
Arch Venture Fund XII, L.P. ⁽²⁾	3,244,435	\$ 19,999,995
Alexis Borisy ⁽³⁾	162,221	\$ 999,995
Entities affiliated with Cormorant ⁽⁴⁾	2,919,991	\$ 17,999,993
Entities affiliated with Fidelity ⁽⁵⁾	8,111,084	\$ 49,999,966
GV 2019, L.P. ⁽⁶⁾	2,108,883	\$ 12,999,998
Jeffrey Leerink ⁽⁷⁾	89,221	\$ 549,994
Milky Way Investments Group Limited ⁽⁸⁾	1,946,661	\$ 11,999,997
Nextech VII Oncology SCSp ⁽⁹⁾	1,946,661	\$ 11,999,997
Entities affiliated with RA Capital ⁽¹⁰⁾	11,112,192	\$ 68,499,996
venBio Fund III SPV I, L.P. ⁽¹¹⁾	3,244,435	\$ 19,999,995

- (1) Additional details regarding these stockholders and their equity holdings are included in the section titled “*Principal Stockholders*.”
- (2) Arch Venture Fund XII, L.P. beneficially owns more than 5% of our outstanding capital stock.
- (3) Alexis Borisy is a member of our board of directors.
- (4) Cormorant collectively refers to Cormorant Global Healthcare Master Fund, LP and Cormorant Private Healthcare Fund VI, LP. Cormorant beneficially owns more than 5% of our outstanding capital stock.
- (5) Fidelity collectively refers to Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund; Fidelity Advisor Series VII: Fidelity Advisor Health Care Fund; Fidelity Growth Company Commingled Pool By: Fidelity Management Trust Company, as Trustee; Fidelity Mount Vernon Street Trust: Fidelity Growth Company Fund; Fidelity Mt. Vernon Street Trust: Fidelity Growth Company K6 Fund; Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund; Fidelity Securities Fund: Fidelity Small Cap Growth Fund Mag & Co.; Fidelity Securities Fund: Fidelity Small Cap Growth K6 Fund; Fidelity Select Portfolios: Biotechnology Portfolio Mag & Co.; Fidelity Select Portfolios: Health Care Portfolio Mag & Co.; and Variable Insurance Products Fund IV: VIP Health Care Portfolio. Fidelity beneficially owns more than 5% of our outstanding capital stock.
- (6) GV 2019, L.P., together with its affiliates (collectively, “GV”), beneficially own more than 5% of our outstanding capital stock. Dr. Yeshwant, a member of our board of directors, was designated to our board of directors by GV and is a general partner at GV.
- (7) Reflects shares purchased by HIF, Leerink Intermediate Holdings LLC, an affiliate of Leerink Partners LLC, and a trust for the benefit of Mr. Leerink's family. Mr. Leerink, a former member of our board of directors, is the Chairman and CEO of Leerink Partners LLC.
- (8) Milky Way Investments Group Limited beneficially owns more than 5% of our outstanding capital stock. Dr. Klausner, a member of our board of directors, was designated to our board of directors by Milky Way Investments Group Limited and is the founder and managing partner of Milky Way Investments Group Limited.
- (9) Nextech VII Oncology SCSp beneficially owns more than 5% of our outstanding capital stock. Mr. Borisy a member of our board of directors, was designated to our board of directors by Nextech VII Oncology SCSp and is Chairman of Nextech Invest.
- (10) RA Capital collectively refers to RA Capital Healthcare Fund, L.P. and RA Capital Nexus Fund III, L.P. RA Capital beneficially owns more than 5% of our outstanding capital stock. Dr. Simson, a member of our board of directors, was designated to our board of directors by RA Capital and is a partner at RA Capital Management.
- (11) venBio Fund III SPV I, L.P., together with its affiliate venBio Global Strategic Fund III, L.P. (together, “venBio”), beneficially owns more than 5% of our outstanding capital stock. Dr. Goodman, a member of our board of directors, was designated to our board of directors by venBio and is managing partner of venBio Partners.

Agreements with Stockholders

Investors' Rights Agreement

We are a party to a sixth amended and restated investors' rights agreement, dated as of January 6, 2026 ("investors' rights agreement"), with certain holders of our convertible preferred stock, including holders of five percent or more of our outstanding capital stock and entities affiliated with certain of our directors.

The investors' rights agreement provides certain holders of our convertible preferred stock with a participation right to purchase their pro rata share of new securities that we may propose to sell and issue, subject to certain exceptions. Such participation right will terminate immediately prior to the closing of this offering. The investors' rights agreement further provides certain holders of our convertible preferred stock with certain rights, including certain registration rights with respect to the registrable securities held by them. See the section titled "*Description of Capital Stock—Registration Rights*" for additional information.

Voting Agreement

We are a party to a fifth amended and restated voting agreement, dated as of January 6, 2026 ("voting agreement"), with the holders of our convertible preferred stock and certain holders of our common stock, including holders of five percent or more of our capital stock, and entities affiliated with certain of our directors. Pursuant to the voting agreement, we agreed to appoint to our board of directors: one representative designated by holders of our Series A convertible preferred stock, currently vacant; one representative designated by GV 2017, L.P., Krishna Yeshwant; one representative designated by venBio Global Strategic Fund III, L.P., currently vacant; one representative designated by Milky Way Investments Group Limited, Rick Klausner; one representative designated by Nextech VII Oncology SCSp, Alexis Borisy; one representative designated by RA Capital, Jake Simson; the Company's Chief Executive Officer, Mathai Mammen, and up to three individuals not otherwise affiliated with the Company or any investor, including Edward Fitzgerald and Barbara Weber. The voting agreement will terminate upon the closing of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by holders of our common stock. The composition of our board of directors after this offering is described in more detail under the section titled "*Management—Board Composition and Filling Vacancies*."

Right of Refusal and Co-Sale Agreement

We are a party to a fifth amended and restated right of first refusal and co-sale agreement, dated as of January 6, 2026 (the "ROFR agreement"), with the holders of our convertible preferred stock and certain holders of our common stock, including holders of five percent or more of our capital stock, and entities affiliated with certain of our directors. Pursuant to the ROFR agreement, we have a right of first refusal on certain transfers of our shares by certain key holders of our convertible preferred stock, certain significant holders of our convertible preferred stock have a secondary right of first refusal on such transfers, and such convertible preferred stockholders have a right of co-sale to participate in respect of such transfers on a pro rata basis. The ROFR agreement will terminate immediately prior to the closing of this offering.

Management Rights and Side Letters

In connection with the initial issuance and sale of our convertible preferred stock, we entered into management rights and side letters with certain purchasers of our preferred stock, including holders of five percent or more of our capital stock and entities affiliated with certain of our directors. Pursuant to these agreements, such entities were granted certain management rights, including, among other things, the right to consult with and advise our management on significant business issues, examine our books and records, inspect our facilities and to receive information concerning the general status of our financial condition and operations, all subject to certain exceptions for highly confidential proprietary information and attorney-client privileged materials. Except for certain confidentiality obligations, publicity restrictions, legend removal matters, rights of investors to conduct investment activities, market standoff provisions and provisions related to material non-public information, the rights under these management rights and side letters will terminate upon closing of this offering.

Sublease

In December 2019, we entered into a sublease with LifeMine Therapeutics, Inc. ("LifeMine"), as subsequently amended, pursuant to which we subleased to LifeMine approximately 56,000 square feet of office and laboratory space at our Cambridge, Massachusetts headquarters. The sublease expired on December 31, 2025. Rick Klausner, M.D., a member of our board of directors, is the Co-Founder and Chairman of LifeMine. Under the terms of the sublease, LifeMine paid us \$6.1 million, \$6.5 million and \$6.2 million for each of the years ended December 31, 2023, 2024 and 2025, respectively.

Employment Arrangements

We have entered into offer letter agreements with certain of our executive officers, and granted stock options to our executive officers, as more fully described in the section titled “*Executive Compensation*.”

Equity Grants

We have granted options to purchase shares of our common stock to certain of our executive officers and directors. For more information regarding the options granted to our executive officers and directors, see the sections titled “*Executive Compensation*” and “*Director Compensation*” included elsewhere in this prospectus.

Indemnification Agreements

Our seventh amended and restated certificate of incorporation will contain provisions limiting the liability of directors and officers, and our amended and restated bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our seventh amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by our board of directors. In addition, we have entered into an indemnification agreement with each of our directors and executive officers, which requires us to indemnify them. For more information regarding these agreements, see the section titled “*Management—Limitations on Liability and Indemnification Agreements*” included elsewhere in this prospectus.

Jeffrey Leerink

Jeffrey Leerink, who stepped down as a member of our board of directors in May 2026, is the Chairman and CEO of Leerink Partners, an underwriter of this offering. In connection with the consummation of this offering, Leerink Partners will receive its proportional share of the underwriting fees described in the “Underwriting” section of this prospectus. We expect the proportional fee paid to Leerink Partners will exceed \$120,000. Mr. Leerink does not have any direct or indirect interest in the underwriting arrangement other than in his position as Chairman and CEO and as a stockholder of Leerink Partners.

Following Mr. Leerink’s departure from our board of directors in May 2026, we and Mr. Leerink entered into an advisory agreement pursuant to which Mr. Leerink will provide advisory services to the Company. As consideration for these advisory services, we have granted Mr. Leerink a non-statutory stock option to purchase 71,479 shares of our common stock, contingent on, and effective immediately following, the IPO Effective Date. If this offering does not close within five business days after the IPO Effective Date, then the stock options will be forfeited at such time. The stock options have a per share exercise price equal to the initial public offering price per share in this offering, which is the fair market value of a share of our common stock on the grant date of the stock options. The stock options will vest monthly over a four-year period, subject to Mr. Leerink’s continued service to us pursuant to the advisory agreement. The stock options were granted under the 2026 Plan.

Policies and Procedures for Transactions with Related Persons

We have adopted a written policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our common stock, and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the approval or ratification of our board of directors or our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of our common stock, or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds \$120,000 (or, if less, 1% of the average of our total assets at year-end for the last two completed fiscal years) and such person would have a direct or indirect interest, must be presented to our board of directors or our audit committee for review, consideration, and approval. In approving or rejecting any such proposal, our board of directors or our audit committee is to consider the material facts of the transaction, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person’s interest in the transaction.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock as of April 30, 2026 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC. Under these rules, beneficial ownership includes any shares of common stock as to which the individual or entity has sole or shared voting power or investment power. Unless otherwise indicated below, to our knowledge the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially own, subject to community property laws where applicable. We have deemed shares of common stock subject to options that are currently exercisable or exercisable within 60 days of April 30, 2026 to be outstanding and to be beneficially owned by the person holding the option for the purpose of computing the percentage ownership of that person but have not treated them as outstanding for the purpose of computing the percentage ownership of any other person.

Applicable percentage ownership before the offering is based on an aggregate of 77,709,009 shares of common stock and no non-voting common stock deemed to be outstanding as of April 30, 2026, after giving effect to the conversion of all outstanding shares of convertible preferred stock upon the closing of this offering and excludes the shares issuable upon the conversion of our outstanding SAFE.

Applicable percentage ownership after the offering and the concurrent private placement is based on 118,153,452 shares of common stock (including 1,581,210 shares of non-voting common stock) assumed to be outstanding as of April 30, 2026 after giving effect to the closing of this offering and concurrent private placement (including the sale of 33,500,000 shares of common stock in this offering, the sale of 4,166,666 shares of common stock in the concurrent private placement, and no exercise of the underwriters' overallotment option) including (1) the conversion of all outstanding shares of convertible preferred stock into an aggregate of 73,992,071 shares of our common stock and 1,581,210 shares of non-voting common stock, and (2) 2,777,777 shares issuable upon the conversion of our outstanding SAFE into shares of our common stock based on the initial public offering price of \$20.00 per share.

Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o Parabilis Medicines, Inc., 30 Acorn Park Drive, Cambridge, MA 02140.

Name of Beneficial Owner	Before this Offering			After this Offering and the Concurrent Private Placement		
	Number of Shares of Common Stock Beneficially Owned	Number of Shares of Non-Voting Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned	Number of Shares of Common Stock Beneficially Owned	Number of Shares of Non-Voting Common Stock Beneficially Owned	Percentage of Common Stock and Non-Voting Common Stock Beneficially Owned
5% or Greater Shareholders:						
ARCH Venture Fund XII, L.P. ⁽¹⁾	6,412,780	—	8.25%	6,412,780	—	5.43%
Entities affiliated with Cormorant ⁽²⁾	4,365,612	—	5.62%	4,365,612	—	3.69%
Entities affiliated with FMR LLC ⁽³⁾	8,757,571	—	11.27%	8,757,571	—	7.41%
Entities affiliated with GV ⁽⁴⁾	4,833,248	—	6.22%	4,833,248	—	4.09%
Milky Way Investments Group Limited ⁽⁵⁾	4,574,328	—	5.89%	4,574,328	—	3.87%
Nextech VII Oncology SCS ⁽⁶⁾	4,163,176	—	5.36%	4,163,176	—	3.52%
Entities affiliated with RA Capital ⁽⁷⁾	7,744,621	—	9.97%	7,744,621	—	6.55%
Entities affiliated with venBio ⁽⁸⁾	5,166,697	—	6.65%	5,166,697	—	4.37%

Name of Beneficial Owner	Before this Offering			After the Offering and the Concurrent Private Placement		
	Number of Shares of Common Stock Beneficially Owned	Number of Shares of Non-Voting Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned	Number of Shares of Common Stock Beneficially Owned	Number of Shares of Non-Voting Common Stock Beneficially Owned	Percentage of Common Stock and Non-Voting Common Stock Beneficially Owned
Named Executive Officers and Directors:						
Mathai Mammen, M.D., Ph.D., <i>Chairman, Chief Executive Officer and President</i> ⁽⁹⁾	2,786,667	—	3.46%	2,786,667	—	2.30%
Fawzi Benzaghrou, M.D., <i>Chief Medical Officer</i> ⁽¹⁰⁾	20,306	—	*	20,306	—	*
Helen Ho, Ph.D., <i>Chief Business and Strategy Officer</i>	—	—	—	—	—	—
Thomas Kotarakos, <i>Chief Financial Officer</i> ⁽¹¹⁾	173,215	—	*	173,215	—	*
Rohin Mhatre, Ph.D., <i>Chief Technical Operations Officer</i> ⁽¹²⁾	165,159	—	*	165,159	—	*
Teresa Jurgensen, J.D., <i>General Counsel</i> ⁽¹³⁾	111,821	—	*	111,821	—	*
Keith Orford, M.D., Ph.D., <i>former Chief Medical Officer</i>	—	—	—	—	—	—
Alexis Borisy ⁽¹⁴⁾	105,414	—	*	105,414	—	*
Edward Fitzgerald ⁽¹⁵⁾	49,885	—	*	49,885	—	*
Rick Klausner, M.D. ⁽¹⁶⁾	39,549	—	*	39,549	—	*
Alan M. Sebulsky	—	—	—	—	—	—
Jake Simson	—	—	—	—	—	—
Barbara Weber, M.D. ⁽¹⁷⁾	35,197	—	*	35,197	—	*
Krishna Yeshwant, M.D.	—	—	—	—	—	—
All executive officers and directors as a group (13 persons) ⁽¹⁸⁾	3,487,213	—	4.30%	3,487,213	—	2.87%

* Represents beneficial ownership of less than 1%.

- (1) Consists of (i) 3,256,984 shares of common stock issuable upon conversion of Series D convertible preferred stock held by ARCH Venture Fund XII, L.P. (“ARCH Venture Fund XII”); (ii) 1,047,515 shares of common stock issuable upon conversion of Series E convertible preferred stock held by ARCH Venture Fund XII; and (iii) 2,108,281 shares of common stock issuable upon conversion of Series F convertible preferred stock held by ARCH Venture Fund XII. In aggregate, the total number of shares of common stock upon conversion issuable to ARCH Venture Fund XII is 6,412,780 (“XII Record Shares”). ARCH Venture Partners XII, L.P. (“AVP XII LP”), as the sole general partner of ARCH Venture Fund XII, may be deemed to beneficially own the XII Record Shares. ARCH Venture Partners XII, LLC (“AVP XII LLC”), as the sole general partner of AVP XII LP, may be deemed to beneficially own the XII Record Shares. As members of the investment committee of AVP XII LLC, each of Kristina M. Burow, Keith Crandell, Steven Gillis and Robert Nelsen (the “AVP XII Committee Members”) may also be deemed to share the power to direct the disposition and vote of the XII Record Shares. Each of AVP XII LP, AVP XII LLC, and the AVP XII Committee Members disclaims beneficial ownership except to the extent of their pecuniary interest therein, if any. The address of ARCH Venture Partners and the individuals listed above is c/o ARCH Venture Partners, 8755 West Higgins Road, Suite 1025, Chicago, IL 60631.
- (2) Consists of (A)(i) 249,187 shares of common stock issuable upon conversion of Series C convertible preferred stock held by Cormorant Global Healthcare Master Fund, LP; (ii) 5,056 shares of common stock issuable upon conversion of Series D convertible preferred stock held by Cormorant Global Healthcare Master Fund, LP; (iii) 48,430 shares of common stock issuable upon conversion of Series E convertible preferred stock held by Cormorant Global Healthcare Master Fund, LP; and (iv) 622,934 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Cormorant Global Healthcare Master Fund, LP; (B) 772,906 shares of common stock issuable upon conversion of Series C convertible preferred stock held by Cormorant Private Healthcare Fund III, LP; (C) (i) 727,764 shares of common stock issuable upon conversion of Series D convertible preferred stock held by Cormorant Private Healthcare Fund IV, LP; and (ii) 179,239 shares of common stock issuable upon conversion of Series E convertible preferred stock held by Cormorant Private Healthcare Fund IV, LP; (D) 485,577 shares of common stock issuable upon conversion of Series E convertible preferred stock held by Cormorant Private Healthcare Fund V, LP; and (E) 1,274,519 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Cormorant Private Healthcare Fund VI, LP (collectively, the “Cormorant Funds”). Cormorant Asset Management, LP is the manager of the Cormorant Funds. Bihua Chen is the founder and managing member of Cormorant Asset Management, LP and has voting and investment discretion with respect

to the shares of common stock held by each Cormorant Fund. The principal address for the Cormorant Funds is 200 Clarendon Street 52nd Floor, Boston, MA 02116.

- (3) Consists of (A) (i) 209,701 shares of common stock issuable upon conversion of Series D convertible preferred stock held by Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund; and (ii) 319,449 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund; (B) 296,640 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Fidelity Advisor Series VII: Fidelity Advisor Health Care Fund; (C) (i) 1,002,864 shares of common stock issuable upon conversion of Series D convertible preferred stock held by Fidelity Growth Company Commingled Pool; (ii) 516,907 shares of common stock issuable upon conversion of Series E convertible preferred stock held by Fidelity Growth Company Commingled Pool; and (iii) 1,484,046 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Fidelity Growth Company Commingled Pool; (D) (i) 774,286 shares of common stock issuable upon conversion of Series D convertible preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund; (ii) 320,361 shares of common stock issuable upon conversion of Series E convertible preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund; and (iii) 1,108,324 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund; (E) (i) 238,899 shares of common stock issuable upon conversion of Series D convertible preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company K6 Fund; (ii) 132,138 shares of common stock issuable upon conversion of Series E convertible preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company K6 Fund; and (iii) 318,919 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company K6 Fund; (F) (i) 216,988 shares of common stock issuable upon conversion of Series D convertible preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund; (ii) 74,727 shares of common stock issuable upon conversion of Series E convertible preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund; and (iii) 283,059 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund; (G) 96,952 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Variable Insurance Products Fund IV: VIP Health Care Portfolio; (H) 319,709 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Fidelity Securities Fund: Fidelity Small Cap Growth Fund; (I) 159,464 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Fidelity Securities Fund: Fidelity Small Cap Growth K6 Fund; (J) 319,449 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Fidelity Select Portfolios: Biotechnology Portfolio; and (K) 564,689 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Fidelity Select Portfolios: Health Care Portfolio. The funds and accounts identified in this footnote are advised or managed by direct or indirect subsidiaries of FMR LLC. Abigail P. Johnson is a Director, the Chairman, and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. The address for each of the funds or accounts identified in this footnote is 245 Summer Street, Boston, Massachusetts 02210.
- (4) Consists of (A) (i) 1,107,993 shares of common stock issuable upon conversion of Series B convertible preferred stock held by GV 2017, L.P. and (ii) 1,257,018 shares of common stock issuable upon conversion of Series E convertible preferred stock held by GV 2017, L.P.; (B) (i) 365,033 shares of common stock issuable upon conversion of Series C convertible preferred stock held by GV 2019, L.P. and (ii) 1,370,383 shares of common stock issuable upon conversion of Series F convertible preferred stock held by GV 2019, L.P.; and (C) 732,821 shares of common stock issuable upon conversion of Series D convertible preferred stock held by GV 2021, L.P. Regarding GV 2017, L.P.: GV 2017 GP, L.P. (the general partner of GV 2017, L.P.), GV 2017 GP, L.L.C. (the general partner of GV 2017 GP, L.P.), Alphabet Holdings LLC (the sole member of GV 2017 GP, L.L.C.), XXVI Holdings Inc. (the sole member of Alphabet Holdings LLC), and Alphabet Inc. (the controlling stockholder of XXVI Holdings Inc.) may each be deemed to share power to vote or dispose of the shares held directly by GV 2017, L.P. Regarding GV 2019, L.P.: GV 2019 GP, L.P. (the general partner of GV 2019, L.P.), GV 2019 GP, L.L.C. (the general partner of GV 2019 GP, L.P.), Alphabet Holdings LLC (the sole member of GV 2019 GP, L.L.C.), XXVI Holdings Inc. (the sole member of Alphabet Holdings LLC), and Alphabet Inc. (the controlling stockholder of XXVI Holdings Inc.) may each be deemed to share power to vote or dispose of the shares held directly by GV 2019, L.P. Regarding GV 2021, L.P.: GV 2021 GP, L.P. (the general partner of GV 2021, L.P.), GV 2021 GP, L.L.C. (the general partner of GV 2021 GP, L.P.), Alphabet Holdings LLC (the sole member of GV 2021 GP, L.L.C.), XXVI Holdings Inc. (the sole member of Alphabet Holdings LLC), and Alphabet Inc. (the controlling stockholder of XXVI Holdings Inc.) may each be deemed to share power to vote or dispose of the shares held directly by GV 2021, L.P. The address for each of these entities is 1600 Amphitheatre Parkway, Mountain View, CA 94043.

- (5) Consists of (i) 3,256,984 shares of common stock issuable upon conversion of Series D convertible preferred stock held by Milky Way Investments Group Limited (“Milky Way”); (ii) 52,376 shares of common stock issuable upon conversion of Series E convertible preferred stock held by Milky Way; and (iii) 1,264,968 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Milky Way. Milky Way is controlled by MWG Caph Limited, its corporate director. The principal business address of Milky Way is c/o Trident Trust Company (B.V.I.) Limited, Trident Chambers, P.O. Box 146, Road Town, Tortola, British Virgin Islands.
- (6) Consists of (i) 2,898,208 shares of common stock issuable upon conversion of Series E convertible preferred stock held by Nextech VII Oncology SCSP; and (ii) 1,264,968 shares of common stock issuable upon conversion of Series F convertible preferred stock held by Nextech VII Oncology SCSP. Nextech VII GP S.à.r.l. is the general partner of Nextech VII Oncology SCSP and may be deemed to beneficially own the shares held by Nextech VII Oncology SCSP. Costas Constantinides, Ian Charoub and Rocco Sgobbo, as managers of Nextech VII GP S.à.r.l., have voting and investment power over the shares held by Nextech VII Oncology SCSP and, accordingly, may be deemed to beneficially own the shares held by Nextech VII Oncology SCSP. The principal address for Nextech VII Oncology SCSP is 8 rue Lou Hemmer, L 1748 Senningerberg, Luxembourg.
- (7) Consists of (A) (i) 419,006 shares of common stock issuable upon conversion of Series E convertible preferred stock held by RA Capital Healthcare Fund, LP; and (ii) 6,137,734 shares of common stock issuable upon conversion of Series F convertible preferred stock held by RA Capital Healthcare Fund, L.P.; and (B) (i) 104,751 shares of common stock issuable upon conversion of Series E convertible preferred stock held by RA Capital Nexus Fund III, L.P.; and (ii) 1,083,130 shares of common stock issuable upon conversion of Series F convertible preferred stock held by RA Capital Nexus Fund III, L.P. (the “RA Funds”). RA Capital Management, L.P. is the investment manager for the RA Funds. The general partner of RA Capital Management, L.P. is RA Capital Management GP, LLC, of which Peter Kolchinsky and Rajeev Shah are the managing members. Each of RA Capital Management, L.P., RA Capital Management GP, LLC, Mr. Kolchinsky and Mr. Shah may be deemed to have voting and investment power over the shares held by the RA Funds. RA Capital Management, L.P., RA Capital Management GP, LLC, Mr. Kolchinsky and Mr. Shah disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The principal business address of the persons and entities listed above is 200 Berkeley Street, 18th Floor, Boston, MA 02116.
- (8) Consists of (A) 2,108,281 shares of common stock issuable upon conversion of Series F convertible preferred stock held by venBio Fund III SPV I, L.P.; and (B) (i) 1,825,164 shares of common stock issuable upon conversion of Series C convertible preferred stock held by venBio Global Strategic Fund III, L.P.; (ii) 814,246 shares of common stock issuable upon conversion of Series D convertible preferred stock held by venBio Global Strategic Fund III, L.P.; and (iii) 419,006 shares of common stock issuable upon conversion of Series E convertible preferred stock held by venBio Global Strategic Fund III, L.P. (the “venBio Funds”). venBio Partners LLC serves as the investment manager of the venBio Funds. The General Partners of venBio Partners LLC include Aaron Royston, Richard Gaster and Corey Goodman and may share voting and dispositive power over securities held by venBio Fund. The address for venBio Fund is located at 1700 Owens Street, Suite 595, San Francisco, CA 94158.
- (9) Consists of 2,786,667 shares of common stock subject to options exercisable within 60 days of April 30, 2026.
- (10) Consists of 20,306 shares of common stock subject to options exercisable within 60 days of April 30, 2026.
- (11) Consists of 173,215 shares of common stock subject to options exercisable within 60 days of April 30, 2026.
- (12) Consists of 165,159 shares of common stock subject to options exercisable within 60 days of April 30, 2026.
- (13) Consists of 111,821 shares of common stock subject to options exercisable within 60 days of April 30, 2026.
- (14) Consists of 105,414 shares of common stock issuable upon the conversion of Series F convertible preferred stock.
- (15) Consists of (i) 5,539 shares of common stock issuable upon the conversion of Series B convertible preferred stock; (ii) 3,878 shares of common stock issuable upon the conversion of Series C convertible preferred stock; and (iii) 5,271 shares of common stock issuable upon the conversion of Series F convertible preferred stock; and (iv) 35,197 shares of common stock subject to options exercisable within 60 days of April 30, 2026.
- (16) Consists of 39,549 shares of common stock subject to options exercisable within 60 days of April 30, 2026.
- (17) Consists of 35,197 shares of common stock subject to options exercisable within 60 days of April 30, 2026.
- (18) Consists of (i) 5,539 shares of common stock issuable upon the conversion of Series B convertible preferred stock, (ii) 3,878 shares of common stock issuable upon the conversion of Series C convertible preferred stock, (iii) 110,685 shares of common stock issuable upon the conversion of Series F convertible preferred stock, and (iv) 3,367,111 shares of common stock subject to options exercisable within 60 days of April 30, 2026.

DESCRIPTION OF CAPITAL STOCK

General

The following description of our capital stock and certain provisions of our seventh amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the seventh amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, and the amended and restated bylaws, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part. Copies of these documents have been filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock, non-voting common stock and preferred stock reflect changes to our capital structure that will be in effect on the completion of this offering.

Upon filing of our seventh amended and restated certificate of incorporation and the closing of this offering, our authorized capital stock will consist of 600,000,000 shares of voting common stock, par value \$0.0001 per share, 200,000,000 shares of non-voting common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share, all of which shares of preferred stock will be undesignated.

As of March 31, 2026, there were 77,701,337 shares of common stock and non-voting common stock outstanding and held of record by 130 stockholders. This amount assumes the conversion of all outstanding shares of our convertible preferred stock into 73,992,071 shares of common stock and 1,581,210 shares of non-voting common stock, which will occur upon closing of this offering.

Voting Common Stock and Non-Voting Common Stock

We will have two series of common stock authorized immediately following this offering: voting common stock and non-voting common stock. We are offering shares of voting common stock in this offering and unless otherwise noted or context otherwise requires, all references in this prospectus to our “common stock” refer to our voting common stock. The non-voting common stock will not be listed for trading on any securities exchange.

The holders of our common stock and non-voting common stock have identical rights, except that, (i) except as otherwise expressly provided in our seventh amended and restated certificate of incorporation or as required by applicable law, on any matter that is submitted to a vote by our stockholders, holders of our voting common stock are entitled to one vote per share of common stock, and holders of our non-voting common stock are not entitled to any votes per share of non-voting common stock, including for the election of directors, and (ii) holders of our voting common stock have no conversion rights, while holders of our non-voting common stock will have the right to convert each share of our non-voting common stock into one share of voting common stock at such holder’s election, provided that as a result of such conversion, such holder, together with its affiliates and any members of a Schedule 13(d) group with such holder, would not beneficially own in excess of 4.99% of our common stock immediately prior to and following such conversion, subject to certain limited exceptions provided for in our seventh amended and restated certificate of incorporation. However, this ownership limitation may be increased or decreased to any other percentage (not to exceed 19.99%) designated by such holder of non-voting common stock upon 61 days’ notice to us. There are no circumstances or events that would result in a mandatory conversion of the non-voting common stock.

The holders of our common stock do not have any cumulative voting rights. Holders of our common stock and non-voting common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock and non-voting common stock have no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock and non-voting common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering and the concurrent private placement will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred Stock

Upon the closing of this offering, all outstanding shares of our convertible preferred stock will be converted into 73,992,071 shares of our common stock and 1,581,210 shares of our non-voting common stock. Upon the closing of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges, and restrictions thereof. These rights, preferences, and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms, and the

number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our Company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Stock Options

As of March 31, 2026, 8,823,077 shares of common stock were issuable upon the exercise of outstanding stock options under the 2016 Plan, at a weighted-average exercise price of \$2.67 per share; 5,986,341 shares of common stock were issuable upon the exercise of outstanding stock options under the January 2026 Plan, at a weighted-average exercise price of \$3.15 per share; no shares of common stock were issuable upon exercise of outstanding stock options outside of our 2016 Plan or January 2026 Plan; and 11,070,000 shares of our common stock reserved for future issuance under the 2026 Plan, which became effective on the date immediately prior to the date on which the registration statement of which this prospectus forms a part was declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under the 2026 Plan and any shares underlying outstanding stock awards granted under the 2016 Plan or January 2026 Plan, that expire or are repurchased, forfeited, cancelled, or withheld. For additional information regarding terms of our equity incentive plans, see the section titled “Executive Compensation—Employee Benefit and Equity Compensation Plans.”

Warrants

In connection with the Loan Agreement, we issued warrants to purchase up to 24,152 shares of our common stock to Silicon Valley Bank, which are exercisable at an exercise price of \$4.82 per share (subject to adjustment) prior to expiration on September 20, 2031.

Simple Agreement for Future Equity (“SAFE”)

On March 27, 2026, the Company issued a SAFE and received proceeds of \$50.0 million. The amount invested by the investor in the SAFE is automatically convertible into the number of shares of our common stock obtained by dividing (i) \$50.0 million by (ii) the IPO Discount Price (as defined below) upon the closing of an initial public offering. The “IPO Discount Price” in connection with an initial public offering is the offering price in the initial public offering (the “IPO Price”) multiplied by 90% (such product, the “Initial IPO Discount Price”), provided that (i) if the IPO Price is greater than or equal to \$9.4864 per share, and (ii) the Initial IPO Discount Price is equal to or less than \$9.4864 per share, then the IPO Discount Price will equal \$9.4864 per share; and provided further that if the IPO Price is less than \$9.4864, the IPO Discount Price will equal the IPO Price. In connection with the automatic conversion of the SAFE, the investor will enter into a lock-up agreement and agree to be bound by the provisions of our investors’ right agreement as a holder thereunder.

Registration Rights

Upon the closing of this offering and the concurrent private placement and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, holders of 75,573,281 shares of our common stock and non-voting common stock, including those shares of our common stock and non-voting common stock that will be issued upon the conversion of our convertible preferred stock in connection with this offering, will initially be entitled to certain rights with respect to registration of the shares of common stock (including those available upon conversion of the non-voting common stock) under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our investors’ rights agreement and are described in additional detail below. In addition, Regeneron Pharmaceuticals, Inc. (“Regeneron”) will have piggyback registration rights (as described below) only with respect to the 4,166,666 shares of common stock (based on the initial public offering price of \$20.00 per share) Regeneron is purchasing in the concurrent private placement. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay all registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and short-form registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and short-form registration rights described below will expire no later than five years after the completion of this offering.

Demand Registration Rights

Upon the closing of this offering, certain holders of our common stock, including those issuable upon the conversion of shares of our convertible preferred stock upon the closing of this offering and those issuable upon exchange of non-voting common stock, will be entitled to certain demand registration rights. At any time beginning 12 months after the completion of this offering, the holders of at least 25% of these shares may request that we register all or a portion of their shares. We are not required to effect more than two registration statements which are declared or ordered effective. Such request for registration must cover shares with an anticipated aggregate offering price of at least \$10 million, net of selling expenses, within 60 days of such request. With certain exceptions, we are not required to effect the filing of a registration statement during the period starting with the date of the filing of, and ending on a date 180 days following the effective date of the registration statement for this offering.

Piggyback Registration Rights

In connection with this offering, certain holders of our common stock, including those issuable upon the conversion of shares of our convertible preferred stock upon the closing of this offering, were entitled to, their rights to notice of this offering and to include their shares of registrable securities in this offering. However, these rights were effectively waived. After this offering, in the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the holders of these shares will be entitled to certain piggyback registration rights allowing the holder to include their shares in such registration, subject to certain marketing and other limitations.

Short Form Registration Rights

Upon the closing of this offering, certain holders of shares of our common stock, including those issuable upon the conversion of shares of our convertible preferred stock upon completion of this offering and those issuable upon conversion of non-voting common stock, will be entitled to certain short form registration rights. Holders of at least 25% of these shares can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3 and if the reasonably anticipated aggregate net proceeds of the shares offered would equal or exceed \$5.0 million, net of selling expenses. We will not be required to effect more than two registrations on Form S-3 within any twelve-month period. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Expiration of Registration Rights

The demand registration rights and short form registration rights granted under the investors' rights agreement will terminate upon the earliest of (i) the closing of a "Deemed Liquidation Event," as such term is defined in our sixth amended and restated certificate of incorporation (as currently in effect), (ii) with respect to each stockholder, the date, following the closing of this offering, on which (x) such holder, together with its affiliates, holds less than 1% of our outstanding capital stock and (y) all registrable shares held by such holder may immediately be sold during any three-month period pursuant to Rule 144 under the Securities Act or another similar exemption, and (iii) the fifth anniversary of the completion of this offering.

Anti-Takeover Effects of Our Certificate of Incorporation and Bylaws and Delaware Law

Delaware law includes, and our seventh amended and restated certificate of incorporation and amended and restated bylaws will include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies

Our seventh amended and restated certificate of incorporation will provide for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our seventh amended and restated certificate of incorporation also will provide that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, will only be able to be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, will have the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our seventh amended and restated certificate of incorporation will provide that all stockholder actions will be required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders will not be able to take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and will prevent the amendment of our amended and restated bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our seventh amended and restated certificate of incorporation and amended and restated bylaws will provide that only the Chairperson of the board of directors, the President of the Company, or a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our amended and restated bylaws will limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our amended and restated bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice will be required to be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our amended and restated bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws

Any amendment of our seventh amended and restated certificate of incorporation will first need to be approved by a majority of our board of directors, and if required by law or our seventh amended and restated certificate of incorporation, will thereafter need to be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, and limitation of liability will need to be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our amended and restated bylaws can be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the amended and restated bylaws; and can also be amended by the affirmative vote of a majority of the outstanding shares entitled to vote on the amendment, voting together as a single class, except that the amendment of the provisions relating to notice of stockholder business and nominations and special meetings will need to be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our seventh amended and restated certificate of incorporation will provide for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest, or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our seventh amended and restated certificate of incorporation will grant our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock and non-voting common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Section 203 of the Delaware General Corporation Law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge, or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges, or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Choice of Forum

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of, or a claim based on, a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees or stockholders to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our seventh amended and restated certificate of incorporation or amended and restated bylaws (including the interpretation, validity or enforceability thereof) or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim governed by the internal affairs doctrine.

However, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Consequently, this choice of forum provision would not apply to claims or causes of action brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction or the Securities Act. Moreover, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

In addition, our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Additionally, our amended and restated bylaws provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

Limitations on Liability and Indemnification

See the section titled “*Management—Limitations on Liability and Indemnification Agreements*” included elsewhere in this prospectus.

Exchange Listing

Our common stock has been approved for listing on The Nasdaq Global Select Market under the symbol “PBL5”. Our non-voting common stock is not listed for trading on any securities exchange and we do not plan to list our non-voting common stock on any securities exchange.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock and non-voting common stock is Computershare Trust Company, N.A. The transfer agent’s address is 150 Royall Street, Canton, Massachusetts 02021.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock, including shares issued on the exercise of outstanding options, in the public market after this offering and the concurrent private placement, or the possibility of these sales or issuances occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital. Although we have obtained approval for the listing of our common stock on The Nasdaq Global Select Market, we cannot assure you that there will be an active public market for our common stock.

Following the completion of this offering and the concurrent private placement, based on our shares outstanding as of March 31, 2026, a total of 118,145,780 shares of common stock and non-voting common stock will be outstanding, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 73,992,071 shares of our common stock and 1,581,210 shares of our non-voting common stock immediately prior to the closing of this offering, the conversion of our outstanding SAFE into 2,777,777 shares of our common stock, based on the initial offering price of \$20.00 per share, assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options or other securities. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act ("Rule 144"), may only be sold in compliance with the limitations described below.

All remaining shares of common stock held by existing stockholders upon the completion of this offering and the concurrent private placement will be "restricted securities" as such term is defined in Rule 144. These restricted securities were issued and sold by us in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701 summarized below.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described below.

In general, under Rule 144 as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell shares subject to the following restrictions and the expiration of the lock-up agreements described below. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately 1,181,458 shares immediately after this offering and the concurrent private placement, assuming no exercise of the underwriters' over-allotment option; or
- the average weekly trading volume of our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 under the Securities Act ("Rule 701") generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below.

Form S-8 Registration Statements

We intend to file one or more registration statements on Form S-8 under the Securities Act with the SEC to register the offer and sale of shares of our common stock that are issuable under the 2016 Plan, the January 2026 Plan, the 2026 Plan, and the ESPP. These registration statements will become effective immediately upon filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below, and Rule 144 limitations applicable to affiliates.

Lock-up Arrangements

We, all of our directors and executive officers, and the holders of substantially all of our capital stock and securities convertible into or exchangeable for our capital stock (including the shares of common stock to be issued in the concurrent private placement) have entered into lock-up agreements with the underwriters and/or are subject to market standoff agreements or other agreements with us, which prevents them from selling any of our common stock or any securities convertible into or exercisable or exchangeable for common stock (including non-voting common stock) for a period of not less than 180 days from the date of this prospectus without the prior written consent of Leerink Partners LLC and BofA Securities, Inc., subject to certain exceptions. See the section titled “*Underwriting*” appearing elsewhere in this prospectus for more information.

Registration Rights

Upon completion of this offering and the concurrent private placement, certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, subject to the expiration of the lock-up agreements described above. See the section titled “*Description of Capital Stock—Registration Rights*” appearing elsewhere in this prospectus for more information.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES FOR NON-U.S. HOLDERS

The following discussion is a summary of material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering. This discussion is based on the Internal Revenue Code of 1986, as amended (referred to as the “Code”), Treasury Regulations promulgated or proposed thereunder, published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the “IRS”) and judicial decisions, all as in effect on the date hereof. These authorities are subject to differing interpretations and may change, possibly with retroactive effect, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, the alternative minimum tax, or the special tax accounting rules under Section 451(b) of the Code, and also does not address any U.S. federal non-income tax consequences, such as estate or gift tax consequences, or any tax consequences arising under any state, local or non-U.S. tax laws. This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a non-U.S. holder in light of such non-U.S. holder’s particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to non-U.S. holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens, or long-term residents of the United States;
- partnerships or other entities or arrangements treated as pass-through or disregarded entities for U.S. federal income tax purposes (and investors therein);
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- “controlled foreign corporations”;
- “passive foreign investment companies”;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, mutual funds, financial institutions, investment funds, insurance companies, brokers, dealers or traders in stock, securities, commodities or currencies;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- qualified foreign pension funds as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons that elect to apply Section 1400Z-2 of the Code to gains recognized with respect to shares of our common stock;
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or synthetic security or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership generally will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of owning and disposing of our common stock.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR NON-U.S. TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of Non-U.S. Holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a corporation or any organization taxable as a corporation for U.S. federal income taxes that is not created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- a foreign trust (i) whose administration is not subject to the primary supervision of a U.S. court or (ii) which does not have one or more U.S. persons who have the authority to control all substantial decisions of the trust (provided that such trust does not have a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person); or
- a foreign estate, the income of which is not subject to U.S. federal income tax on a net income basis.

Distributions on Our Common Stock

As described under “*Dividend Policy*,” we do not currently anticipate declaring or paying, for the foreseeable future, any distributions on our capital stock. However, if we were to distribute cash or other property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will then constitute a return of capital and will first be applied against and reduce a holder’s tax basis in our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under “—Gain on sale or other taxable disposition of our common stock” below.

Subject to the discussions below regarding effectively connected income, backup withholding and FATCA (as defined below), dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish to us or our withholding agent with a timely and valid IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying such holder’s qualification for the reduced rate. This certification must be provided to us or our withholding agent before the payment of the dividends and must be updated periodically. If the non-U.S. holder holds our common stock through a financial institution or other agent acting on the non-U.S. holder’s behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our withholding agent, either directly or through other intermediaries.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder’s U.S. trade or business (and, if required by an applicable tax treaty, are attributable to such holder’s permanent establishment or fixed base in the United States), such non-U.S. holder generally will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder generally must furnish a valid IRS Form W-8ECI (or applicable successor form), certifying that the dividends are effectively connected with the non-U.S. Holder’s conduct of a trade or business within the United States to the applicable withholding agent.

However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected dividends, as adjusted for certain items.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on Disposition of Our Common Stock

Subject to the discussions below regarding backup withholding and FATCA (as defined below), a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other taxable disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder’s conduct of a trade or business in the United States and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States;

- the non-U.S. holder is a nonresident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a “United States real property interest” by reason of our status as a United States real property holding corporation (“USRPHC”) for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder’s holding period for our common stock, and our common stock is not “regularly traded” on an “established securities market” within the meaning of applicable Treasury Regulations, during the calendar year in which the sale or other disposition occurs.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net (assuming a U.S. tax return is timely filed, otherwise gross) income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.- source capital losses of the non-U.S. holder (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

Determining whether we are a USRPHC depends on the fair market value of our United States real property interests relative to the fair market value of our worldwide real property interests and our other trade or business assets. We believe that we are not currently and we do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we have not been, are not currently, or will not in the future become a USRPHC. Even if we are treated as a USRPHC, gain realized by a non-U.S. holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the non-U.S. holder owned, directly, indirectly and constructively, no more than 5% of our common stock at all times within the shorter of (a) the five-year period preceding the disposition or (b) the holder’s holding period and (2) our common stock is “regularly traded” on an “established securities market” within the meaning of applicable U.S. Treasury Regulations. There can be no assurance that our common stock qualifies as regularly traded on an established securities market for purposes of the rules described above. Prospective investors are encouraged to consult their own tax advisors regarding the possible consequences to them if we have been, are or were to become a USRPHC.

Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of distributions on our common stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply even if no withholding was required because the distributions were effectively connected with the holder’s conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of distributions on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or otherwise establishes an exemption, and if the payor does not have actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder’s U.S. federal income tax liability, if any.

Withholding on Foreign Entities

Sections 1471 through 1474 of the Code, which are commonly referred to as “FATCA”, impose a U.S. federal withholding tax of 30% on certain payments made to a “foreign financial institution” (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally imposes a U.S. federal withholding tax of 30% on certain payments made to a “non-financial foreign entity” (as specially defined under these rules) unless such entity provides the withholding agent a certification that it does not have any “substantial United States owners” or provides information identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our common stock and would have applied also to payments of gross proceeds from the sale or other disposition of our common stock. However, proposed regulations under FATCA provide for the elimination of the federal withholding tax of 30% applicable to gross proceeds of a sale or other disposition of from property of a type that can produce U.S. source dividends or interest. Under these proposed Treasury Regulations (which may be relied upon by taxpayers prior to finalization), FATCA withholding does not apply to gross proceeds from sales or other dispositions of our common stock.

Prospective investors are encouraged to consult with their tax advisors regarding the possible implications of FATCA on their investment in our common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY RECENT AND PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS.

UNDERWRITING

Leerink Partners LLC, BofA Securities, Inc., Evercore Group L.L.C. and Guggenheim Securities, LLC are acting as representatives of each of the underwriters named below and as active bookrunning managers for this offering. LifeSci Capital LLC is acting as a passive bookrunning manager for this offering. Subject to the terms and conditions set forth in the underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
Leerink Partners LLC	10,552,500
BofA Securities, Inc.	10,552,500
Evercore Group L.L.C.	6,700,000
Guggenheim Securities, LLC	4,020,000
LifeSci Capital LLC	1,675,000
Total	<u>33,500,000</u>

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of the shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and subject to other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers' certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Discounts and Commissions

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the initial public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$0.84 per share. After the initial offering of the shares, the public offering price, concession or any other term of this offering may be changed by the representatives.

The following table shows the initial public offering price, underwriting discounts and commissions and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their overallotment option.

	Per Share	Total	
		Without Option	With Option
Initial public offering price	\$ 20.00	\$ 670,000,000	\$ 770,500,000
Underwriting discounts and commissions	\$ 1.40	\$ 46,900,000	\$ 53,935,000
Proceeds, before expenses, to us	\$ 18.60	\$ 623,100,000	\$ 716,565,000

We estimate expenses payable by us in connection with this offering and the concurrent private placement, other than the underwriting discounts and commissions referred to above, will be approximately \$4.9 million. We also have agreed to reimburse the underwriters for up to \$50,000 for their FINRA counsel fee. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering.

Jeffrey Leerink is the Chairman and CEO of Leerink Partners LLC, an underwriter of this offering. As consideration for certain advisory services to be provided following his departure from our board of directors in May 2026, we have granted Mr. Leerink a non-statutory stock option to purchase 71,479 shares of our common stock, effective immediately following the IPO Effective Date, as further described in the section titled "*Certain Relationships and Related Person Transactions -- Jeffrey Leerink*." In accordance with FINRA Rule 5110, this stock option is deemed to be underwriting compensation in connection with this offering. For a period of 180 days from the date of this prospectus, Mr. Leerink (and any permitted assignee under FINRA Rule 5110) will not sell, transfer, assign,

pledge or hypothecate the stock option or the underlying shares of common stock, nor will he engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of any such securities.

Overallotment Option

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 5,025,000 additional shares at the initial public offering price, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to the conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table. The underwriters may exercise this option solely for the purpose of covering overallotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus.

No Sales of Similar Securities

We, our executive officers and directors and substantially all of our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into or exchangeable or exercisable for common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Leerink Partners LLC and BofA Securities, Inc. on behalf of the underwriters. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common stock;
- sell any option or contract to purchase any common stock;
- purchase any option or contract to sell any common stock;
- grant any option, right or warrant for the sale of any common stock;
- otherwise dispose of or transfer any common stock;
- request or demand that we file a registration statement related to the common stock; or
- enter into any swap or other agreement or any transaction that transfers, in whole or in part, the economic consequence of ownership of any common stock, whether any such swap, agreement or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

The lock-up provisions apply to common stock and to securities convertible into or exchangeable or exercisable for common stock.

The restrictions on our actions, as described above, do not apply to certain transactions, including: (i) the issuance of shares of common stock in this offering or in the concurrent private placement; (ii) the issuance of shares of common stock upon the exercise of an option or warrant or the conversion of a convertible security outstanding on the date of the Underwriting Agreement and referred to in this prospectus; (iii) the issuance of any shares of common stock or grant of any options to purchase common stock granted pursuant to existing employee benefit plans referred to in this prospectus; (iv) the issuance of shares of common stock pursuant to any existing non-employee director stock plan or dividend reinvestment plan referred to in this prospectus; or (v) the filing by the Company of any registration statement on Form S-8 or a successor form thereto.

The restrictions on the actions of our executive officers, directors and other stockholders described above do not apply, subject in certain cases to various conditions, to certain transactions, including transfers (i) as a bona fide gift or gifts, including, without limitation, to a charitable organization or educational institution, or for bona fide estate planning purposes; (ii) to any trust, partnership, limited liability company or any other entities for the direct or indirect benefit of the locked-up party or the immediate family of the locked-up party; (iii) pursuant to distributions by a trust to its beneficiaries; (iv) to any corporation, partnership, limited liability company or other entity, all of the ownership interests of which are held by the locked-up party; (v) as a distribution or other transfer by a partnership to its partners or former partners or by a limited liability company to its members or retired members or by a corporation to its stockholders or former stockholders or to any wholly-owned subsidiary of such corporation; (vi) to the locked-up party's affiliates or to any investment fund or other entity controlled or managed by the locked-up party; (vii) pursuant to a qualified domestic relations order or in connection with a divorce settlement, divorce decree or separation agreement; (viii) by will, testamentary document or intestate succession upon the death of the locked-up party; or (ix) to the Company in satisfaction of any tax withholding obligation. Furthermore, the lock-up agreements do not restrict or prohibit, subject in certain cases to various conditions, (a) transfers to the Company in connection with the termination of the locked-up party's services to the Company; (b) the exercise, vesting, settlement or exchange by the locked-up party of any option or warrant to acquire any shares of common stock or options to purchase shares of common stock, in each case for cash or on a "cashless" or "net exercise" basis, pursuant to any warrant, stock option, stock bonus or other stock plan or arrangement; (c) transfers upon the completion of a bona fide third-party tender offer, merger, consolidation or other similar transaction made to all holders of the Company's securities involving a change of control of the

Company; (d) the conversion of outstanding preferred stock and simple agreements for future equity (SAFEs) of the Company; (e) the transfer or disposition of shares of common stock purchased by the locked-up party in this offering or on the open market following this offering; or (f) the establishment of a 10b5-1 trading plan that complies with Rule 10b5-1 under the Exchange Act or from amending any existing such plan so long as, among other things, there are no sales thereunder for the duration of the lock-up.

Nasdaq Global Select Market Listing

Our common stock has been approved for listing on The Nasdaq Global Select Market, subject to notice of issuance, under the symbol “PBL5”.

Determination of Offering Price

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors considered in determining the initial public offering price were:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us;
- our financial information;
- the history of, and the prospects for, our company and the industry in which we compete;
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after this offering, our common stock will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with this offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ overallotment option described above. The underwriters may close out any covered short position by either exercising their overallotment option or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the overallotment option granted to them under the underwriting agreement described above. “Naked” short sales are sales in excess of such overallotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the closing of this offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on The Nasdaq Global Select Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Some of the underwriters and certain of their affiliates may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us and our affiliates, for which they may in the future receive customary fees, commissions and expenses.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

In addition, we have requested that the underwriters make an issuer-directed allocation of 705,500 shares of our common stock to certain investors.

Selling Restrictions

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area (each, a "Relevant State"), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that shares may be offered to the public in that Relevant State at any time:

- A. to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;
- B. to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- C. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129, as amended.

Notice to Prospective Investors in the United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the Shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

- A. to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;
- B. to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- C. in any other circumstances falling within Section 86 of the Financial Services and Markets Act 2000 (the “FSMA”),

provided that no such offer of the shares shall require us or any representative to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an “offer to the public” in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the shares of our common stock being offered in this prospectus will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Covington & Burling LLP, New York, New York, is counsel to the underwriters in connection with this offering.

EXPERTS

The financial statements as of December 31, 2025 and 2024 and for the years then ended included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-296032) under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC also maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov/edgar.

We currently do not file periodic reports with the SEC. On the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for review at the website of the SEC referred to above.

We also maintain a website at www.parabilismed.com. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference. Upon the closing of this offering, you may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

Parabilis Medicines, Inc.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Parabilis Medicines, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Parabilis Medicines, Inc. and its subsidiary (the “Company”) as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock and stockholders’ deficit and of cash flows for the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

April 2, 2026, except for the effects of the reverse stock split discussed in Note 18 to the consolidated financial statements, as to which the date is June 4, 2026.

We have served as the Company’s auditor since 2023, which includes periods before the Company became subject to SEC reporting requirements.

Parabilis Medicines, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2024	2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 47,284	\$ 27,711
Marketable securities	40,694	—
Prepaid expenses and other current assets	3,870	1,647
Rent receivable – related party	258	—
Due from related party	102	—
Total current assets	92,208	29,358
Property and equipment, net	8,864	6,715
Restricted cash	2,855	2,855
Operating lease right-of-use assets	44,064	39,360
Other assets	1,262	2,532
Total assets	<u>\$ 149,253</u>	<u>\$ 80,820</u>
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 9,514	\$ 17,272
Accrued expenses and other current liabilities	13,522	18,630
Operating lease liabilities, current portion	6,295	7,174
Finance lease liabilities, current portion	581	638
Current portion of term loan, net of discount	2,500	13,077
Total current liabilities	32,412	56,791
Term loan, net of discount and current portion	12,788	—
Operating lease liabilities, net of current portion	41,926	36,341
Finance lease liabilities, net of current portion	2,108	1,470
Preferred stock tranche right liability	2,167	—
Other liabilities	1,413	2,742
Total liabilities	92,814	97,344
Commitments and contingencies (Note 11)		
Convertible preferred stock (Series A, B, C, D and E), \$0.0001 par value; 53,296,426 shares authorized at December 31, 2024 and 2025; 42,459,887 and 53,296,426 shares issued and outstanding at December 31, 2024 and 2025, respectively (liquidation preference of \$550,437 and \$658,972 at December 31, 2024 and 2025, respectively)	440,375	509,971
Stockholders' deficit:		
Common stock, \$0.0001 par value; 81,000,000 shares authorized at December 31, 2024 and 2025; 2,017,588 and 2,035,357 shares issued and outstanding at December 31, 2024 and 2025, respectively	—	—
Additional paid-in capital	11,658	15,009
Accumulated other comprehensive income	21	—
Accumulated deficit	(395,615)	(541,504)
Total stockholders' deficit	(383,936)	(526,495)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 149,253</u>	<u>\$ 80,820</u>

The accompanying notes are an integral part of the consolidated financial statements.

Parabilis Medicines, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2024	2025
Operating expenses:		
Research and development	\$ 100,829	\$ 125,583
General and administrative	25,296	26,496
Total operating expenses	126,125	152,079
Loss from operations	(126,125)	(152,079)
Other income (expense):		
Interest income	6,408	3,386
Interest expense	(1,486)	(1,522)
Sublease income - related party	4,166	4,228
Change in fair value of preferred stock tranche right liability	(975)	—
Other income	98	98
Total other income, net	8,211	6,190
Net loss	\$ (117,914)	\$ (145,889)
Cumulative dividends on convertible preferred stock	(34,581)	(41,044)
Deemed dividend upon down-round of convertible preferred stock	(8,986)	—
Net loss allocable to common stockholders	\$ (161,481)	\$ (186,933)
Net loss per share allocable to common stockholders, basic and diluted	\$ (83.48)	\$ (92.40)
Weighted average common shares outstanding, basic and diluted	1,934,297	2,023,175
Comprehensive loss:		
Net loss	\$ (117,914)	\$ (145,889)
Change in unrealized gain on marketable securities	(5)	(21)
Comprehensive loss	\$ (117,919)	\$ (145,910)

The accompanying notes are an integral part of the consolidated financial statements.

Parabilis Medicines, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	30,014,863	\$ 364,557	1,769,819	\$ —	\$ 6,277	\$ 26	\$ (277,701)	\$ (271,398)
Issuance of common stock upon exercise of stock options	—	—	247,769	—	1,071	—	—	1,071
Issuance of Series E convertible preferred stock, net of preferred stock tranche right liability of \$1,192 and issuance costs of \$498	12,445,024	75,818	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	4,310	—	—	4,310
Change in unrealized gain on marketable securities	—	—	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	(117,914)	(117,914)
Balance at December 31, 2024	42,459,887	\$ 440,375	2,017,588	\$ —	\$ 11,658	\$ 21	\$ (395,615)	\$ (383,936)
Issuance of common stock upon exercise of stock options	—	—	17,769	—	34	—	—	34
Issuance of Series E convertible preferred stock, inclusive of preferred stock tranche right liability of \$2,167, net of issuance costs of \$62	10,836,539	69,596	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	3,317	—	—	3,317
Change in unrealized gain on marketable securities	—	—	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	—	—	(145,889)	(145,889)
Balance at December 31, 2025	53,296,426	\$ 509,971	2,035,357	\$ —	\$ 15,009	\$ —	\$ (541,504)	\$ (526,495)

The accompanying notes are an integral part of the consolidated financial statements.

Parabilis Medicines, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2024	2025
Cash flows from operating activities		
Net loss	\$ (117,914)	\$ (145,889)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,107	2,502
Accretion of discounts on marketable securities	(609)	609
Stock-based compensation expense	4,310	3,317
Change in fair value of preferred stock tranche right liability	975	—
Non-cash interest expense	457	289
Non-cash lease expense	5,791	6,342
Losses on fixed asset disposals	360	—
Changes in operating assets and liabilities:		
Rent receivable - related party	208	258
Due from related party	(102)	102
Due to related party	(474)	—
Prepaid expenses and other assets	(2,468)	1,511
Operating lease liabilities	(5,538)	(6,344)
Accounts payable, accrued expenses and other liabilities	9,284	13,590
Net cash used in operating activities	(103,613)	(123,713)
Cash flows from investing activities		
Purchases of marketable securities	(90,858)	(16,664)
Proceeds from maturities of marketable securities	121,979	56,728
Purchases of property and equipment	(879)	(306)
Net cash provided by investing activities	30,242	39,758
Cash flows from financing activities		
Proceeds from issuance of Series E convertible preferred stock and preferred stock tranche right liability	77,508	67,491
Payments of Series E convertible preferred stock issuance costs	(494)	(62)
Principal payments on finance leases	—	(581)
Principal payments on debt	—	(2,500)
Proceeds from exercise of stock options	1,071	34
Payments of debt issuance costs and fees	(17)	—
Net cash provided by financing activities	78,068	64,382
Increase (decrease) in cash, cash equivalents and restricted cash	4,697	(19,573)
Cash, cash equivalents and restricted cash at beginning of period	45,442	50,139
Cash, cash equivalents and restricted cash at end of period	\$ 50,139	\$ 30,566
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 1,029	\$ 1,247
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable	\$ 13	\$ 60
Deferred offering costs included in accounts payable and accrued expenses	\$ —	\$ 558
Settlement of Series E preferred stock tranche right liability	\$ —	\$ 2,167

The accompanying notes are an integral part of the consolidated financial statements.

Parabilis Medicines, Inc.
Notes to Consolidated Financial Statements

1. Nature of the Business and Basis of Presentation

Nature of Business

Parabilis Medicines, Inc. (the “Company”) is a clinical-stage biopharmaceutical company developing medicines addressing some of the most consequential, yet historically undruggable, protein targets driving human disease. The Company leverages its platform to pioneer a therapeutic modality, Helicons, which are stabilized helical peptides engineered to bind and precisely modulate proteins. The Company, formerly known as FOG Pharmaceuticals, Inc., was incorporated in Delaware on July 10, 2015. On October 25, 2024, the Company changed its name from FOG Pharmaceuticals, Inc. to Parabilis Medicines, Inc. The Company is developing preclinical and clinical drug candidates, operates in the United States of America, and, to date, has devoted substantially all its efforts on research and development and fundraising activities.

Risk and Uncertainties

The Company is subject to risks and uncertainties common to clinical-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to secure additional capital to fund operations. Product candidates resulting from the Company’s current discovery efforts will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel, infrastructure, and extensive compliance reporting capabilities. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Liquidity

The Company’s consolidated financial statements have been prepared on the basis of continuity of operations, the realization of assets and satisfaction of liabilities in the ordinary course of business. From its inception through December 31, 2025, the Company has received aggregate gross proceeds of \$506.6 million from sales of convertible preferred stock and \$15.0 million from borrowings under a term loan. The Company has incurred net losses and negative operating cash flows since inception and has an accumulated deficit of \$541.5 million at December 31, 2025. The Company expects that its cash and cash equivalents, including the \$305.2 million of gross proceeds received from its sale of Series F convertible preferred stock (the “Series F Preferred Stock”) in January 2026 and the \$50.0 million of gross proceeds received from the sale of a simple agreement for future equity (“SAFE”) in March 2026 (see Note 18, *Subsequent Events*), will be sufficient to fund its operations through at least twelve months from the date the consolidated financial statements were available to be issued.

The Company is seeking to complete an initial public offering (“IPO”) of its common stock. Upon the completion of a qualified public offering on specified terms, the Company’s outstanding convertible preferred stock will be automatically converted into shares of common stock (see Note 6, *Convertible Preferred Stock*). Additionally, the Company’s outstanding SAFE will be automatically converted into shares of common stock upon an IPO. In the event the Company does not complete an IPO, the Company expects to finance its cash needs through a combination of equity offerings, debt or royalty financings, and collaborations. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company’s stockholders. If the Company is unable to raise additional funds through these sources or other sources of funding when needed, the Company could be forced to delay, reduce or eliminate its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, FOG Security Corporation. All intercompany accounts and transactions have been eliminated in consolidation.

The Company’s consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”).

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates reflected within these consolidated financial statements include the estimated fair value of the Company's common stock utilized in the determination of stock-based compensation expense, the determination of the incremental borrowing rate for leases, the estimated fair value of the preferred stock tranche right liability, and convertible preferred stock, as well as accrued research and development expenses. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company's cash equivalents consist of funds deposited in money market mutual funds and are recorded at fair value.

A reconciliation of the cash, cash equivalents, and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the consolidated statements of cash flows is as follows (in thousands):

	December 31,	
	2024	2025
Cash and cash equivalents	\$ 47,284	\$ 27,711
Restricted cash – long-term	2,855	2,855
Total cash, cash equivalents and restricted cash	<u>\$ 50,139</u>	<u>\$ 30,566</u>

Restricted Cash

As of December 31, 2024 and 2025, restricted cash consists of \$2.9 million serving as collateral for a letter of credit required under the Company's facility lease arrangement.

Marketable Securities

The Company's marketable securities consist of investments in debt securities, including U.S. Treasury bills, with remaining maturities beyond three months at the date of purchase. The Company's marketable securities are classified as available-for-sale and are carried at fair value, with any unrealized gains or losses reported as a component of accumulated other comprehensive income within stockholders' deficit. The Company has classified its investments as current as all of the securities had maturity dates within twelve months of December 31, 2024 and 2025. Changes in unrealized gains or losses are recorded in other comprehensive loss in the consolidated statements of operations and comprehensive loss. Premiums and discounts on marketable securities are amortized and accreted, respectively, to earliest call date and maturity, respectively, and are included in interest income in the consolidated statements of operations and comprehensive loss.

Marketable securities in an unrealized loss position are evaluated for impairment at least quarterly. For marketable securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the investment security's amortized cost basis is written down to fair value through net loss.

For marketable securities that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In conducting this assessment for marketable securities in an unrealized loss position, management evaluates the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors.

If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the investment security are compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded for the credit loss, limited by the amount that the fair value is less than the amortized cost basis. Any unrealized loss that has not been recorded through an allowance for credit loss is recognized in other comprehensive loss. There were no credit losses recorded for the years ended December 31, 2024 or 2025.

Comprehensive Loss

Comprehensive loss consists of net loss plus other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2024 and 2025, other comprehensive loss consisted of changes in unrealized gains or losses on marketable securities.

Concentration of Risk

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents, and marketable securities. The Company's cash deposits generally do not exceed Federal Deposit Insurance Corporation ("FDIC") limits. The Company's cash equivalents consist of money market funds that are not insured by the FDIC; however, the Company has not experienced any losses in such accounts and believes that such funds are not exposed to any significant credit or concentration risk beyond the risks associated with commercial banking relationships. The Company maintains each of its cash and cash equivalents balances with financial institutions that management believes are creditworthy. The Company's investment policy includes guidelines on the quality of the financial institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. The Company's marketable securities consist of U.S. Treasury bills. The Company believes these investments present minimal credit risk.

The Company relies, and expects to continue to rely, on a small number of vendors and contract research organizations to manufacture certain supplies and raw materials for its research and development programs and to conduct clinical trials. These programs could be adversely affected by a significant interruption in these manufacturing services or the availability of raw materials, or an interruption in the provision of services provided by the Company's contract research organizations.

Research and Development Expenses

Research and development expenses include personnel-related expenses, such as salaries, bonuses, benefits, and stock-based compensation expense, consulting, contract research and manufacturing, depreciation, allocated facility and related costs, and other costs attributable to research and development activities and are expensed as incurred. Non-refundable pre-payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as expense as the goods or services are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered.

Upfront payments under license agreements are expensed upon receipt of the license, and annual maintenance fees under license agreements are expensed over the maintenance period. Contingent milestone payments, if any, are expensed when the milestone results are probable and estimable, which is generally upon the achievement of the milestone.

The Company has entered into various research and development-related contracts with third parties. The expenses related to these agreements and related payments are recorded as research and development expenses as incurred. At each balance sheet date, the Company records accruals for estimated research costs incurred. When evaluating the adequacy of the accrued liabilities, the Company analyzes the progress of the studies, including the phase or completion of events, invoices received and contracted costs. Certain judgments and estimates are made in determining the accrued balances at the end of any reporting period.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses, including salaries, bonuses, benefits, and stock-based compensation expense for employees in certain executive, accounting and finance, business development, human resources, information technology, legal, and other administrative functions. Other significant general and administrative expenses include allocated facility and related costs, legal fees relating to corporate and intellectual property matters, professional fees for accounting, audit and tax services, consulting fees, information technology costs and insurance costs. General and administrative costs are expensed as incurred.

Patent Costs

All patent-related costs incurred for filing and prosecuting patent applications are expensed as incurred. Amounts incurred are classified as general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each of the asset categories as follows:

Asset Classification	Estimated Useful Life
Laboratory equipment	5 years
Computers	3 years
Furniture and fixtures	5 years
Leasehold improvements	Shorter of remaining life of lease or useful life

Costs for capital assets not yet placed in service are capitalized and depreciation begins once placed into service. Upon retirement or sale, the cost of disposed assets and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the consolidated statements of operations and comprehensive loss. Expenditures for repairs and maintenance that do not improve or extend the life of the respective assets are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets to be held and used, comprised of property and equipment and operating lease right-of-use assets, are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in determining when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If the Company performs an impairment review to evaluate a long-lived asset or asset group for recoverability, it compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset or asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset or asset group are less than its carrying amount. The impairment loss would be equal to the excess of the carrying value of the impaired asset or asset group over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes in the consolidated statements of operations and comprehensive loss. The Company assesses the likelihood that its deferred tax assets will be realized and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees, directors and non-employees based on the award's fair value on the date of the grant and recognizes compensation expense related to those awards over the requisite service period, which is generally the vesting period of the respective award. The Company primarily issues stock options with only service-based vesting conditions and records the expense for these awards using the straight-line method. To a lesser extent, the Company has also granted awards with either service and performance-based vesting conditions or market and performance-based vesting conditions, and records expense based on the grant-date fair value over the requisite service period using the accelerated attribution method if the achievement of the performance condition is considered probable. At each reporting date, the Company estimates the probability that specified performance criteria will be achieved and does not begin to recognize compensation expense until it is probable that the performance-based vesting condition will be achieved.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs or service payments are classified.

The fair values of stock options with only service-based or performance-based conditions are estimated using the Black-Scholes option-pricing model. The Company's board of directors (the "Board of Directors") determines the fair value of the Company's common stock, with input from management, considering the Company's most recently available third-party valuations of common stock, as well as additional factors which may have changed since the date of the most recent valuation through the date of grant. The Company is a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a set of publicly-traded peer companies. The expected term of the Company's stock options granted has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options, which is presumed to be the midpoint between the vesting date and the end of the contractual term. If vesting is subject to a performance condition, the expected term is based on the mid-point between the explicit service period and the contractual term of the option. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield is zero, because the Company has never paid cash dividends on common stock and does not expect to pay any such dividends in the foreseeable future. The Company accounts for forfeitures of share-based compensation awards as they occur.

Leases

The Company determines whether an arrangement is, or contains, a lease at inception. The Company determines a contract contains a lease when all of the following criteria based on the specific circumstances of the arrangement are met: (1) there is an identified asset for which there are no substantive substitution rights; (2) the Company has the right to obtain substantially all of the economic benefits from the identified asset; and (3) the Company has the right to direct the use of the identified asset.

The Company classifies each of its leases as operating or financing considering factors such as the length of the lease term, the present value of the lease payments, the nature of the leased asset, and the potential for ownership of the asset to transfer during the lease term. Leases with terms greater than one year are recognized on the consolidated balance sheets as right-of-use assets and lease liabilities and are measured at the present value of the fixed payments due over the expected lease term, with the asset value reduced by the present value of any incentives, rebates or abatements the Company expects to receive from the lessor. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for a period equal to the expected lease term. Options to extend a lease by the Company are included in the expected lease term if exercise of the option is deemed reasonably certain. Options to extend the lease held by the lessor are included in the calculation of the lease term. Variable lease payments are amounts the Company owes to a lessor that are not fixed, such as reimbursement for common area maintenance and utilities costs for facility leases. Variable lease payments are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when incurred. The Company recognizes expense for fixed lease payments on its operating leases on a straight-line basis over the expected lease term as an operating expense. For its finance leases, amortization expense and interest expense are recognized separately in the consolidated statements of operations and comprehensive loss, with amortization expense recognized on a straight-line basis and interest expense recognized using the effective interest method. The Company has elected the practical expedient not to separate lease and non-lease components for leases.

The Company's operating lease assets and liabilities are reflected in its consolidated balance sheets with the captions operating lease right-of-use assets; operating lease liabilities, current portion; and operating lease liabilities, net of current portion. The Company's finance lease assets and liabilities are reflected in its consolidated balance sheets as property and equipment, net; finance lease liabilities, current portion; and finance lease liabilities, net of current portion. The Company does not record short-term leases, defined as leases that have a term of 12 months or less at the commencement date, on its consolidated balance sheets. The related expenses are recognized in the consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term.

Convertible Preferred Stock

The Company has presented all series of its convertible preferred stock as temporary equity in the accompanying consolidated balance sheets since redemption of the preferred shares is outside the control of the Company. The Company recorded its convertible preferred stock at fair value upon issuance, net of preferred stock tranche right liabilities, when applicable, and associated issuance costs. The holders of all series of convertible preferred stock are entitled to receive cumulative dividends if and when declared by the Company's Board of Directors or upon redemption. The Company recognizes dividends when declared. The Company has not recorded periodic accretion to the carrying values of its outstanding convertible preferred stock such that the carrying value of the convertible preferred stock would equal the redemption value, which includes the applicable original issue price plus all accrued but unpaid dividends, at the earliest date of redemption; as such, accretion or adjustment to redemption value is unnecessary unless or until it becomes probable that the convertible preferred stock will become redeemable. If redemption becomes probable, adjustments to the carrying values of the convertible preferred stock would be made at the relevant reporting date which would result in a decrease to additional paid-in capital or increase to accumulated deficit, as applicable.

Preferred Stock Tranche Right Liability

The purchase agreement for the Company's Series E convertible preferred stock provided the Company an obligation to issue additional shares of Series E convertible preferred stock in a subsequent closing upon the satisfaction of certain conditions (refer to Note 6, *Convertible Preferred Stock*). The Company classified the preferred stock tranche right as a liability on its consolidated balance sheets as the preferred stock tranche right was determined to be a freestanding financial instrument that may have required the Company to transfer assets to settle its obligation upon events outside of its control. The preferred stock tranche right liability was initially recorded at fair value upon the initial issuance date and was subsequently remeasured to fair value at each reporting date and immediately prior to being settled. Changes in fair value of the preferred stock tranche right liability were recognized as a component of other income (expense) in the consolidated statements of operations and comprehensive loss. Upon settlement of the preferred stock tranche right, the Company derecognized the related liability and stopped recognizing changes in the fair value of the preferred stock tranche right liability.

Fair Value Measurements

Under GAAP, certain assets and liabilities are carried at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1 – Quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2 – Inputs other than quoted prices within Level 1 that are observable, either directly or indirectly, for substantially the full term through corroboration with observable market data.

Level 3 – Unobservable inputs for which there is little or no market data, which requires the Company to develop its own assumptions.

The Company's cash equivalents, marketable securities and preferred stock tranche right liability were carried at fair value, as determined according to the fair value hierarchy (refer to Note 3, *Fair Value Measurements*).

Collaborative Arrangements

The Company analyzes its collaboration agreements to assess whether they are within the scope of ASC Topic 808, *Collaborative Arrangements* ("ASC 808"), by determining whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. To the extent the arrangement is within the scope of ASC 808, the Company assesses whether aspects of the arrangement between the Company and the collaboration partner are within the scope of other accounting literature. If the Company concludes that some or all aspects of the arrangement represent a transaction with a customer, the Company accounts for those aspects of the arrangement within the scope of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). For a collaborative arrangement that is wholly or partially outside the scope of other topics, including ASC 606, the Company accounts for the arrangement based on an analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational, and consistently applied accounting policy election.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the convertible preferred stock or in stockholders' deficit as a reduction of additional paid-in capital. Should the planned equity financing be abandoned, the deferred offering costs are expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. The Company had no deferred offering costs as of December 31, 2024. As of December 31, 2025, the Company had \$0.6 million of deferred offering costs included in other assets on the consolidated balance sheet.

Net Loss Per Share

Basic net loss per common share is calculated by dividing net loss adjusted for cumulative dividends on convertible preferred stock accrued during the period, whether or not declared, and the value of any deemed dividends resulting from down-round adjustments to convertible preferred stock, where applicable, by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss allocable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the convertible preferred stock, common stock warrants, preferred stock tranche rights and stock options are considered potentially dilutive securities.

Basic and diluted net loss allocable to common stockholders per share is presented in conformity with the two-class method required for participating securities as all series of convertible preferred stock are considered participating securities. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders.

Segment Information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker ("CODM"), in deciding how to allocate resources and assess performance. The Company's CODM, its chief executive officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources. All of the Company's long-lived assets are held in the United States. Refer to Note 17, *Segment Reporting*, for further disclosure regarding the Company's segment information.

Recently Issued Accounting Pronouncements Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and non-public companies, the Company can adopt the new or revised standard at the time non-public companies adopt the new or revised standard and can do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to adopt any new or revised accounting standards early whenever such early adoption is permitted for non-public companies.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"). ASU 2024-03 requires disclosure of disaggregated information about certain income statement expense line items on an annual and interim basis, including purchases of inventory, employee compensation, depreciation, intangible asset amortization and depletion for each income statement line item that contains those expenses. ASU 2024-03 also requires certain amounts already disclosed under existing GAAP to also be disclosed as a separate category in disaggregated expense tables, if those amounts are recognized in the relevant expense line item. The amendments in ASU 2024-03 will be effective for the Company in annual reporting periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. The standard may be applied prospectively or retrospectively. The Company is currently evaluating the impact of adopting ASU 2024-03.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280) - Improvements to Reportable Segment Disclosures*, which improves reportable segment disclosure requirements, primarily through additional disclosures about significant segment expenses. This standard became effective for the Company for the year ended December 31, 2024, using the retrospective method. The amendments were applied retroactively to all prior periods presented in the consolidated financial statements. Refer to Note 17, *Segment Reporting*, in the accompanying notes to the consolidated financial statements for further details.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which requires public entities to disclose specific categories in the effective tax rate reconciliation, as well as additional information for reconciling items that exceed a quantitative threshold. ASU 2023-09 also requires all entities to disclose income taxes paid disaggregated by federal, state and foreign taxes, and further disaggregated for specific jurisdictions that exceed 5% of total income taxes paid, among other expanded disclosures. The Company early adopted this standard for the year ended December 31, 2025 and applied the disclosure requirements on a retrospective basis for all periods presented. The adoption did not have a material impact on the Company's consolidated financial statements. Refer to Note 13, *Income Taxes*, in the accompanying notes to the consolidated financial statements for the Company's updated income tax disclosure.

3. Fair Value Measurements

The carrying values of cash, prepaid expenses and other current assets, rent receivable – related party, amounts due from related parties, accounts payable, and accrued expenses and other current liabilities approximate their fair values due to their short-term nature. The carrying value of the Company’s term debt (refer to Note 9, *Term Loan*) approximates its fair value due to its time to maturity.

The following tables present information about the Company’s financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

Fair Value Measurements as of December 31, 2024:				
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	\$ 46,443	\$ —	\$ —	\$ 46,443
Marketable securities:				
U.S. Treasury bills	—	40,694	—	40,694
Total assets	<u>\$ 46,443</u>	<u>\$ 40,694</u>	<u>\$ —</u>	<u>\$ 87,137</u>
Liabilities				
Series E preferred stock tranche right liability	\$ —	\$ —	\$ 2,167	\$ 2,167
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,167</u>	<u>\$ 2,167</u>

Fair Value Measurements as of December 31, 2025:				
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	\$ 27,133	\$ —	\$ —	\$ 27,133
Total assets	<u>\$ 27,133</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 27,133</u>

During the years ended December 31, 2024 and 2025, there were no transfers among the Level 1, Level 2 and Level 3 categories.

The Company’s cash equivalents are classified within Level 1 of the fair value hierarchy as they are invested in highly liquid money market funds which are based on a quoted price with a net asset value of \$1 per share.

The fair values of the Company’s marketable securities are based on prices obtained from independent pricing sources. Consistent with the fair value hierarchy described in Note 2, *Summary of Significant Accounting Policies*, marketable securities with validated quotes from pricing services are reflected within Level 2, as they are primarily based on observable pricing for similar assets or other market observable inputs. Typical inputs used by these pricing services include, but are not limited to, reported trades, benchmark yields, issuer spreads, bids, offers or estimates of cash flow, prepayment spreads and default rates.

The following table summarizes the gross unrealized gains and losses of the Company’s marketable securities (in thousands):

December 31, 2024				
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Marketable securities:				
U.S. Treasury bills	\$ 40,673	\$ 21	\$ —	\$ 40,694

As of December 31, 2024, none of the Company’s marketable securities were in an unrealized loss position. The Company held no marketable securities as of December 31, 2025.

As of December 31, 2024 and 2025, there was no allowance for credit losses recorded on the Company’s consolidated balance sheets.

Valuation of Preferred Stock Tranche Right Liability

The preferred stock tranche right liability represents the fair value of an obligation to issue shares of Series E convertible preferred stock (refer to Note 6, *Convertible Preferred Stock*). The fair value of the preferred stock tranche right liability was determined based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy.

The Company estimated the fair value of the preferred stock tranche right liability at the time of issuance and subsequently remeasured its fair value at each reporting period and prior to settlement. The initial fair value of the preferred stock tranche right liability was determined using a contingent forward model, which considered as inputs the risk-free interest rate of 5.2%, and estimated time to tranche settlement of 8.4 months. The risk-free rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining estimated time to the tranche settlement.

As of December 31, 2024, in light of the near-term completion of the Series E convertible preferred stock second closing in January 2025 (refer to Note 6, *Convertible Preferred Stock*), the fair value of the preferred stock tranche right liability was determined based on the difference between the estimated fair value of the Series E convertible preferred stock, or \$6.43 per share, and its contractual purchase price, or \$6.23 per share. The Company estimated the fair value per share of the underlying Series E convertible preferred stock by taking into consideration the results obtained from third-party valuations which included the most recent sales of its preferred stock, market conditions and trends since the last preferred stock issuance.

The following table presents changes in the aggregate fair value of the Company's Series E preferred stock tranche right liability (in thousands):

	Amount
Balance as of December 31, 2023	\$ —
Fair value of Series E preferred stock tranche right liability at issuance	1,192
Changes in fair value of Series E preferred stock tranche right liability	975
Balance as of December 31, 2024	\$ 2,167
Settlement of Series E preferred stock tranche right liability	(2,167)
Balance as of December 31, 2025	\$ —

4. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2024	2025
Laboratory equipment	\$ 13,728	\$ 13,830
Leasehold improvements	4,498	4,563
Computer equipment	382	307
Furniture and fixtures	697	697
Assets not yet in service	13	131
Property and equipment	19,318	19,528
Less: accumulated depreciation and amortization	(10,454)	(12,813)
Property and equipment, net	\$ 8,864	\$ 6,715

Included in laboratory equipment are finance lease right-of-use assets with a cost basis of \$2.9 million as of December 31, 2024 and 2025, and accumulated amortization expense of \$0.1 million and \$0.7 million as of December 31, 2024 and 2025, respectively.

During the years ended December 31, 2024 and 2025, depreciation and amortization expense amounted to \$2.1 million and \$2.5 million, respectively, which includes \$0.1 million and \$0.6 million of finance lease right-of-use asset amortization, respectively.

5. Accrued Expenses and Other Current Liabilities

The following table summarizes accrued expenses and other current liabilities (in thousands):

	December 31,	
	2024	2025
Accrued employee compensation and benefits	\$ 6,349	\$ 9,079
Accrued research and development expenses	6,551	8,334
Other	622	1,217
Total	<u>\$ 13,522</u>	<u>\$ 18,630</u>

6. Convertible Preferred Stock

Prior to January 1, 2024, the Company issued Series A convertible preferred stock, (the “Series A Preferred Stock”), Series B convertible preferred stock (the “Series B Preferred Stock”), Series C convertible preferred stock (the “Series C Preferred Stock”) and Series D convertible preferred stock (the “Series D Preferred Stock”) totaling 30,014,863 shares and aggregate gross proceeds of \$361.6 million. Aggregate issuance costs incurred were \$1.1 million.

On February 29, 2024, the Company entered into the Series E Preferred Stock Purchase Agreement with the purchaser’s party thereto (the “Series E Agreement”). On the initial closing (the “Series E Initial Closing”), the Company issued to the purchasers an aggregate of 12,445,024 shares of Series E convertible preferred stock (the “Series E Preferred Stock”) at a purchase price of \$6.23 per share for gross proceeds of \$77.5 million. The gross proceeds were offset by \$0.5 million of issuance costs.

In connection with entering into the Series E Agreement, the Company was also obligated to sell up to 10,836,539 additional shares (the “Series E Second Closing Shares”) of Series E Preferred Stock to certain purchasers at the same purchase price as the Series E Initial Closing. The sale of Series E Second Closing Shares (the “Series E Second Closing”) was contingent upon the election and approval of the Company’s Board of Directors, and may have occurred at any time from October 1, 2024 through December 31, 2025. In addition, if elected by a purchaser, the Company was obligated to sell Series E Second Closing Shares to such purchaser prior to the Series E Second Closing.

The Company concluded that the Series E preferred stock tranche right met the definition of a freestanding instrument as the Series E preferred stock tranche right was legally detachable and separately exercisable from the Series E Preferred Stock. Since the Series E preferred stock tranche right liability was subject to fair value accounting, the Company allocated the proceeds to the liability based on the fair value at the date of issuance of \$1.2 million, with the remaining proceeds of \$75.8 million being allocated to the Series E Preferred Stock. Refer to Note 3, *Fair Value Measurements*, for further details regarding the fair value of the Series E preferred stock tranche right liability.

In accordance with the terms of the Company’s certificate of incorporation, the Series E Preferred Stock issued in connection with the Series E Initial Closing triggered adjustments to the respective conversion prices of the Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock (as described further below). As a result, the Company recorded an increase to additional paid-in capital and a deemed dividend of \$9.0 million which is equal to the change in fair value of the Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock due to the triggering of the down-round feature. As the Company did not have retained earnings at the time of the Series E Initial Closing, the deemed dividend was charged against additional paid-in capital resulting in no net impact to additional paid-in capital.

The fair value of each preferred share class was determined using a “with-and-without” model under which the equity value of the Company was allocated to the various classes of equity using the option-pricing method based on the rights and preferences of the convertible preferred stock, both before and after the adjustment to the respective conversion price. Under the option-pricing method, equity value is allocated across each equity class by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options. The following table summarizes the significant Level 3 unobservable inputs used to estimate the fair value of the Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock at the date of the Series E Initial Closing:

	February 29, 2024
Expected volatility	97.0%
Expected dividend yield	—
Expected term (in years)	2.0
Risk-free interest rate	4.6%

On January 22, 2025, the Company completed the Series E Second Closing and issued to the purchasers an aggregate of 10,836,539 shares of Series E Preferred Stock at a purchase price of \$6.23 per share for gross proceeds of \$67.5 million. The Series E Preferred Stock was recorded at its fair value of \$69.6 million which included the proceeds and the settlement of the preferred stock tranche right liability of \$2.2 million, net of issuance costs of \$0.1 million.

Upon the issuance of each series of convertible preferred stock, the Company assessed the embedded conversion and liquidation features of the securities and determined that the Company was not required to separately account for these features.

Convertible preferred stock consisted of the following at December 31, 2024 (in thousands, except share and per share amounts):

	Shares of Preferred Stock Authorized	Original Issuance Price Per Share	Shares of Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Shares of Common Stock Issuable Upon Conversion
Series A	1,434,062	\$ 7.75	1,434,062	\$ 14,914	\$ 18,588	1,002,805
Series B	4,658,112	\$ 14.06	4,658,112	65,388	101,110	4,069,102
Series C	7,384,710	\$ 14.49	7,384,710	106,674	141,031	6,540,022
Series D	16,537,979	\$ 10.76	16,537,979	177,581	209,508	12,669,755
Series E	23,281,563	\$ 6.23	12,445,024	75,818	80,200	8,086,980
	<u>53,296,426</u>		<u>42,459,887</u>	<u>\$ 440,375</u>	<u>\$ 550,437</u>	<u>32,368,664</u>

Convertible preferred stock consisted of the following at December 31, 2025 (in thousands, except share and per share amounts):

	Shares of Preferred Stock Authorized	Original Issuance Price Per Share	Shares of Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Shares of Common Stock Issuable Upon Conversion
Series A	1,434,062	\$ 7.75	1,434,062	\$ 14,914	\$ 19,477	1,002,805
Series B	4,658,112	\$ 14.06	4,658,112	65,388	106,351	4,069,102
Series C	7,384,710	\$ 14.49	7,384,710	106,674	152,175	6,540,022
Series D	16,537,979	\$ 10.76	16,537,979	177,581	225,956	12,669,755
Series E	23,281,563	\$ 6.23	23,281,563	145,414	155,013	15,128,745
	<u>53,296,426</u>		<u>53,296,426</u>	<u>\$ 509,971</u>	<u>\$ 658,972</u>	<u>39,410,429</u>

The rights and preferences of all series of convertible preferred stock at December 31, 2025 are summarized below:

Voting Rights

The holders of all series of convertible preferred stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Each preferred stockholder is entitled to a number of votes equal to the number of shares of common stock into which their convertible preferred stock would be convertible at the time of such vote. In addition, the holders of all series of convertible preferred stock are entitled to vote on certain matters as a separate class.

Dividends

The holders of all series of convertible preferred stock are entitled to receive cumulative dividends in preference to any dividend on common stock. Holders of Series A Preferred Stock and Series B Preferred Stock are entitled to preferential dividends at the rate per annum of \$0.62 and \$1.125176, respectively, per share. Holders of Series C Preferred Stock, Series D Preferred Stock and Series E Preferred Stock are entitled to preferential dividends at the rate per annum of 8.0% of the respective original issue price on each share of convertible preferred stock, plus the amount of previously accrued dividends, compounded annually. Dividends are only payable when declared by the Company's Board of Directors or upon redemption. As of December 31, 2025, the Company has not declared nor paid any dividends.

Cumulative dividends on the convertible preferred stock were as follows (in thousands):

	December 31,	
	2024	2025
Series A Preferred Stock	\$ 7,474	\$ 8,363
Series B Preferred Stock	35,595	40,836
Series C Preferred Stock	34,031	45,175
Series D Preferred Stock	31,508	47,956
Series E Preferred Stock	2,691	10,013
Total	<u>\$ 111,299</u>	<u>\$ 152,343</u>

Conversion

Each share of convertible preferred stock is convertible at any time, at the option of the stockholder into a number of shares of the Company's common stock determined by dividing the original issue price of the respective series of preferred stock by the conversion price of the respective series of preferred stock in effect at the time of conversion (conversion ratio). The conversion price is subject to certain customary adjustments, including those resulting from the triggering of down-round features during the year ended December 31, 2024 as a result of the issuance of the Series E Preferred Stock in connection with the Series E Initial Closing. As of December 31, 2024 and 2025, the conversion ratio for Series A Preferred Stock was 0.70 to 1, the conversion ratio for Series B Preferred Stock was 0.87 to 1, the conversion ratio for Series C Preferred Stock was 0.89 to 1, the conversion ratio for Series D Preferred Stock was 0.77 to 1, and the conversion ratio for Series E Preferred Stock was 0.65 to 1.

Pursuant to the Company's certificate of incorporation in effect as of December 31, 2025, the shares of all series of convertible preferred stock would automatically convert into shares of the Company's common stock at the conversion ratio then in effect in the event of (i) an initial public offering of the Company's common stock at a price of at least \$11.5013 per share and resulting in at least \$50.0 million in gross proceeds to the Company, or (ii) a vote or written consent of the holders of at least 70% of the then issued and outstanding shares convertible preferred stock, voting on an as-converted basis and together as a single class.

Redemption

The holders of all series of convertible preferred stock do not have the option to demand redemption except in the case of a liquidation or Deemed Liquidation Event (defined below), nor does the Company have the right to call the shares.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company, or in a Deemed Liquidation Event, the holders of convertible preferred stock then outstanding are entitled to be paid out of the assets of the Company available for distribution to its stockholders before any payment shall be made to holders of common stock in an amount per share equal to the applicable original issue price, plus all accrued but unpaid dividends (the "Preference Amount"). The Preference Amounts are paid first to holders of Series E Preferred Stock, then Series D Preferred Stock, then Series C Preferred Stock, then Series B Preferred Stock, and then Series A Preferred Stock.

After the payment of all Preference Amounts required to be paid to the holders of shares of all series of convertible preferred stock, the remaining assets of the Company available for distribution to its stockholders will be distributed among the holders of the shares of all series of convertible preferred stock and common stock, pro rata, based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to common stock pursuant to the terms of the Company's certificate of incorporation immediately prior to such liquidation, dissolution or winding-up of the Company.

Unless each of (i) the holders of at least 70% of the issued and outstanding shares of convertible preferred stock, voting on an as-converted basis and together as a single class, (ii) the holders of at least 66 2/3% of the issued and outstanding shares of Series C Preferred Stock, exclusively and as a separate class, (iii) the holders of a majority of the issued and outstanding shares of Series D Preferred Stock, voting on an as-converted basis and together as a single class, and (iv) the holders of at least 60% of the issued and outstanding shares of Series E Preferred Stock, voting on an as-converted basis and together as a single class elect otherwise, the following events are considered a "Deemed Liquidation Event": a merger, consolidation, statutory conversion, transfer, domestication, or continuance (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets or intellectual property of the Company.

Protective Rights

The holders of all series of convertible preferred stock are entitled to protective rights, which require the affirmative vote of 70% of the then issued and outstanding shares of convertible preferred stock, voting on an as-converted basis and together as a single class, for certain corporate actions, which include, but are not limited to the sale of the Company, its liquidation, and the authorization of additional shares of the Company's capital.

7. Stockholders' Deficit

Common Stock Warrants

The Company issued common stock warrants as part of the Loan Agreement (refer to Note 9, *Term Loan*) which were determined to be a freestanding instrument and met the criteria for equity classification as they are indexed to the Company's own common stock and settled in a fixed number of shares for a fixed exercise price, with no cash settlement feature. As of December 31, 2024 and 2025, warrants to purchase 24,152 shares of common stock with an exercise price of \$4.82 per share were outstanding. The common stock warrants expire in September 2031.

Common Stock

The voting, dividend and liquidation rights of the holders of common stock are subject to and qualified by the rights, powers, and preferences of the holders of the Company's convertible preferred stock. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company's Board of Directors, if any, subject to the preferential dividend rights of holders of all series of convertible preferred stock. As of December 31, 2025, the Company has not declared nor paid any dividends.

The Company has reserved shares of common stock for the conversion or exercise of the following securities:

	December 31,	
	2024	2025
Series A Preferred Stock	1,002,805	1,002,805
Series B Preferred Stock	4,069,102	4,069,102
Series C Preferred Stock	6,540,022	6,540,022
Series D Preferred Stock	12,669,755	12,669,755
Series E Preferred Stock	8,086,980	15,128,745
Preferred stock tranche rights	7,041,765	—
Common stock warrants	24,152	24,152
Outstanding stock options	8,935,785	9,098,233
Unissued stock-based awards under the 2016 Employee, Director and Consultant Equity Incentive Plan	131,781	1,097,518
Total	48,502,147	49,630,332

8. Equity Incentive Plan

2016 Employee, Director and Consultant Equity Incentive Plan

The Company's 2016 Employee, Director and Consultant Equity Incentive Plan, as amended (the "2016 Plan"), provides for the Company to sell or award restricted common stock or to grant incentive and nonqualified stock options for the purchase of common stock (or other stock-based awards) to its founders, employees, officers, directors and consultants. The 2016 Plan is administered by the Board of Directors, or at the discretion of the Board of Directors, by a committee of the Board of Directors. The exercise prices, vesting and other restrictions are determined at the discretion of the Board of Directors, or its committee if so delegated.

As of December 31, 2024, 9,680,270 shares of common stock were authorized and reserved for issuance under the 2016 Plan. In January 2025, the Board of Directors further increased the number of shares of common stock authorized and reserved for issuance under the 2016 Plan to 10,826,224 shares. As of December 31, 2025, there were 1,097,518 shares available for future issuance under the 2016 Plan. Shares of unused common stock underlying any awards that are forfeited, canceled or reacquired by the Company will again be available for grant under the 2016 Plan. Upon stock option exercise, the Company delivers newly issued shares to the participant.

Stock option vesting typically occurs over four years for employees and directors and is at the discretion of the Company's Board of Directors. Stock options typically have a maximum term of ten years.

Stock Option Valuation

The fair value of each stock option granted was estimated on the date of grant using the Black-Scholes option-pricing model and the assumptions summarized in the following table:

	Year Ended December 31,	
	2024	2025
Expected volatility	93.28% - 94.56%	91.99% - 93.00%
Expected dividend yield	—	—
Expected term (in years)	6.25	6.25
Risk-free interest rate	3.56% - 4.26%	3.66% - 4.04%
Fair value of common stock	\$1.22 - \$1.91	\$2.42

The following table presents a summary of all stock option activity under the 2016 Plan:

	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	8,935,785	\$ 2.67	8.54	\$ 1,448
Granted	619,719	2.42		
Exercised	(17,769)	1.89		
Canceled or forfeited	(439,502)	3.10		
Outstanding at December 31, 2025	9,098,233	\$ 2.64	7.72	\$ 3,386
Vested and expected to vest at December 31, 2025	9,098,233	\$ 2.64	7.72	\$ 3,386
Vested and exercisable at December 31, 2025	5,113,876	\$ 2.93	7.33	\$ 1,541

The weighted-average grant date fair values of stock options granted during the years ended December 31, 2024 and 2025 were \$1.05 and \$1.89 per share, respectively. The intrinsic values of stock options exercised was less than \$0.1 million during each of the years ended December 31, 2024 and 2025.

Total unrecognized compensation expense related to unvested stock options was approximately \$5.4 million as of December 31, 2025, which the Company expects to recognize over a weighted-average period of approximately 2.0 years.

During the year ended December 31, 2024, the Company granted performance-based stock options to an officer for the purchase of 590,940 shares of common stock with vesting contingent upon the achievement of the Series E Second Closing and a four-year service period from the grant date. As of December 31, 2024, the criteria for the performance-based vesting condition was considered probable and was subsequently achieved in January 2025. The Company recognized stock-based compensation expense of \$0.3

million and \$0.2 million in the years ended December 31, 2024 and 2025, respectively. As of December 31, 2025, the total unrecognized stock-based compensation expense related to these awards was \$0.1 million, which is expected to be recognized over the remaining 2.1 years.

During the year ended December 31, 2023, the Company granted stock options to an officer for the purchase of 419,506 shares of common stock with vesting contingent on both a performance and a market condition, specifically the closing of a future financing transaction at a specific price per share. The Company estimated the service period as four years. As of December 31, 2024, the criteria for the performance-based vesting condition was considered probable and was subsequently achieved in January 2025 in connection with the Series E Second Closing. The Company recognized stock-based compensation expense of \$0.4 million and \$0.2 million in the years ended December 31, 2024 and 2025, respectively. As of December 31, 2025, the total unrecognized stock-based compensation expense related to these awards was \$0.3 million, which is expected to be recognized over the remaining 1.2 years.

Stock-Based Compensation Expense

The following table presents the classification of stock-based compensation expense included in the Company's consolidated statements of operations and comprehensive loss (in thousands):

	Year Ended December 31,	
	2024	2025
Research and development	\$ 845	\$ 792
General and administrative	3,465	2,525
Total	<u>\$ 4,310</u>	<u>\$ 3,317</u>

9. Term Loan

On September 21, 2021, the Company entered into a Loan and Security Agreement with Silicon Valley Bank (the "Lender"), which was subsequently amended (the "Loan Agreement"), that provided for aggregate term loans of \$15.0 million. In connection with the Loan Agreement, the Company also issued common stock warrants to the Lender (refer to Note 7, *Stockholders' Deficit*).

On November 22, 2024, the Company and the Lender executed an amendment to the Loan Agreement under which the Lender extended the term loan amortization date to April 1, 2025 and added two interest-only extension events that could further extend the term loan amortization date. The amendment also required the Company to maintain the lesser of \$60.0 million or 50% of the Company's consolidated cash within the Company's primary operating account with the Lender. The amendment was accounted for as a debt modification, rather than an extinguishment, as the difference in the present value of the cash flows under the terms of the original debt agreement and the terms immediately after the amendment was less than 10%. As a result, issuance costs paid to the Lender in connection with the amendment, which were not significant, were recorded as a reduction of the carrying amount of the debt liability. Unamortized issuance costs as of the date of the modification are amortized to interest expense using the effective interest method through the loan maturity date.

Term loan balances, including final payments, are summarized as follows (in thousands):

	December 31,	
	2024	2025
Total term loan principal	\$ 15,000	\$ 12,500
Final payments	476	647
Unamortized debt discount and issuance costs	(188)	(70)
Term loan, net of discount	15,288	13,077
Less current portion	(2,500)	(13,077)
Term loan, net of discount and current portion	<u>\$ 12,788</u>	<u>\$ —</u>

The term loan matures on October 1, 2026. After triggering an interest-only extension upon the Series E Second Closing in January 2025, which extended the interest-only period on the term loan, the Company began paying principal in 12 equal monthly payments of approximately \$1.3 million each on November 1, 2025. The term loan bears interest at a floating rate equal to the greater of (i) 6.75% and (ii) the prime rate plus a margin; provided that the interest rate will not exceed 6.75%. The term loan calls for an additional final payment equal to 4.5% of the aggregate principal amount borrowed, as well as a fee of approximately \$0.1 million, due upon (a) the term loan maturity date, (b) the repayment of the term loan in full, (c) as required pursuant to permitted prepayment or mandatory prepayment upon an acceleration, or (d) the termination of the Loan Agreement. The Company may, at its option,

prepay the term loan in full or in part at any time prior to maturity, subject to a prepayment fee ranging between 0% and 3% of the outstanding principal amount of the term loan. The prepayment fee would also be due and payable in the event of an acceleration of the principal amount of the loan due to an event of default. The Loan Agreement contains affirmative covenants and certain restrictive covenants. The Company is in compliance with all financial and nonfinancial covenants as of December 31, 2025.

In addition, the Company is accreting the final payments over the term of the Loan Agreement as interest expense using the effective interest method. As of December 31, 2024 and 2025, the Company accreted a cumulative final payment of \$0.5 million and \$0.6 million, respectively, which is presented within term loan, net of discount and current portion, and current portion of term loan, net of discount, respectively, on its consolidated balance sheets.

As of December 31, 2025, the effective interest rate of the term loan is 8.8%.

The term loan includes an embedded derivative related to the payment of interest upon an event of default. The Company determined the estimated fair value of the embedded derivative was not material to the consolidated financial statements. Additionally, the term loan includes contingent payment features which also represent an embedded derivative which requires bifurcation from the debt host. As of December 31, 2025, the Company determined the estimated fair value of the contingent payment features embedded derivative was not material to the consolidated financial statements. The Company will reassess the probability of these contingent payment events and the estimated fair value of the related embedded derivatives at each reporting period and revise the estimated fair value of the derivative in the Company's consolidated financial statements.

10. Leases

Operating Leases

30 Acorn Park Drive

On April 23, 2019, the Company entered into a non-cancelable operating lease for office, research and manufacturing space located at 30 Acorn Park Drive in Cambridge, Massachusetts through February 28, 2031. The lease commenced in January 2020 and includes two five-year lease renewal options.

The lease also includes certain free rentals and rent escalations over the term of the lease, which are deferred and recognized on a straight-line basis as rent expense over the term of the lease.

In connection with the lease agreement, the Company provided a security deposit to the lessor in the form of a bank letter of credit, which is supported by \$2.9 million of restricted cash. The letter of credit automatically renews annually until the lease ends. The Company is also responsible for its utilities and a proportional share of property taxes and other operating costs.

Rent expense for the leased space at 30 Acorn Park Drive amounted to \$9.1 million for each of the years ended December 31, 2024 and 2025.

As discussed in Note 14, *Related Party Transactions*, in December 2019, the Company entered into a non-cancelable sublease arrangement with a related party to sublease approximately 50% of the leased space through February 2025. In January 2024, the Company and the sublessee amended the sublease arrangement to extend the sublease date through December 2025. Sublease rental income amounted to \$4.2 million during each of the years ended December 31, 2024 and 2025, and is reflected in the consolidated statements of operations and comprehensive loss with the caption sublease income—related party. The sublease expired in December 2025.

Vivarium Facility #1

The Company leased space at a vivarium facility which is classified as an operating lease. In December 2025, the lease expired. Rent expense for the lease amounted to \$0.6 million for each of the years ended December 31, 2024 and 2025.

Vivarium Facility #2

On November 1, 2025, the Company entered into a non-cancelable operating lease for two private animal suites in order to conduct *in vivo* studies. The lease, which commenced in November 2025, includes two free months of rent and is otherwise subject to rental payments of approximately \$0.1 million per month over the lease term. The lease term extends through December 2027 and the lease includes an extension option subject to mutual agreement between the parties.

Upon the lease commencement date, the Company recorded an operating lease liability and operating lease right-of-use asset of \$1.6 million each. Additionally, the Company provided a refundable cash deposit to the lessor of \$0.2 million which is classified in other assets as of December 31, 2025. Rent expense for the lease amounted to \$0.1 million during the year ended December 31, 2025.

The components of operating lease expense were as follows (in thousands):

	Year Ended December 31,	
	2024	2025
Operating lease cost	\$ 9,657	\$ 9,813
Variable lease cost	1,797	1,900
Short-term lease cost	—	—
Sublease income	(4,166)	(4,228)
Total net lease expense	<u>\$ 7,288</u>	<u>\$ 7,485</u>

Expected future minimum operating lease payments as of December 31, 2025 are as follows (in thousands):

Year Ending December 31:	Amount
2026	\$ 10,174
2027	10,510
2028	9,822
2029	10,068
2030	10,320
Thereafter	1,727
Total future minimum lease payments	52,621
Less: imputed interest	(9,106)
Total operating lease liabilities	<u>\$ 43,515</u>

The weighted-average remaining lease term and incremental borrowing rate for the year ended December 31, 2024 was 6.1 years and 8.0%, respectively. The weighted-average remaining lease term and incremental borrowing rate for the year ended December 31, 2025 was 5.0 years and 8.0%, respectively.

The following table presents supplemental disclosure of cash flow information related to the Company's operating leases (in thousands):

	Year Ended December 31,	
	2024	2025
Operating cash used for operating leases	\$ 9,404	\$ 9,816
Right-of-use assets obtained in exchange for operating lease liabilities	\$ 595	\$ 1,638

Finance Leases

The Company entered into finance lease agreements for laboratory equipment during the year ended December 31, 2024, which mature in December 2028. The following table summarizes the Company's finance lease costs and other information, including supplemental disclosure of cash flow information related to the Company's finance leases (in thousands, except for lease term and borrowing rate):

	Classification	Year Ended December 31,	
		2024	2025
Finance Lease Cost:			
Amortization of finance lease right-of-use assets	Research and development expense	\$ 91	\$ 569
Interest expense on finance lease liabilities	Interest expense	49	227
Total finance lease cost		<u>\$ 140</u>	<u>\$ 796</u>
Other Information:			
Operating cash used for finance leases		\$ —	\$ 227
Financing cash used for finance leases		\$ —	\$ 581
Right-of use assets obtained in exchange for finance lease liabilities		\$ 2,858	\$ —
Weighted-average remaining lease term (in years)		4.0	3.0
Weighted-average incremental borrowing rate		9.37%	9.37%

Maturities of finance lease liabilities as of December 31, 2025 were as follows (in thousands):

	Amount
Year Ending December 31:	
2026	\$ 809
2027	809
2028	809
Total future minimum lease payments	2,427
Less: imputed interest	(319)
Total finance lease liabilities	\$ 2,108

11. Commitments and Contingencies

Harvard Agreement

In August 2017, the Company entered into a license agreement, as amended (the "Harvard Agreement"), with the President and Fellows of Harvard College ("Harvard"), to obtain a worldwide, exclusive, royalty-bearing license to certain intellectual property which was developed by the Company's founder.

Under the terms of the Harvard Agreement, the Company is required to make payments to Harvard upon the achievement of certain development, regulatory and sales milestones up to an aggregate of \$18.3 million, as well as future royalty payments, based on a percentage of aggregate net sales ranging in the low single digits. In addition, the Company is required to make payments to Harvard for non-royalty income received under sublicenses or strategic partnerships with third parties, with the applicable payment based on the stage of development of the first licensed product at the time the Company enters into such agreement (before or after enrollment of the first patient in a Phase 2 clinical study of a licensed product), ranging from a single-digit percentage to a mid-teens percentage. During the year ended December 31, 2025, the Company met one milestone of \$0.2 million. The Company recorded \$0.2 million of research and development expense for the milestone which is included in accounts payable on the consolidated balance sheet as of December 31, 2025. As of December 31, 2025, the Company has achieved milestones totaling \$0.3 million under the Harvard Agreement. None of the remaining milestones were deemed probable of achievement as of December 31, 2025.

The Company is also required to pay a low six-digit annual maintenance fee for the duration of the Harvard Agreement, which can be credited against future royalty payments.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings or other litigation relating to claims arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Legal fees and other costs associated with such proceedings are expensed as incurred. As of December 31, 2024 and 2025, the Company was not a party to any material legal proceedings or claims.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with the Board of Directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2024 and 2025.

12. Collaboration Agreement

In May 2024, the Company entered into a research collaboration agreement with ARTBIO, Inc. (“ARTBIO”) to co-develop multiple Helicon-enabled alpha particle radioligand therapies (HEARTs) for the treatment of cancer. Under the terms of this agreement, the Company is responsible for equally participating on joint committees and carrying out at least four research programs with respect to each collaboration target. The Company and ARTBIO share in the costs of the research programs equally, with ARTBIO responsible for funding the first \$10.0 million of development costs incurred by both parties and the Company responsible for funding the next \$10.0 million of development costs. Any further development costs beyond these initial funding amounts will also be shared equally by both parties. Under certain circumstances, either party can terminate the agreement, and the Company may be obligated to refund, to ARTBIO, amounts received during the initial funding periods, such that the total costs incurred through the effective date of termination would be shared equally.

Upon later regulatory approval and commercialization of related product(s), the parties will share equally in all net profits or losses. The agreement expires upon (1) the date on which products arising from the collaboration are no longer commercialized or developed for commercialization, or (2) termination by one or both parties.

The Company determined the agreement was a collaboration arrangement under ASC 808. The Company and ARTBIO are jointly overseeing and are active participants in the research and development activities under the agreement. In addition, both parties are exposed to the significant risks and potential rewards under the agreement.

During the years ended December 31, 2024 and 2025, the Company incurred \$2.6 million and \$2.4 million, respectively, in costs related to the research programs within the scope of the agreement, which have been fully reimbursed by ARTBIO. Pursuant to the contract termination and funding provisions noted above, and based on the current development plan, the Company has recorded a long-term liability of \$1.3 million and \$2.7 million as of December 31, 2024 and 2025, respectively, to represent its portion of the research and development expense incurred to date. The Company recorded the remaining amounts, totaling \$1.3 million and \$1.0 million, as a reduction of research and development expenses within the statements of operations and comprehensive loss for the years ended December 31, 2024 and 2025, respectively. In addition, the Company had a receivable due from ARTBIO with respect to the reimbursement of development costs totaling \$1.4 million, which was recorded within prepaid expenses and other current assets on the consolidated balance sheet at December 31, 2024.

13. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2024 and 2025 due to the Company incurring net losses and maintaining a full valuation allowance against its net deferred tax assets.

The following table summarizes the loss before income tax expense by jurisdiction for the periods indicated (in thousands):

	Year Ended December 31,	
	2024	2025
Domestic	\$ 117,914	\$ 145,889
Foreign	—	—
Loss before income tax expense	\$ 117,914	\$ 145,889

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows (in thousands):

	Year Ended December 31,			
	2024		2025	
	Amount	Rate	Amount	Rate
U.S. federal statutory income tax rate	\$ (24,762)	21.0%	\$ (30,637)	21.0%
Tax credits				
Research and development tax credits	(4,490)	3.8%	(4,316)	3.0%
Nontaxable and nondeductible items	562	(0.5)%	429	(0.3)%
Changes in valuation allowance	28,690	(24.3)%	34,524	(23.7)%
State and local income taxes, net of federal effect	—	—%	—	—%
Total	\$ —	—%	\$ —	—%

There were no income taxes paid (net of refunds received) for the years ended December 31, 2024 and 2025.

The components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2024	2025
Deferred tax assets:		
Net operating loss carryforwards	\$ 53,563	\$ 97,074
Research and development credits	17,537	23,287
Accrued expenses and other	2,009	3,522
Lease liabilities	12,968	11,630
Capitalized research and development expenses	46,553	39,519
Equity based compensation	1,749	2,251
Depreciation	432	361
Total deferred tax assets	134,811	177,644
Less valuation allowance	(122,217)	(166,536)
Total deferred tax assets, net	12,594	11,108
Deferred tax liabilities:		
Right-of-use lease assets	(12,594)	(11,108)
Total deferred tax liabilities	(12,594)	(11,108)
Net deferred tax asset	\$ —	\$ —

As of December 31, 2025, the Company had net operating loss carryforwards for federal income tax purposes of \$357.9 million, of which \$348.9 million can be carried forward indefinitely and the remainder of which begin to expire in 2036. In addition, as of December 31, 2025 the Company had state net operating loss carryforwards of \$347.4 million, of which \$2.7 million can be carried forward indefinitely and the remainder of which begin to expire in 2036. As of December 31, 2025, the Company had federal and state research and development tax credit carryforwards of \$17.2 million and \$7.7 million, respectively, which are available to reduce future tax liabilities, and which begin to expire in 2030.

Net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service ("IRS") and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50% as defined under Sections 382 and 383 in the Internal Revenue Code, which could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the Company's value immediately prior to the ownership change. Subsequent

ownership changes may further affect the limitation in future years. To date, the Company has not yet conducted a study to determine if any such changes have occurred that could limit its ability to use its net operating loss and tax credit carryforwards.

The Company has not yet conducted a study of its research and development credit carryforwards. This study may result in an increase or decrease to the Company's credit carryforwards; however, until a study is completed, and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's credits; therefore, there would be no impact to the consolidated statements of operations and comprehensive loss or consolidated statements of cash flows if an adjustment were required.

The Company has recorded a valuation allowance against its deferred tax assets as of December 31, 2024 and 2025, because the Company's management believes that it is more likely than not that these assets will not be realized. The valuation allowance increased by approximately \$36.6 million and \$44.3 million during the years ended December 31, 2024 and 2025, respectively, primarily as a result of operating losses incurred, research and development credits generated, and capitalized research expenditures incurred during the respective years.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,	
	2024	2025
Beginning balance	\$ 85,622	\$ 122,217
Change in valuation allowance	36,595	44,319
Ending balance	<u>\$ 122,217</u>	<u>\$ 166,536</u>

The Company had no unrecognized tax benefits or related interest and penalties accrued as of December 31, 2024 and 2025. The Company's accounting policy is to recognize any interest and penalties related to uncertain tax positions as components of income tax expense.

The Company is subject to U.S. federal income tax as well as state income tax in various U.S. states. The statutes of limitations for assessment by the IRS and state tax authorities are open for the tax years since 2021. Currently, no federal or state income tax returns are under examination by the respective taxing authorities. All tax years remain open to examination by these jurisdictions, as carryforward attributes generated in past years may be adjusted in a future period.

On July 4, 2025, the U.S. government enacted The One Big Beautiful Bill Act of 2025 ("OBBBA") which includes, among other provisions, changes to the U.S. corporate income tax system. Key corporate tax provisions include the restoration of 100% bonus depreciation, immediate expensing for domestic research and experimental expenditures, changes to Section 163(j) interest limitations, updates to GILTI and FDII rules, amendments to energy credits, and expanded Section 162(m) aggregation requirements. In accordance with ASC 740, the Company recognized the effects of the new tax law in the period that includes the enactment date. While OBBBA did not have a material impact on the Company's consolidated financial statements as of and for year ended December 31, 2025, the Company will continue to assess the changes. However, the Company does not expect such changes will have a material effect on its consolidated financial statements in future periods.

14. Related Party Transactions

The Company subleased a portion of the 30 Acorn Park Drive property discussed in Note 10, *Leases*, to a subtenant that is considered a related party due to common board members and stockholders. The related party is required to make lease payments and payments for its proportionate share of related occupancy costs to the Company.

The Company recorded sublease income of \$4.2 million for each of the years ended December 31, 2024 and 2025. In addition, the Company received payments from the related party of \$2.3 million and \$2.0 million during the years ended December 31, 2024 and 2025, respectively, representing the related party's share of occupancy costs. Of the amounts received, \$2.1 million and \$1.8 million were recorded as a reduction of research and development expense for the years ended December 31, 2024 and 2025, respectively, and \$0.2 million was recorded as a reduction of general and administrative expense for each of the years ended December 31, 2024 and 2025 in the consolidated statements of operations and comprehensive loss.

As of December 31, 2024, there was \$0.1 million due from the related party on the consolidated balance sheet related to rent and occupancy costs. The Company recorded a rent receivable from the related party of \$0.3 million as of December 31, 2024 which was classified as current on the consolidated balance sheet. The sublease expired in December 2025.

15. Retirement Plan

The Company has a U.S. tax-qualified employee savings and retirement 401(k) plan, covering all qualified employees. Participants may elect a salary deferral up to the statutorily prescribed annual limit for tax-deferred contributions. The Company may make matching contributions to each eligible participant's account based on a percentage of the participant's elective deferral contribution. Matching contributions were \$0.9 million and \$1.2 million during the years ended December 31, 2024 and 2025, respectively.

16. Net Loss Per Share

The following table sets forth the outstanding shares of common stock equivalents, presented based on amounts outstanding at each period end, that were excluded from the calculation of diluted net loss per share allocable to common stockholders for the periods indicated because including them would have been anti-dilutive:

	Year Ended December 31,	
	2024	2025
Series A Preferred Stock	1,002,805	1,002,805
Series B Preferred Stock	4,069,102	4,069,102
Series C Preferred Stock	6,540,022	6,540,022
Series D Preferred Stock	12,669,755	12,669,755
Series E Preferred Stock	8,086,980	15,128,745
Common stock warrants	24,152	24,152
Outstanding stock options	7,925,339	8,087,787
Preferred stock tranche rights	7,041,765	—
Total	47,359,920	47,522,368

The amounts of outstanding stock options in the table above for the years ended December 31, 2024 and 2025 exclude 1,010,446 potentially dilutive securities as these outstanding stock options relate to contingently issuable shares for which the market condition was not satisfied as of the respective period end.

17. Segment Reporting

The Company manages its operations as a single operating and reportable segment that is focused on developing Helicon medicines targeting historically undruggable proteins. The CODM manages the Company's operations on a consolidated basis and uses consolidated net loss to assess financial performance and allocate resources. Consolidated net loss is used by the CODM to make key operating decisions, such as the determination of the rate at which the Company seeks to grow its research and development initiatives and the allocation of capital between research and development and general and administrative expenses. The CODM does not review assets in evaluating the results of the segments, and therefore, such information is not presented.

The following table presents selected financial information with respect to the Company's single operating segment (in thousands):

	Year Ended December 31,	
	2024	2025
Operating expenses:		
External research and development expense		
- Zolucetide	\$ 32,633	\$ 41,798
External research and development expense		
- B-Catenin Degradar	4,067	1,132
External research and development expense - ERG	4,594	7,355
External research and development expense - AR ^{ON}	1,358	4,043
External research and development expense		
- Early discovery and other programs	4,432	4,765
Other research and development expenses	24,249	28,758
Personnel-related research and development expenses (excluding stock-based compensation expense)	26,732	34,555
Personnel-related general and administrative expenses (excluding stock-based compensation expense)	8,080	9,115
Other general and administrative expenses	13,563	14,739
Depreciation and amortization expense	2,107	2,502
Stock-based compensation expense	4,310	3,317
Other segment items ⁽¹⁾	(8,211)	(6,190)
Consolidated net loss	\$ 117,914	\$ 145,889

Notes

- (1) Other segment items consist of interest income, interest expense, sublease income – related party, changes in fair value of preferred stock tranche right liability and other income.

18. Subsequent Events

The Company has evaluated subsequent events through April 2, 2026, the date these consolidated financial statements were available to be issued and, with respect to the reverse stock split discussed below, through June 4, 2026, the date the consolidated financial statements were available to be reissued. The Company has concluded that no events or transactions have occurred that require disclosure in the accompanying consolidated financial statements, except as follows:

Series F Preferred Stock

On January 6, 2026, the Company entered into the Series F Preferred Stock Purchase Agreement (the "Series F Agreement") and issued to investors an aggregate of 49,518,175 shares of Series F Preferred Stock at a purchase price of \$6.16 per share for gross proceeds of \$305.2 million. The issuance of the Series F Preferred Stock triggered adjustments to the respective conversion prices of the Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock, Series D Preferred Stock and Series E Preferred Stock.

2026 Stock Option and Grant Plan

On January 6, 2026, the Company's Board of Directors and stockholders approved the 2026 Stock Option and Grant Plan (the "January 2026 Plan"). The January 2026 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock awards and other stock-based awards. The number of shares of common stock authorized and reserved for issuance under the January 2026 Plan is 8,873,223 shares. The shares of common stock underlying any awards that are forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of common stock or otherwise terminated and shares that are withheld upon exercise of an option or settlement of an award to satisfy the exercise price or tax withholding under the 2016 Plan and January 2026 Plan will be added back to the shares of common stock available for issuance under the January 2026 Plan. No further grants will be made under the 2016 Plan.

Grants of Stock Options

In February 2026, the Company granted stock options to purchase an aggregate of 5,981,740 shares of common stock, at an exercise price of \$3.14 per share. In March 2026, the Company granted stock options to purchase an aggregate of 46,591 shares of common stock, at an exercise price of \$4.09 per share. The stock options are expected to vest over a four-year period.

Simple Agreement for Future Equity

On March 27, 2026, the Company issued a SAFE for gross proceeds of \$50.0 million. The amount invested by the investor in the SAFE is automatically convertible into either shares of common stock upon the closing of an initial public offering or in connection with a direct listing, or shares of preferred stock in connection with an equity financing. The number of shares to be received by the SAFE investor upon conversion is based on a 10% discount to the pricing in the applicable initial public offering, direct listing, or equity financing, subject to certain adjustments.

Reverse Stock Split

On June 3, 2026, the Company effected a 1-for-1.5389 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock (see Note 6). Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

Events Subsequent to Original Issuance of Consolidated Financial Statements (Unaudited)

In connection with the reissuance of the consolidated financial statements, the Company has evaluated subsequent events through June 4, 2026, the date the consolidated financial statements were available to be reissued.

Parabilis Medicines, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	December 31, 2025	March 31, 2026
Assets		
Current assets:		
Cash and cash equivalents	\$ 27,711	\$ 329,039
Prepaid expenses and other current assets	1,647	3,033
Total current assets	29,358	332,072
Property and equipment, net	6,715	6,658
Restricted cash	2,855	2,855
Operating lease right-of-use assets	39,360	37,697
Other assets	2,532	4,891
Total assets	<u>\$ 80,820</u>	<u>\$ 384,173</u>
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 17,272	\$ 15,038
Due to related party	—	211
Accrued expenses and other current liabilities	18,630	21,557
Operating lease liabilities, current portion	7,174	7,380
Finance lease liabilities, current portion	638	653
Term loan, net of discount	13,077	9,401
Total current liabilities	56,791	54,240
Operating lease liabilities, net of current portion	36,341	34,412
Finance lease liabilities, net of current portion	1,470	1,301
Simple agreement for future equity	—	50,000
Other liabilities	2,742	—
Total liabilities	97,344	139,953
Commitments and contingencies (Note 11)		
Convertible preferred stock, \$0.0001 par value; 53,296,426 and 102,814,601 shares authorized at December 31, 2025 and March 31, 2026, respectively; 53,296,426 and 102,814,601 shares issued and outstanding at December 31, 2025 and March 31, 2026, respectively (liquidation preference of \$658,972 and \$989,587 at December 31, 2025 and March 31, 2026, respectively)	509,971	814,540
Stockholders' deficit:		
Common stock, \$0.0001 par value; 81,000,000 and 150,132,000 shares authorized at December 31, 2025 and March 31, 2026, respectively; 2,035,357 and 2,128,056 shares issued and outstanding at December 31, 2025 and March 31, 2026, respectively	—	—
Additional paid-in capital	15,009	16,500
Accumulated deficit	(541,504)	(586,820)
Total stockholders' deficit	(526,495)	(570,320)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 80,820</u>	<u>\$ 384,173</u>

The accompanying notes are an integral part of the condensed consolidated financial statements.

Parabilis Medicines, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2025	2026
Operating expenses:		
Research and development	\$ 33,905	\$ 37,753
General and administrative	6,336	9,700
Total operating expenses	40,241	47,453
Loss from operations	(40,241)	(47,453)
Other income (expense):		
Interest income	1,257	2,429
Interest expense	(399)	(292)
Sublease income - related party	1,057	—
Total other income, net	1,915	2,137
Net loss	\$ (38,326)	\$ (45,316)
Cumulative dividends on convertible preferred stock	(9,781)	(17,689)
Deemed dividend upon down-round of convertible preferred stock	—	(7,875)
Net loss allocable to common stockholders	\$ (48,107)	\$ (70,880)
Net loss per share allocable to common stockholders, basic and diluted	\$ (23.84)	\$ (34.58)
Weighted average common shares outstanding, basic and diluted	2,017,610	2,050,028
Comprehensive loss:		
Net loss	\$ (38,326)	\$ (45,316)
Change in unrealized gain on marketable securities	(16)	—
Comprehensive loss	\$ (38,342)	\$ (45,316)

The accompanying notes are an integral part of the condensed consolidated financial statements.

Parabilis Medicines, Inc.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share amounts)
(unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2024	42,459,887	\$ 440,375	2,017,588	\$ —	\$ 11,658	\$ 21	\$ (395,615)	\$ (383,936)
Issuance of Series E convertible preferred stock, inclusive of preferred stock tranche right liability of \$2,167, net of issuance costs of \$62	10,836,539	69,596	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	852	—	—	852
Change in unrealized gain on marketable securities	—	—	—	—	—	(16)	—	(16)
Net loss	—	—	—	—	—	—	(38,326)	(38,326)
Balance at March 31, 2025	53,296,426	\$ 509,971	2,017,588	\$ —	\$ 12,510	\$ 5	\$ (433,941)	\$ (421,426)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2025	53,296,426	\$ 509,971	2,035,357	\$ —	\$ 15,009	\$ —	\$ (541,504)	\$ (526,495)
Issuance of common stock upon exercise of stock options	—	—	92,699	—	187	—	—	187
Issuance of Series F convertible preferred stock, net of issuance costs of \$680	49,518,175	304,569	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,304	—	—	1,304
Net loss	—	—	—	—	—	—	(45,316)	(45,316)
Balance at March 31, 2026	102,814,601	\$ 814,540	2,128,056	\$ —	\$ 16,500	\$ —	\$ (586,820)	\$ (570,320)

The accompanying notes are an integral part of the condensed consolidated financial statements.

Parabilis Medicines, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2025	2026
Cash flows from operating activities		
Net loss	\$ (38,326)	\$ (45,316)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	654	606
Accretion of discounts on marketable securities	188	—
Stock-based compensation expense	852	1,304
Non-cash interest expense	84	74
Non-cash lease expense	1,523	1,663
Changes in operating assets and liabilities:		
Rent receivable - related party	51	—
Due from related party	24	—
Due to related party	—	211
Prepaid expenses and other assets	(1,132)	(2,812)
Operating lease liabilities	(1,512)	(1,723)
Accounts payable, accrued expenses and other liabilities	3,440	(3,207)
Net cash used in operating activities	<u>(34,154)</u>	<u>(49,200)</u>
Cash flows from investing activities		
Purchases of marketable securities	(16,664)	—
Proceeds from maturities of marketable securities	23,427	—
Purchases of property and equipment	(74)	(369)
Net cash provided by (used in) investing activities	<u>6,689</u>	<u>(369)</u>
Cash flows from financing activities		
Proceeds from issuance of Series E convertible preferred stock and preferred stock tranche right liability	67,491	—
Proceeds from issuance of Series F convertible preferred stock	—	305,249
Payments of convertible preferred stock issuance costs	(62)	(635)
Proceeds from issuance of simple agreement for future equity	—	50,000
Principal payments on finance leases	(140)	(154)
Principal payments on debt	—	(3,750)
Proceeds from exercise of stock options	—	187
Net cash provided by financing activities	<u>67,289</u>	<u>350,897</u>
Increase in cash, cash equivalents and restricted cash	<u>39,824</u>	<u>301,328</u>
Cash, cash equivalents and restricted cash at beginning of period	50,139	30,566
Cash, cash equivalents and restricted cash at end of period	<u><u>\$ 89,963</u></u>	<u><u>\$ 331,894</u></u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 315	\$ 239
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	\$ —	\$ 240
Deferred offering costs included in accounts payable and accrued expenses	\$ —	\$ 1,491
Convertible preferred stock issuance costs included in accounts payable	\$ —	\$ 45
Settlement of Series E preferred stock tranche right liability	\$ 2,167	\$ —

The accompanying notes are an integral part of the condensed consolidated financial statements.

Parabilis Medicines, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Nature of the Business and Basis of Presentation

Nature of Business

Parabilis Medicines, Inc. (the “Company”) is a clinical-stage biopharmaceutical company developing medicines addressing some of the most consequential, yet historically undruggable, protein targets driving human disease. The Company leverages its platform to pioneer a therapeutic modality, Helicons, which are stabilized helical peptides engineered to bind and precisely modulate proteins. The Company, formerly known as FOG Pharmaceuticals, Inc., was incorporated in Delaware on July 10, 2015. On October 25, 2024, the Company changed its name from FOG Pharmaceuticals, Inc. to Parabilis Medicines, Inc. The Company is developing preclinical and clinical drug candidates, primarily operates in the United States of America, and, to date, has devoted substantially all its efforts on research and development and fundraising activities.

Risk and Uncertainties

The Company is subject to risks and uncertainties common to clinical-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to secure additional capital to fund operations. Product candidates resulting from the Company’s current discovery efforts will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel, infrastructure, and extensive compliance reporting capabilities. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Liquidity

The Company’s condensed consolidated financial statements have been prepared on the basis of continuity of operations, the realization of assets and satisfaction of liabilities in the ordinary course of business. From its inception through March 31, 2026, the Company has received aggregate gross proceeds of \$811.8 million from sales of convertible preferred stock, \$15.0 million from borrowings under a term loan, and \$50.0 million of gross proceeds from the sale of a simple agreement for future equity (“SAFE”). Additionally, under the terms of the License and Collaboration Agreement (the “Regeneron Agreement”) which the Company entered into with Regeneron Pharmaceuticals, Inc. (“Regeneron”) in May 2026, the Company expects to receive a \$50.0 million upfront payment, and Regeneron has also agreed to invest \$75.0 million in the Company’s next equity financing, subject to certain conditions, which includes a private placement of common stock concurrent with the Company’s initial public offering (see Note 17, *Subsequent Events*). The Company has incurred net losses and negative operating cash flows since inception and has an accumulated deficit of \$586.8 million at March 31, 2026. The Company expects that its cash and cash equivalents will be sufficient to fund its operations through at least twelve months from the date the condensed consolidated financial statements were available to be issued.

The Company is seeking to complete an initial public offering (“IPO”) of its common stock. Upon the completion of a qualified public offering on specified terms, the Company’s outstanding convertible preferred stock will be automatically converted into shares of common stock (see Note 6, *Convertible Preferred Stock*). Additionally, the Company’s outstanding SAFE will be automatically converted into shares of common stock upon an IPO (see Note 10, *Simple Agreement for Future Equity*). In the event the Company does not complete an IPO, the Company expects to finance its cash needs through a combination of equity offerings, debt or royalty financings, and collaborations. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company’s stockholders. If the Company is unable to raise additional funds through these sources or other sources of funding when needed, the Company could be forced to delay, reduce or eliminate its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Parabilis Security Corporation, formerly known as FOG Security Corporation, and Parabilis Medicines (Shanghai) Ltd. Co. All intercompany accounts and transactions have been eliminated in consolidation.

Parabilis Medicines, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

The Company's unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") for interim reporting and as required by Regulation S-X, Rule 10-01. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The condensed consolidated interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's financial position as of March 31, 2026, and the results of its operations and cash flows for the three months ended March 31, 2025 and 2026. The condensed balance sheet as of December 31, 2025 was derived from audited annual financial statements but does not include all disclosures required by GAAP. The results of operations for the interim periods are not necessarily indicative of results to be expected for the year ending December 31, 2026, any other interim periods, or any future year or period.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in Note 2 of the "Notes to Consolidated Financial Statements" in the audited annual financial statements included elsewhere in this prospectus. During the three months ended March 31, 2026, there were no material changes to the Company's significant accounting policies.

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates reflected within these condensed consolidated financial statements include the estimated fair value of the Company's common stock utilized in the determination of stock-based compensation expense, the determination of the incremental borrowing rate for leases, the estimated fair value of the preferred stock tranche right liability, convertible preferred stock and SAFE, as well as accrued research and development expenses. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company's cash equivalents consist of funds deposited in money market mutual funds and are recorded at fair value.

A reconciliation of the cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same amounts shown in the condensed consolidated statements of cash flows is as follows (in thousands):

	March 31,	
	2025	2026
Cash and cash equivalents	\$ 87,108	\$ 329,039
Restricted cash – long-term	2,855	2,855
Total cash, cash equivalents and restricted cash	<u>\$ 89,963</u>	<u>\$ 331,894</u>

Restricted Cash

As of December 31, 2025 and March 31, 2026, restricted cash consists of \$2.9 million serving as collateral for a letter of credit required under the Company's facility lease arrangement.

Parabilis Medicines, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Concentration of Risk

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents, and marketable securities. The Company's cash deposits generally do not exceed Federal Deposit Insurance Corporation ("FDIC") limits. The Company's cash equivalents consist of money market funds that are not insured by the FDIC; however, the Company has not experienced any losses in such accounts and believes that such funds are not exposed to any significant credit or concentration risk beyond the risks associated with commercial banking relationships. The Company maintains each of its cash and cash equivalents balances with financial institutions that management believes are creditworthy. The Company's investment policy includes guidelines on the quality of the financial institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. The Company's marketable securities consist of U.S. Treasury bills. The Company believes these investments present minimal credit risk.

The Company relies, and expects to continue to rely, on a small number of vendors and contract research organizations to manufacture certain supplies and raw materials for its research and development programs and to conduct clinical trials. These programs could be adversely affected by a significant interruption in these manufacturing services or the availability of raw materials, or an interruption in the provision of services provided by the Company's contract research organizations.

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees, directors and non-employees based on the award's fair value on the date of the grant and recognizes compensation expense related to those awards over the requisite service period, which is generally the vesting period of the respective award. The Company primarily issues stock options with only service-based vesting conditions and records the expense for these awards using the straight-line method. To a lesser extent, the Company has also granted awards with either service and performance-based vesting conditions or market and performance-based vesting conditions, and records expense based on the grant-date fair value over the requisite service period using the accelerated attribution method if the achievement of the performance condition is considered probable. At each reporting date, the Company estimates the probability that specified performance criteria will be achieved and does not begin to recognize compensation expense until it is probable that the performance-based vesting condition will be achieved.

The Company classifies stock-based compensation expense in its condensed consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs or service payments are classified.

The fair values of stock options with only service-based or performance-based conditions are estimated using the Black-Scholes option-pricing model. The Company's board of directors (the "Board of Directors") determines the fair value of the Company's common stock, with input from management, considering the Company's most recently available third-party valuations of common stock, as well as additional factors which may have changed since the date of the most recent valuation through the date of grant. The Company is a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a set of publicly-traded peer companies. The expected term of the Company's stock options granted has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options, which is presumed to be the midpoint between the vesting date and the end of the contractual term. If vesting is subject to a performance condition, the expected term is based on the mid-point between the explicit service period and the contractual term of the option. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield is zero, because the Company has never paid cash dividends on common stock and does not expect to pay any such dividends in the foreseeable future. The Company accounts for forfeitures of share-based compensation awards as they occur.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the convertible preferred stock or in stockholders' deficit as a reduction of additional paid-in capital. Should the planned equity financing be abandoned, the deferred offering costs are expensed immediately as a charge to operating expenses in the condensed consolidated statements of operations and comprehensive loss. As of December 31, 2025 and March 31, 2026, the Company had \$0.6 million and \$1.5 million, respectively, of deferred offering costs included in other assets on the condensed consolidated balance sheets.

Parabilis Medicines, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Net Loss Per Share

Basic net loss per common share is calculated by dividing net loss adjusted for cumulative dividends on convertible preferred stock accrued during the period, whether or not declared, and the value of any deemed dividends resulting from down-round adjustments to convertible preferred stock, where applicable, by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss allocable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the convertible preferred stock, common stock warrants, preferred stock tranche rights, stock options, and SAFE are considered potentially dilutive securities.

Basic and diluted net loss allocable to common stockholders per share is presented in conformity with the two-class method required for participating securities as all series of convertible preferred stock and SAFE are considered participating securities. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders.

Segment Information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker ("CODM"), in deciding how to allocate resources and assess performance. The Company's CODM, its chief executive officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources. All of the Company's long-lived assets are held in the United States. Refer to Note 16, *Segment Reporting*, for further disclosure regarding the Company's segment information.

Recently Issued Accounting Pronouncements Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and non-public companies, the Company can adopt the new or revised standard at the time non-public companies adopt the new or revised standard and can do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to adopt any new or revised accounting standards early whenever such early adoption is permitted for non-public companies.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"). ASU 2024-03 requires disclosure of disaggregated information about certain income statement expense line items on an annual and interim basis, including purchases of inventory, employee compensation, depreciation, intangible asset amortization and depletion for each income statement line item that contains those expenses. ASU 2024-03 also requires certain amounts already disclosed under existing GAAP to also be disclosed as a separate category in disaggregated expense tables, if those amounts are recognized in the relevant expense line item. The amendments in ASU 2024-03 will be effective for the Company in annual reporting periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. The standard may be applied prospectively or retrospectively. The Company is currently evaluating the impact of adopting ASU 2024-03.

3. Fair Value Measurements

The carrying values of cash, prepaid expenses and other current assets, accounts payable, due to related party and accrued expenses and other current liabilities approximate their fair values due to their short-term nature. The carrying value of the Company's term debt (refer to Note 9, *Term Loan*) approximates its fair value due to its time to maturity.

Parabilis Medicines, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Fair Value Measurements as of December 31, 2025:			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	\$ 27,133	\$ —	\$ —	\$ 27,133
Total assets	<u>\$ 27,133</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 27,133</u>
Fair Value Measurements as of March 31, 2026:				
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	\$ 328,463	\$ —	\$ —	\$ 328,463
Total assets	<u>\$ 328,463</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 328,463</u>
Liabilities				
SAFE	\$ —	\$ —	\$ 50,000	\$ 50,000
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 50,000</u>	<u>\$ 50,000</u>

During the three months ended March 31, 2025 and 2026, there were no transfers among the Level 1, Level 2 and Level 3 categories.

The Company's cash equivalents are classified within Level 1 of the fair value hierarchy as they are invested in highly liquid money market funds which are based on a quoted price with a net asset value of \$1 per share.

Valuation of Preferred Stock Tranche Right Liability

The preferred stock tranche right liability represents the fair value of an obligation to issue shares of Series E convertible preferred stock. The fair value of the preferred stock tranche right liability was determined based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy.

The Company estimated the fair value of the preferred stock tranche right liability at the time of issuance and subsequently remeasured its fair value at each reporting period and prior to settlement.

As of December 31, 2024, in light of the near-term completion of the Series E convertible preferred stock second closing in January 2025, the fair value of the preferred stock tranche right liability was determined based on the difference between the estimated fair value of the Series E convertible preferred stock, or \$6.43 per share, and its contractual purchase price, or \$6.23 per share. The Company estimated the fair value per share of the underlying Series E convertible preferred stock by taking into consideration the results obtained from third-party valuations which included the most recent sales of its preferred stock, market conditions and trends since the last preferred stock issuance.

The following table presents changes in the aggregate fair value of the Company's Series E preferred stock tranche right liability (in thousands):

	Amount
Balance as of December 31, 2024	\$ 2,167
Settlement of Series E preferred stock tranche right liability	(2,167)
Balance as of March 31, 2025	<u>\$ —</u>

Parabilis Medicines, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Valuation of Simple Agreement for Future Equity

On March 27, 2026, the Company issued a SAFE to an investor (refer to Note 10, *Simple Agreement for Future Equity*). The SAFE is accounted for as a liability and represents a Level 3 measurement within the fair value hierarchy.

The fair value of the SAFE upon issuance was determined to be equal to the proceeds received of \$50.0 million. There was no change in fair value of the SAFE during the three months ended March 31, 2026.

4. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31, 2025	March 31, 2026
Laboratory equipment	\$ 13,830	\$ 13,916
Leasehold improvements	4,563	4,692
Computer equipment	307	307
Furniture and fixtures	697	697
Assets not yet in service	131	422
Property and equipment	19,528	20,034
Less: accumulated depreciation and amortization	(12,813)	(13,376)
Property and equipment, net	<u>\$ 6,715</u>	<u>\$ 6,658</u>

Included in laboratory equipment are finance lease right-of-use assets with a cost basis of \$2.9 million as of December 31, 2025 and March 31, 2026, and accumulated amortization expense of \$0.7 million and \$0.8 million as of December 31, 2025 and March 31, 2026, respectively.

During the three months ended March 31, 2025 and 2026, depreciation and amortization expense amounted to \$0.7 million and \$0.6 million, respectively, which includes \$0.1 million of finance lease right-of-use asset amortization in each period.

5. Accrued Expenses and Other Current Liabilities

The following table summarizes accrued expenses and other current liabilities (in thousands):

	December 31, 2025	March 31, 2026
Accrued employee compensation and benefits	\$ 9,079	\$ 3,736
Accrued research and development expenses	8,334	12,626
Accrued deferred offering costs	491	1,318
Other	726	3,877
Total	<u>\$ 18,630</u>	<u>\$ 21,557</u>

6. Convertible Preferred Stock

On January 6, 2026, the Company entered into the Series F Preferred Stock Purchase Agreement (the “Series F Agreement”) and issued to certain investors an aggregate of 49,518,175 shares of Series F convertible preferred stock (the “Series F Preferred Stock”) at a purchase price of \$6.16 per share for gross proceeds of \$305.2 million. The gross proceeds were offset by \$0.7 million of issuance costs.

Parabilis Medicines, Inc.
Notes to Condensed Consolidated Financial Statements
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In accordance with the terms of the Company's certificate of incorporation, the issuance of the Series F Preferred Stock triggered adjustments to the respective conversion prices of the Series A convertible preferred stock (the "Series A Preferred Stock"), the Series B convertible preferred stock (the "Series B Preferred Stock"), the Series C convertible preferred stock (the "Series C Preferred Stock"), the Series D convertible preferred stock (the "Series D Preferred Stock") and the Series E convertible preferred stock (the "Series E Preferred Stock") (as described further below). As a result, the Company recorded an increase to additional paid-in capital and a deemed dividend of \$7.9 million which is equal to the change in fair value of the Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock, Series D Preferred Stock and Series E Preferred Stock due to the triggering of the down-round feature. As the Company did not have retained earnings at the time the Series F Preferred Stock was issued, the deemed dividend was charged against additional paid-in capital resulting in no net impact to additional paid-in capital. The fair value of each preferred share class was determined using a "with-and-without" model under which the equity value of the Company was allocated using a hybrid method, whereby the equity value in the IPO scenario was allocated to each class of shares using the fully-diluted shares outstanding and whereby the equity value in the non-IPO scenario was allocated using an option-pricing model to reflect the full distribution of possible non-IPO outcomes, both before and after the adjustment to the respective conversion price. The following table summarizes the significant Level 3 unobservable inputs used to estimate the fair value of the Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock, Series D Preferred Stock and Series E Preferred Stock at the Series F Preferred Stock issuance date:

	January 6, 2026
Expected volatility	78.0%
Expected dividend yield	—
Expected term (in years)	0.85 - 2.5
Risk-free interest rate	3.6%

Upon the issuance of each series of convertible preferred stock, the Company assessed the embedded conversion and liquidation features of the securities and determined that the Company was not required to separately account for these features.

Convertible preferred stock consisted of the following at December 31, 2025 (in thousands, except share and per share amounts):

	Shares of Preferred Stock Authorized	Original Issuance Price Per Share	Shares of Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Shares of Common Stock Issuable Upon Conversion
Series A	1,434,062	\$ 7.75	1,434,062	\$ 14,914	\$ 19,477	1,002,805
Series B	4,658,112	\$ 14.06	4,658,112	65,388	106,351	4,069,102
Series C	7,384,710	\$ 14.49	7,384,710	106,674	152,175	6,540,022
Series D	16,537,979	\$ 10.76	16,537,979	177,581	225,956	12,669,755
Series E	23,281,563	\$ 6.23	23,281,563	145,414	155,013	15,128,745
	<u>53,296,426</u>		<u>53,296,426</u>	<u>\$ 509,971</u>	<u>\$ 658,972</u>	<u>39,410,429</u>

Convertible preferred stock consisted of the following at March 31, 2026 (in thousands, except share and per share amounts):

	Shares of Preferred Stock Authorized	Original Issuance Price Per Share	Shares of Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Shares of Common Stock Issuable Upon Conversion
Series A	1,434,062	\$ 7.75	1,434,062	\$ 14,914	\$ 19,699	1,062,074
Series B	4,658,112	\$ 14.06	4,658,112	65,388	107,662	4,839,338
Series C	7,384,710	\$ 14.49	7,384,710	106,674	155,348	7,811,705
Series D	16,537,979	\$ 10.76	16,537,979	177,581	230,909	14,493,574
Series E	23,281,563	\$ 6.23	23,281,563	145,414	165,032	15,188,963
Series F	49,518,175	\$ 6.16	49,518,175	304,569	310,937	32,177,627
	<u>102,814,601</u>		<u>102,814,601</u>	<u>\$ 814,540</u>	<u>\$ 989,587</u>	<u>75,573,281</u>

The rights and preferences of all series of convertible preferred stock at March 31, 2026 are summarized below:

Parabilis Medicines, Inc.
Notes to Condensed Consolidated Financial Statements
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Voting Rights

The holders of all series of convertible preferred stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Each preferred stockholder is entitled to a number of votes equal to the number of shares of common stock into which their convertible preferred stock would be convertible at the time of such vote. In addition, the holders of all series of convertible preferred stock are entitled to vote on certain matters as a separate class.

Dividends

The holders of all series of convertible preferred stock are entitled to receive cumulative dividends in preference to any dividend on common stock. Holders of Series A Preferred Stock and Series B Preferred Stock are entitled to preferential dividends at the rate per annum of \$0.62 and \$1.125176, respectively, per share. Holders of Series C Preferred Stock, Series D Preferred Stock, Series E Preferred Stock and Series F Preferred Stock are entitled to preferential dividends at the rate per annum of 8.0% of the respective original issue price on each share of convertible preferred stock, plus the amount of previously accrued dividends, compounded annually. Dividends are only payable when declared by the Company's Board of Directors or upon redemption. As of March 31, 2026, the Company has not declared nor paid any dividends.

Cumulative dividends on the convertible preferred stock were as follows (in thousands):

	December 31, 2025	March 31, 2026
Series A Preferred Stock	\$ 8,363	\$ 8,585
Series B Preferred Stock	40,836	42,147
Series C Preferred Stock	45,175	48,348
Series D Preferred Stock	47,956	52,910
Series E Preferred Stock	10,013	20,032
Series F Preferred Stock	—	5,687
Total	<u>\$ 152,343</u>	<u>\$ 177,709</u>

Conversion

Each share of convertible preferred stock is convertible at any time, at the option of the stockholder into a number of shares of the Company's common stock determined by dividing the original issue price of the respective series of preferred stock by the conversion price of the respective series of preferred stock in effect at the time of conversion (conversion ratio). The conversion price is subject to certain customary adjustments, including those resulting from the triggering of down-round features which occurred during the three months ended March 31, 2026 as a result of the issuance of the Series F Preferred Stock. The original issue price and conversion price for each class of convertible preferred stock at March 31, 2026 was as follows:

	Original Issue Price	Conversion Price
Series A Preferred Stock	\$ 7.75	\$ 10.4644
Series B Preferred Stock	\$ 14.0647	\$ 13.5380
Series C Preferred Stock	\$ 14.4894	\$ 13.6974
Series D Preferred Stock	\$ 10.7631	\$ 12.2813
Series E Preferred Stock	\$ 6.2281	\$ 9.5464
Series F Preferred Stock	\$ 6.1644	\$ 9.4864

Pursuant to the Company's certificate of incorporation in effect as of March 31, 2026, the shares of all series of convertible preferred stock would automatically convert into shares of the Company's common stock at the conversion ratio then in effect in the event of (i) an initial public offering of the Company's common stock at a price of at least \$10.9108 per share and resulting in at least \$50.0 million in gross proceeds to the Company, or (ii) a vote or written consent of (a) the holders of a majority of the issued and outstanding shares of convertible preferred stock, voting on an as-converted basis and together as a single class (in the case of a conversion effected other than in connection with a Deemed Liquidation Event), or (b) the holders of 60% of the issued and outstanding shares of convertible preferred stock, voting on an as-converted basis and together as a single class (in the case of a conversion effected in connection with a Deemed Liquidation Event).

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Redemption

The holders of all series of convertible preferred stock do not have the option to demand redemption except in the case of a liquidation or Deemed Liquidation Event (defined below), nor does the Company have the right to call the shares.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company, or in a Deemed Liquidation Event, the holders of convertible preferred stock then outstanding are entitled to be paid out of the assets of the Company available for distribution to its stockholders before any payment shall be made to holders of common stock in an amount per share equal to the applicable original issue price, plus all accrued but unpaid dividends (the “Preference Amount”). The Preference Amounts are paid first to holders of Series F Preferred Stock, then Series E Preferred Stock, then Series D Preferred Stock, then Series C Preferred Stock, then Series B Preferred Stock, and then Series A Preferred Stock.

After the payment of all Preference Amounts required to be paid to the holders of shares of all series of convertible preferred stock, the remaining assets of the Company available for distribution to its stockholders will be distributed among the holders of the shares of all series of convertible preferred stock and common stock, pro rata, based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to common stock pursuant to the terms of the Company’s certificate of incorporation immediately prior to such liquidation, dissolution or winding-up of the Company.

Unless each of (i) the holders of a majority of the issued and outstanding shares of convertible preferred stock, voting on an as-converted basis and together as a single class, (ii) the holders of at least 66 2/3% of the issued and outstanding shares of Series C Preferred Stock, exclusively and as a separate class, (iii) the holders of a majority of the issued and outstanding shares of Series D Preferred Stock, voting on an as-converted basis and together as a single class, (iv) the holders of at least 60% of the issued and outstanding shares of Series E Preferred Stock, voting on an as-converted basis and together as a single class, and (v) the holders of at least 65% of the issued and outstanding shares of Series F Preferred Stock, voting on an as-converted basis and together as a single class, elect otherwise, the following events are considered a “Deemed Liquidation Event”: a merger, consolidation, statutory conversion, transfer, domestication, or continuance (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets or intellectual property of the Company.

Protective Rights

The holders of all series of convertible preferred stock are entitled to protective rights, which require the affirmative vote the majority of the issued and outstanding shares of convertible preferred stock, voting on an as-converted basis and together as a single class, for certain corporate actions, which include, but are not limited to the sale of the Company, its liquidation, and the authorization of additional shares of the Company’s capital.

7. Stockholders’ Deficit**Common Stock Warrants**

The Company issued common stock warrants as part of the Loan Agreement (refer to Note 9, *Term Loan*) which were determined to be a freestanding instrument and met the criteria for equity classification as they are indexed to the Company’s own common stock and settled in a fixed number of shares for a fixed exercise price, with no cash settlement feature. As of December 31, 2025 and March 31, 2026, warrants to purchase 24,152 shares of common stock with an exercise price of \$4.82 per share were outstanding. The common stock warrants expire in September 2031.

Common Stock

The voting, dividend and liquidation rights of the holders of common stock are subject to and qualified by the rights, powers, and preferences of the holders of the Company’s convertible preferred stock. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company’s stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company’s Board of Directors, if any, subject to the preferential dividend rights of holders of all series of convertible preferred stock. As of March 31, 2026, the Company has not declared nor paid any dividends.

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The Company has reserved shares of common stock for the conversion or exercise of the following securities:

	December 31, 2025	March 31, 2026
Series A Preferred Stock	1,002,805	1,062,074
Series B Preferred Stock	4,069,102	4,839,338
Series C Preferred Stock	6,540,022	7,811,705
Series D Preferred Stock	12,669,755	14,493,574
Series E Preferred Stock	15,128,745	15,188,963
Series F Preferred Stock	—	32,177,627
Common stock warrants	24,152	24,152
Outstanding stock options	9,098,233	14,809,418
Unissued stock-based awards under the 2016 Employee, Director and Consultant Equity Incentive Plan	1,097,518	—
Unissued stock-based awards under the 2026 Stock Option and Grant Plan	—	3,069,339
Total	49,630,332	93,476,190

The SAFE was excluded from the table above as of March 31, 2026 as the number of shares that would be issuable upon conversion was indeterminable.

8. Stock-Based Compensation

2016 Employee, Director and Consultant Equity Incentive Plan

The Company's 2016 Employee, Director and Consultant Equity Incentive Plan, as amended (the "2016 Plan"), provides for the Company to sell or award restricted common stock or to grant incentive and nonqualified stock options for the purchase of common stock (or other stock-based awards) to its founders, employees, officers, directors and consultants.

As of December 31, 2025, 10,826,224 shares of common stock were authorized and reserved for issuance under the 2016 Plan. The remaining shares reserved for issuance under the 2016 Plan ceased to be available for issuance at the time the January 2026 Plan was adopted. There will be no further awards granted under the 2016 Plan, but all outstanding awards under the 2016 Plan will continue to be governed by the 2016 Plan.

2026 Stock Option and Grant Plan

On January 6, 2026, the Company's Board of Directors adopted and its stockholders approved the 2026 Stock Option and Grant Plan (the "January 2026 Plan"). The January 2026 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock awards and other stock-based awards to the Company's officers, employees, directors, consultants, and other key persons.

The number of shares of common stock authorized and reserved for issuance under the January 2026 Plan was initially 8,873,223 shares. As of March 31, 2026, there were 3,069,339 shares available for future issuance under the January 2026 Plan. The shares of common stock underlying any awards that are forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of common stock or otherwise terminated and shares that are withheld upon exercise of an option or settlement of an award to satisfy the exercise price or tax withholding under the 2016 Plan and January 2026 Plan will be added back to the shares of common stock available for issuance under the January 2026 Plan.

Upon stock option exercise, the Company delivers newly issued shares to the participant. Stock option vesting typically occurs over four years for employees and directors and is at the discretion of the Company's Board of Directors. Stock options typically have a maximum term of ten years.

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Stock Option Valuation

The fair value of each stock option granted was estimated on the date of grant using the Black-Scholes option-pricing model and the assumptions summarized in the following table:

	Three Months Ended March 31,	
	2025	2026
Expected volatility	93.00%	89.80% - 90.15%
Expected dividend yield	—	—
Expected term (in years)	6.25	6.25
Risk-free interest rate	4.04%	3.70% - 4.14%
Fair value of common stock	\$2.42	\$3.14 - \$4.09

The following table presents a summary of all stock option activity under the 2016 Plan and January 2026 Plan:

	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	9,098,233	\$ 2.64	7.72	\$ 3,386
Granted	6,028,331	3.15		
Exercised	(92,699)	2.01		
Canceled or forfeited	(224,447)	1.82		
Outstanding at March 31, 2026	14,809,418	\$ 2.86	8.44	\$ 18,660
Vested and expected to vest at March 31, 2026	14,809,418	\$ 2.86	8.44	\$ 18,660
Vested and exercisable at March 31, 2026	5,555,683	\$ 2.90	7.18	\$ 7,023

The weighted-average grant date fair values of stock options granted during the three months ended March 31, 2025 and 2026 were \$1.89 and \$2.42 per share, respectively. The intrinsic value of stock options exercised was \$0.2 million during the three months ended March 31, 2026. No stock options were exercised during the three months ended March 31, 2025.

Total unrecognized compensation expense related to unvested stock options was approximately \$18.4 million as of March 31, 2026, which the Company expects to recognize over a weighted-average period of approximately 3.3 years.

Total unrecognized compensation expense related to unvested stock options with a market condition was approximately \$0.2 million as of March 31, 2026, which the Company expects to recognize over a weighted-average period of approximately 1.0 year.

Stock-Based Compensation Expense

The following table presents the classification of stock-based compensation expense included in the Company's condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended March 31,	
	2025	2026
Research and development	\$ 212	\$ 469
General and administrative	640	835
Total	\$ 852	\$ 1,304

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9. Term Loan

On September 21, 2021, the Company entered into a Loan and Security Agreement with Silicon Valley Bank (the “Lender”), which was subsequently amended (the “Loan Agreement”), that provided for aggregate term loans of \$15.0 million. In connection with the Loan Agreement, the Company also issued common stock warrants to the Lender (refer to Note 7, *Stockholders’ Deficit*).

On November 22, 2024, the Company and the Lender executed an amendment to the Loan Agreement under which the Lender extended the term loan amortization date to April 1, 2025 and added two interest-only extension events that could further extend the term loan amortization date. The amendment also required the Company to maintain the lesser of \$60.0 million or 50% of the Company’s consolidated cash within the Company’s primary operating account with the Lender. The amendment was accounted for as a debt modification, rather than an extinguishment, as the difference in the present value of the cash flows under the terms of the original debt agreement and the terms immediately after the amendment was less than 10%. As a result, issuance costs paid to the Lender in connection with the amendment, which were not significant, were recorded as a reduction of the carrying amount of the debt liability. Unamortized issuance costs as of the date of the modification are amortized to interest expense using the effective interest method through the loan maturity date.

Term loan balances, including final payments, are summarized as follows (in thousands):

	December 31, 2025	March 31, 2026
Total term loan principal	\$ 12,500	\$ 8,750
Final payments	647	691
Unamortized debt discount and issuance costs	(70)	(40)
Term loan, net of discount	<u>\$ 13,077</u>	<u>\$ 9,401</u>

The term loan matures on October 1, 2026. After triggering an interest-only extension upon the issuance of the Series E Preferred Stock in January 2025, which extended the interest-only period on the term loan, the Company began paying principal in 12 equal monthly payments of approximately \$1.3 million each on November 1, 2025. The term loan bears interest at a floating rate equal to the greater of (i) 6.75% and (ii) the prime rate plus a margin; provided that the interest rate will not exceed 6.75%. The term loan calls for an additional final payment equal to 4.5% of the aggregate principal amount borrowed, as well as a fee of approximately \$0.1 million, due upon (a) the term loan maturity date, (b) the repayment of the term loan in full, (c) as required pursuant to permitted prepayment or mandatory prepayment upon an acceleration, or (d) the termination of the Loan Agreement. The Company may, at its option, prepay the term loan in full or in part at any time prior to maturity, subject to a prepayment fee ranging between 0% and 3% of the outstanding principal amount of the term loan. The prepayment fee would also be due and payable in the event of an acceleration of the principal amount of the loan due to an event of default. The Loan Agreement contains affirmative covenants and certain restrictive covenants. The Company was in compliance with all financial and nonfinancial covenants as of March 31, 2026.

In addition, the Company is accreting the final payments over the term of the Loan Agreement as interest expense using the effective interest method. As of December 31, 2025 and March 31, 2026, the Company accreted a cumulative final payment of \$0.6 million and \$0.7 million, respectively, which is presented within term loan, net of discount on its condensed consolidated balance sheets.

For the three months ended March 31, 2025 and 2026, the effective interest rate of the term loan was 8.9% and 8.8%, respectively.

The term loan includes an embedded derivative related to the payment of interest upon an event of default. The Company determined the estimated fair value of the embedded derivative was not material to the condensed consolidated financial statements. Additionally, the term loan includes contingent payment features which also represent an embedded derivative which requires bifurcation from the debt host. As of December 31, 2025 and March 31, 2026, the Company determined the estimated fair value of the contingent payment features embedded derivative was not material to the condensed consolidated financial statements. The Company will reassess the probability of these contingent payment events and the estimated fair value of the related embedded derivatives at each reporting period and revise the estimated fair value of the derivative in the Company’s condensed consolidated financial statements.

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10. Simple Agreement for Future Equity

On March 27, 2026, the Company issued a SAFE to an investor for gross proceeds of \$50.0 million. The SAFE has no interest rate or maturity date. The SAFE investor has no voting rights prior to conversion, and if the Company pays a dividend on outstanding shares of its common stock while the SAFE is outstanding, the investor will also receive a dividend.

The SAFE will automatically convert into the number of shares of common stock obtained by dividing (i) \$50.0 million by (ii) the IPO Discount Price upon the closing of an IPO. The “IPO Discount Price” in connection with an IPO is the offering price in the IPO (the “IPO Price”) multiplied by 90% (such product, the “Initial IPO Discount Price”), provided that (i) if the IPO Price is greater than or equal to \$9.4864 per share, and (ii) the Initial IPO Discount Price is equal to or less than \$9.4864 per share, then the IPO Discount Price will equal \$9.4864 per share; and provided further that if the IPO Price is less than \$9.4864, the IPO Discount Price will equal the IPO Price. The SAFE will also automatically convert into preferred stock or common stock upon an equity financing other than an IPO based on similar conversion terms and discount rate.

Upon a liquidation event, if not converted earlier, the investor will automatically be entitled, subject to its liquidation priority, to receive a portion of proceeds equal to the greater of (i) \$50.0 million, or (ii) the amount payable on the number of common shares equal to \$50.0 million divided by the Liquidity Price. The “Liquidity Price” is the price per share equal to the fair market value of the common stock at the time of the liquidation event, as determined by reference to the purchase price payable in connection with such liquidation event, multiplied by 90%. Upon a dissolution event, if not converted earlier, the investor will automatically be entitled, subject to its liquidation priority, to receive a portion of proceeds equal to \$50.0 million.

The Company concluded the SAFE is a freestanding financial instrument that requires liability classification pursuant to the guidance in ASC Topic 480, *Distinguishing Liabilities from Equity* as it embodies a conditional obligation to issue a variable number of shares based predominately on a fixed monetary amount known at inception. The SAFE was initially recorded at fair value upon the issuance date, with subsequent changes in fair value recorded in the condensed consolidated statements of operations and comprehensive loss at each reporting date. The fair value of the SAFE at issuance was \$50.0 million. There was no change in fair value of the SAFE during the three months ended March 31, 2026.

11. Commitments and Contingencies

Harvard Agreement

In August 2017, the Company entered into a license agreement, as amended (the “Harvard Agreement”), with the President and Fellows of Harvard College (“Harvard”), to obtain a worldwide, exclusive, royalty-bearing license to certain intellectual property which was developed by the Company’s founder.

Under the terms of the Harvard Agreement, the Company is required to make payments to Harvard upon the achievement of certain development, regulatory and sales milestones up to an aggregate of \$18.3 million, as well as future royalty payments, based on a percentage of aggregate net sales ranging in the low single digits. In addition, the Company is required to make payments to Harvard for non-royalty income received under sublicenses or strategic partnerships with third parties, with the applicable payment based on the stage of development of the first licensed product at the time the Company enters into such agreement (before or after enrollment of the first patient in a Phase 2 clinical study of a licensed product), ranging from a single-digit percentage to a mid-teens percentage. During the year ended December 31, 2025, the Company met one milestone of \$0.2 million which is included in accounts payable on the condensed consolidated balance sheet as of December 31, 2025 and which the Company paid during the three months ended March 31, 2026. As of March 31, 2026, the Company has achieved milestones totaling \$0.3 million under the Harvard Agreement. None of the remaining milestones were deemed probable of achievement as of March 31, 2026.

The Company is also required to pay a low six-digit annual maintenance fee for the duration of the Harvard Agreement, which can be credited against future royalty payments.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings or other litigation relating to claims arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Legal fees and other costs associated with such proceedings are expensed as incurred. As of December 31, 2025 and March 31, 2026, the Company was not a party to any material legal proceedings or claims.

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Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with the Board of Directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of December 31, 2025 and March 31, 2026.

12. Collaboration Agreement

In May 2024, the Company entered into a research collaboration agreement with ARTBIO, Inc. (“ARTBIO”) to co-develop multiple Helicon-enabled alpha particle radioligand therapies (HEARTs) for the treatment of cancer. Under the terms of this agreement, the Company is responsible for equally participating on joint committees and carrying out at least four research programs with respect to each collaboration target. The Company and ARTBIO share in the costs of the research programs equally, with ARTBIO responsible for funding the first \$10.0 million of development costs incurred by both parties and the Company responsible for funding the next \$10.0 million of development costs. Any further development costs beyond these initial funding amounts will also be shared equally by both parties. Under certain circumstances, either party can terminate the agreement, or opt out of further participation in any research programs, and the Company may be obligated to refund, to ARTBIO, amounts received during the initial funding periods, such that the total costs incurred through the effective date of termination would be shared equally.

Upon later regulatory approval and commercialization of related product(s), the parties will share equally in all net profits or losses. The agreement expires upon (1) the date on which products arising from the collaboration are no longer commercialized or developed for commercialization, or (2) termination by one or both parties.

The Company determined the agreement was a collaboration arrangement under ASC Topic 808, *Collaborative Arrangements*. The Company and ARTBIO are jointly overseeing and are active participants in the research and development activities under the agreement. In addition, both parties are exposed to the significant risks and potential rewards under the agreement.

During the three months ended March 31, 2025, the Company incurred \$1.6 million in costs related to the research programs within the scope of the agreement, which have been fully reimbursed by ARTBIO. No costs were incurred by the Company during the three months ended March 31, 2026. Pursuant to the contract termination and funding provisions noted above, and based on the current development plan, the Company recorded a liability representing its portion of the research and development expense incurred to date. During the three months ended March 31, 2025, the Company recorded an increase to the liability of \$0.9 million. The Company recorded the remaining amount of \$0.7 million as a reduction of research and development expenses within the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2025. No increase in the liability balance was recorded during the three months ended March 31, 2026. As of December 31, 2025 and March 31, 2026, the liability balance totaled \$2.7 million and is classified in other liabilities and accrued expenses and other current liabilities, respectively, on the condensed consolidated balance sheets (refer to Note 17, *Subsequent Events*).

13. Related Party Transactions

In December 2019, the Company entered into a non-cancelable sublease arrangement with a related party to sublease approximately 50% of the Company’s leased space at 30 Acorn Park Drive in Cambridge, Massachusetts through February 2025. In January 2024, the Company and the sublessee amended the sublease arrangement to extend the sublease date through December 2025. The sublessee is considered a related party due to common board members and stockholders. The related party was required to make lease payments and payments for its proportionate share of related occupancy costs to the Company. The sublease expired in December 2025.

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The Company recorded sublease income of \$1.1 million for the three months ended March 31, 2025. In addition, the Company received payments from the related party of \$0.6 million during the three months ended March 31, 2025, representing the related party's share of occupancy costs. Of the amounts received, \$0.5 million was recorded as a reduction of research and development expense and \$0.1 million was recorded as a reduction of general and administrative expense for the three months ended March 31, 2025 in the condensed consolidated statements of operations and comprehensive loss. As of March 31, 2026, there was \$0.2 million recorded as due to related party on the condensed consolidated balance sheet resulting from a refund of an overpayment of occupancy costs by the sublessee.

14. Net Loss Per Share

The following table sets forth the outstanding shares of common stock equivalents, presented based on amounts outstanding at each period end, which were excluded from the calculation of diluted net loss per share allocable to common stockholders for the periods indicated because including them would have been anti-dilutive:

	Three Months Ended March 31,	
	2025	2026
Series A Preferred Stock	1,002,805	1,062,074
Series B Preferred Stock	4,069,102	4,839,338
Series C Preferred Stock	6,540,022	7,811,705
Series D Preferred Stock	12,669,755	14,493,574
Series E Preferred Stock	15,128,745	15,188,963
Series F Preferred Stock	—	32,177,627
Common stock warrants	24,152	24,152
Outstanding stock options	8,604,429	14,389,912
Total	48,039,010	89,987,345

The amounts of outstanding stock options in the table above for the three months ended March 31, 2025 and 2026 exclude 419,506 potentially dilutive securities as these outstanding stock options relate to contingently issuable shares for which the market condition was not satisfied as of the respective period end. The SAFE was excluded from the table above for the three months ended March 31, 2026 as the number of shares that would be issuable upon conversion was indeterminable.

15. Retirement Plan

The Company has a U.S. tax-qualified employee savings and retirement 401(k) plan, covering all qualified employees. Participants may elect a salary deferral up to the statutorily prescribed annual limit for tax-deferred contributions. The Company may make matching contributions to each eligible participant's account based on a percentage of the participant's elective deferral contribution. Matching contributions were \$0.4 million and \$0.5 million during the three months ended March 31, 2025 and 2026, respectively.

16. Segment Reporting

The Company manages its operations as a single operating and reportable segment that is focused on developing Helicon medicines targeting historically undruggable proteins. The CODM manages the Company's operations on a consolidated basis and uses consolidated net loss to assess financial performance and allocate resources. Consolidated net loss is used by the CODM to make key operating decisions, such as the determination of the rate at which the Company seeks to grow its research and development initiatives and the allocation of capital between research and development and general and administrative expenses. The CODM does not review assets in evaluating the results of the segments, and therefore, such information is not presented.

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The following table presents selected financial information with respect to the Company's single operating segment (in thousands):

	Three Months Ended March 31,	
	2025	2026
Operating expenses:		
External research and development expense - Zolucetide	\$ 13,145	\$ 13,094
External research and development expense - β -Catenin Degradar	719	416
External research and development expense - ERG	1,640	2,912
External research and development expense - AR ^{ON}	865	1,406
External research and development expense - Early discovery and other programs	994	994
Other research and development expenses	6,572	7,650
Personnel-related research and development expenses (excluding stock-based compensation expense)	9,138	10,232
Personnel-related general and administrative expenses (excluding stock-based compensation expense)	2,411	3,109
Other general and administrative expenses	3,251	5,730
Depreciation and amortization expense	654	606
Stock-based compensation expense	852	1,304
Other segment items ⁽¹⁾	(1,915)	(2,137)
Consolidated net loss	<u>\$ 38,326</u>	<u>\$ 45,316</u>

Notes

(1) Other segment items consist of interest income, interest expense and sublease income – related party.

17. Subsequent Events

The Company has evaluated subsequent events through May 19, 2026, the date these condensed consolidated financial statements were available to be issued, and through June 4, 2026, the date the consolidated financial statements were available to be reissued, and has concluded that no events or transactions have occurred that require disclosure in the accompanying condensed consolidated financial statements, except as follows:

ARTBIO Collaboration

On April 16, 2026, ARTBIO sent notice of its intent to opt out of all the research programs under the research collaboration agreement described in Note 12, *Collaboration Agreement*. No eligible costs were incurred by the Company or ARTBIO during the three months ended March 31, 2026.

Grants of Stock Options

In April 2026, the Company granted stock options to purchase an aggregate of 1,174,922 shares of common stock, at an exercise price of \$4.09 per share. The stock options are expected to vest over a four-year period.

License and Collaboration Agreement with Regeneron

On May 15, 2026, the Company entered into the Regeneron Agreement with Regeneron to discover, develop, and commercialize Helicons, with a particular focus on Antibody-Helicon Conjugates ("AHCs"), directed to a set of specified targets (each, a "Collaboration Target").

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Under the terms of the Regeneron Agreement and during the research term for each Collaboration Target, the Company will collaborate with Regeneron to perform certain research and preclinical development activities, including screening, generating, testing and evaluating new Helicons and AHCs directed to such Collaboration Target (each, a “Product”). Under the Regeneron Agreement, there are five initial Collaboration Targets, with Regeneron having the right to replace up to two targets and the option to nominate up to five additional Collaboration Targets, subject to an additional option payment from Regeneron. For one initial Collaboration Target, Regeneron may add one or more additional programs with respect to such Collaboration Target, subject to payment of additional program fees.

Following Regeneron’s nomination of a Product to be a “Licensed Product” during the research term for the applicable Collaboration Target (including additional Collaboration Targets), Regeneron has the sole right to advance through development, manufacturing and worldwide commercialization of Licensed Products, including clinical and regulatory strategy, pricing, and promotion.

Under the terms of the Regeneron Agreement, Regeneron has agreed to make a \$50.0 million upfront payment and invest \$75.0 million in the Company's next equity financing, subject to certain conditions, which includes a private placement of common stock concurrent with the Company’s IPO at a price per share equal to 90% of the IPO price per share. For the initial Collaboration Targets, the Company is eligible to receive: (i) up to \$470.0 million in development milestone payments; (ii) up to \$575.0 million in regulatory milestone payments; (iii) up to \$1.15 billion in commercial milestone payments; and (iv) tiered royalty payments, ranging in the high single digits to low double digits during the period commencing upon the first commercial sale of such Licensed Product in a given country and expiring on the latest of: (a) expiration of the last valid claim of a royalty term-extending patent right of such Licensed Product in such country, (b) 12 years after the first commercial sale of such Licensed Product in such country, and (c) loss of regulatory exclusivity for such Licensed Product in such country, subject to customary reductions.

Under the terms of the Regeneron Agreement, the Company is subject to an exclusivity obligation for each Collaboration Target until the last to expire royalty term for Licensed Products directed to such Collaboration Target. Unless earlier terminated pursuant to its terms, the Regeneron Agreement will remain in effect until the expiration of the last royalty term for the last Licensed Product under the Regeneron Agreement.

Regeneron has the right to terminate the Regeneron Agreement for convenience and for certain violations of the Company’s exclusivity covenants.

Reverse Stock Split

On June 3, 2026, the Company effected a 1-for-1.5389 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock and the IPO Discount Price of the Company's outstanding SAFE (see Notes 6 and 10, respectively). Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustments of the preferred stock conversion ratios and the IPO Discount Price for the SAFE.

2026 Stock Option and Incentive Plan

On May 28, 2026, the Company’s board of directors adopted, and its stockholders approved on June 1, 2026, the Company's 2026 Stock Option and Incentive Plan (the “2026 Plan”). The Company expects to grant stock options and other equity awards under the 2026 Plan. The Company initially reserved 11,070,000 shares of its common stock for the issuance of awards under the 2026 Plan. The 2026 Plan provides that the number of shares reserved and available for issuance under the 2026 Plan will automatically increase on January 1, 2027 and each January 1 thereafter during the term of the 2026 Plan, by (i) 5% of the sum of (A) the number of shares of common stock issued and outstanding on the immediately preceding December 31, (B) the number of shares underlying the Company's outstanding preferred stock (determined on an as-converted basis) on the immediately preceding December 31, and (C) the number of shares of common stock issuable pursuant to the exercise of any outstanding pre-funded warrants on the immediately preceding December 31, or (ii) such lesser number of shares as determined by the Company’s compensation committee.

The number of shares reserved for issuance under the 2026 Plan will be subject to adjustment in the event of a stock split, stock dividend, or other change in the Company’s capitalization. The shares of common stock underlying any awards under the 2026 Plan and the January 2026 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire, or are otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2026 Plan.

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2026 Employee Stock Purchase Plan

On May 28, 2026, the Company's board of directors adopted, and its stockholders approved on June 1, 2026, the 2026 Employee Stock Purchase Plan (the "ESPP"). A total of 1,110,000 shares of common stock were initially reserved for issuance under the ESPP. The ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2027 and each January 1 thereafter through January 1, 2036, by the least of (i) 1,110,000 shares of common stock, (ii) 1% of the sum of (A) the number of shares of common stock issued and outstanding on the immediately preceding December 31, (B) the number of shares underlying the Company's outstanding preferred stock (determined on an as-converted basis) on the immediately preceding December 31, and (C) the number of shares of common stock issuable pursuant to the exercise of any outstanding pre-funded warrants on the immediately preceding December 31, or (iii) such lesser number of shares of common stock as determined by the administrator of the ESPP. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend, or other change in the Company's capitalization.

Amended and Restated Certificate of Incorporation

On May 28, 2026, the Company's board of directors adopted, and its stockholders approved on June 1, 2026, the seventh amended and restated certificate of incorporation, which, among other things, increased the Company's number of shares of common stock authorized for issuance to 600,000,000 shares of voting common stock and 200,000,000 shares of non-voting common stock.

33,500,000 Shares



Common Stock

Leerink Partners BofA Securities Evercore ISI Guggenheim Securities LifeSci Capital

Through and including July 4, 2026 (the 25th day after the date of this prospectus), all dealers effecting transactions in our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

