UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-42272

MBX Biosciences, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**84-1882872**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11711 N. Meridian Street, Suite 300 Carmel, Indiana	**46032**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (317) 659-0200

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	MBX	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☒ NO ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Global Select Market on June 30, 2025 was $237,327,692.

The number of shares of Registrant's common stock, par value $0.0001 per share, outstanding as of March 6, 2026 was 47,510,243.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to the Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2025, are incorporated herein by reference into Part III of this Annual Report.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains forward looking statements, including the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors". These sections contain express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- the initiation, timing, progress and results of our current and future research and development programs, preclinical studies and clinical trials;
- our ability to successfully complete our clinical trials;
- our ability to finalize the design or formulation of any product candidate;
- the ability of our platform to optimize pharmacokinetic and/or pharmacologic properties;
- our ability to advance any product candidates that we may identify and successfully complete any clinical studies, including the manufacture of any such product candidates;
- our ability to quickly leverage programs within our initial target indications and to progress additional programs to further develop our pipeline;
- our ability to internalize certain of our discovery capabilities;
- the prevalence of certain diseases and conditions we intend to treat and the size of the market opportunity for our product candidates;
- estimates of the number of patients with certain diseases and conditions we intend to treat and the number of patients that we will enroll in our clinical trials;
- the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates;
- the timing of our investigational new drug applications submissions;
- the timing of announcement of interim and final results from clinical trials;
- our projected operating expenses and capital expenditure requirements;
- the implementation of our strategic plans for our business, programs and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our technology and platform;
- developments related to our competitors and our industry;
- the success of competing therapies that are or may become available;
- our ability to leverage the clinical, regulatory, and manufacturing advancements to accelerate our clinical trials and approval of product candidates;
- our ability to meet future regulatory standards with respect to our product candidates, if approved;
- our ability to identify and enter into future license agreements and collaborations;
- our reliance on third parties to conduct clinical trials of our product candidates;
- our reliance on third parties for the manufacture of our product candidates;
- developments related to our technology and platform;
- regulatory or other geopolitical developments in the United States and foreign countries and their potential impacts, if any, on us;
- our commercialization, marketing and manufacturing capabilities;

- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 or a smaller reporting company;
- our ability to attract and retain key scientific and management personnel; and
- our anticipated use of our existing cash, cash equivalents and marketable securities, including the proceeds from our public offerings, our financial performance, estimates of our expenses, capital requirements, and need for additional financing.

In some cases, you can identify forward-looking statements by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled "Risk Factors" and elsewhere in this Annual Report. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Annual Report and the documents that we reference in this Annual Report and have filed with the SEC as exhibits to this Annual Report and previous filings, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Annual Report represent our views as of the date of this Annual Report. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

This Annual Report also contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this Annual Report, 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 entitled "Risk Factors" and elsewhere in this Annual Report.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, which include, but are not limited to, the following:

- We have incurred significant losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

- The results observed from preclinical studies or early-stage clinical trials of our product candidates may not necessarily be predictive of the results of later-stage clinical trials that we may conduct. Similarly, positive results from such preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials.

- We have never generated revenue from product sales and may never become profitable.

- We will need substantial additional funding. If we are unable to raise additional capital when needed on acceptable terms, or at all, we may be forced to delay, reduce, or terminate certain of our research and product development programs, future commercialization efforts or other operations.

- Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.

- If we fail to discover, develop and commercialize other product candidates, or successfully build out our own internal discovery capacities, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

- We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

- Our product candidates may cause undesirable side effects, including injection site reactions, or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.

- We may find it difficult to enroll patients in our clinical trials.

- The number of patients with the diseases and disorders for which we are developing our product candidates has not been established with precision. If the actual number of patients with the diseases or disorders we elect to pursue with our product candidates is smaller than we anticipate, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates.

- We face significant competition in an environment of rapid change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, or that we are unable to compete with existing entities that have made substantial investment into novel treatments for disease, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.

- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. We have not yet demonstrated an ability to obtain regulatory approvals.

- 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 our product candidates.

- If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

- We rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

- Our use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, raw materials, active pharmaceutical ingredients or drug products when needed or at an acceptable cost.

- We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

- Our commercial success depends on our ability to obtain, maintain, enforce, and otherwise protect our intellectual property and proprietary technology, and if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products and product candidates similar to ours and our ability to successfully develop and commercialize our product candidates may be adversely affected.

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 Annual Report, as well as in other documents that we file with the SEC. The risks summarized above or described in full elsewhere in this Annual Report 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.

PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel precision peptide therapies for the treatment of endocrine and metabolic disorders. Our company was founded by global leaders with a transformative approach to peptide drug design and development. Leveraging this expertise, we designed our proprietary Precision Endocrine Peptide™ ("PEP™") platform to overcome the key limitations of unmodified and modified peptide therapies and to improve clinical outcomes and simplify disease management for patients. Our PEPs are selectively engineered to have optimized pharmaceutical properties, including extended time-action profiles and consistent drug concentrations with low peak-to-trough concentration ratios, consistent exposure to target tissues, and less frequent dosing. We are advancing a pipeline of novel candidates for endocrine and metabolic disorders with clinically validated targets, established endpoints for regulatory approval, significant unmet medical needs and large potential market opportunities. Our product candidates and programs include:

- **Canvuparatide:** Our lead product candidate, canvuparatide (MBX 2109), is a parathyroid hormone ("PTH") peptide prodrug that is designed as a potential long-acting hormone replacement therapy for the treatment of chronic hypoparathyroidism ("HP"). Leveraging our proprietary PEP™ platform, we designed canvuparatide to treat the underlying pathophysiology of HP by providing a continuous, infusion-like exposure to PTH, with convenient once-weekly administration. In a Phase 1 clinical trial, canvuparatide demonstrated a low ratio between the highest concentration of active drug observed after a dose and the concentration of active drug observed immediately prior to the next dose ("peak-to-trough ratio"). This result is consistent with a continuous, infusion-like profile, and an extended half-life, potentially enabling the first once-weekly PTH dosing regimen for patients with HP. Canvuparatide was generally well-tolerated with no drug-related severe or serious adverse effects. In a Phase 2 clinical trial of 64 patients with HP, canvuparatide achieved the primary endpoint with a statistically significant responder rate at Week 12 and further demonstrated positive six-month responder results from the open-label extension portion of the trial. All patients completed the 12-week trial, and canvuparatide was generally well-tolerated, with no treatment-related serious adverse events or discontinuations. We completed an End of Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") and expect to receive Scientific Advice with the European Medicines Agency ("EMA") in the first half of 2026. We also intend to present results from our Phase 2 clinical trial and report one-year follow-up data from our ongoing open-label extension study at a medical meeting in the second quarter of 2026; and initiate a Phase 3 clinical trial of canvuparatide in the third quarter of 2026.
- **Obesity portfolio:** Our lead obesity product candidate, MBX 4291, is designed to be a long-acting and highly potent "PEP™ glucagon-like peptide 1 ("GLP-1") / glucose-dependent insulinotropic polypeptide ("GIP") co-agonist prodrug with the goal of potential once-monthly dosing frequency and improved efficacy and tolerability relative to existing standards of care. In our preclinical studies, the active component of MBX 4291 demonstrated a similar activity profile and body weight loss in mice as tirzepatide, an approved weekly GLP-1/GIP co-agonist, and an extended duration of action of the active component of MBX 4291, supporting the potential for once-monthly administration. The results observed from our preclinical studies may not necessarily be predictive of the results of later-stage clinical trials that we may conduct. We are conducting a randomized, double-blind, placebo controlled Phase 1 clinical trial designed to evaluate safety, tolerability, pharmacokinetics, and pharmacodynamics of SAD and MAD doses in adults with obesity. Following the SAD and four-week MAD portions of the trial, we plan to evaluate multiple ascending doses of MBX 4291, or matching placebo, administered over 12 weeks in up to two cohorts consisting of 30 participants. Results from the planned 12-week MAD portion are expected in the fourth quarter of 2026. Beyond MBX 4291, we have a robust discovery pipeline including multiple programs in the lead optimization stage of development, and we expect to nominate two additional candidates in the second and third quarters of 2026.
- **Imapextide:** Our program, imapextide (MBX 1416), is designed to be a long-acting GLP-1 receptor antagonist as a potential therapy for post-bariatric hypoglycemia ("PBH"), a chronic complication of bariatric surgery. Imapextide is designed as a convenient once-weekly therapy to reduce insulin secretion and increase blood glucose to reduce the frequency and severity of hypoglycemic events. In January 2025, we announced positive topline results from our Phase 1 SAD and MAD clinical trial of imapextide in healthy adult volunteers. Results from the Phase 1 clinical trial demonstrated dose-proportional increases in imapextide exposure, a median half-life of 90 hours, which is supportive of a once-weekly dosing regimen, and, at steady state, the median T_{max} was between 36 and 48 hours. Imapextide was generally well-tolerated with a favorable safety profile and no treatment-related serious adverse events. We are conducting a Phase 2a, open-label clinical trial evaluating primary efficacy of subcutaneous imapextide in adult patients with PBH. Topline results are expected in the second quarter of 2026.

Endocrine organs secrete peptide hormones into the blood stream that act on distant organs to calibrate their function and maintain homeostasis, which impact metabolism, growth, reproduction and other bodily functions. Underproduction of a hormone, known as a hormonal deficiency, can lead to endocrine diseases, such as diabetes and HP. In addition to using peptides as hormone replacement therapies, peptide-based drugs have been developed as pharmacologic agents to treat endocrine and other diseases. However, whether as replacement therapies or novel pharmacological actions, these therapeutic peptides often have significant drawbacks. Unmodified peptides often have short half-lives and are rapidly degraded by enzymes and swiftly cleared within minutes to hours by the liver and kidney. This often necessitates frequent daily injections of these peptides, which can result in wide fluctuations of the peptide concentration in the bloodstream leading to diminished effectiveness of the therapy or side effects caused by high levels of the peptide.

Modified peptide therapies have been developed to allow less frequent once-daily and once-weekly dosing regimens. Although these convenient, patient-friendly therapies could increase compliance and result in improved effectiveness in the real-world setting, they can still produce significant fluctuations in peptide blood levels or high peak-to-trough ratios, which can lead to side effects and limit potential efficacy. Therefore, there remains a significant unmet need to develop modified peptide therapies with extended time-action profiles and low peak-to-trough ratios that allow for less frequent injections and have the potential to provide improved efficacy, tolerability and convenience. Leveraging the proprietary technologies in our PEP™ platform, we are designing and developing novel peptide therapeutics with the goal of achieving four key, distinct attributes: 1) high potency, 2) high target selectivity, 3) half-lives that allow a dosing at weekly or less frequent intervals, and 4) low or flat peak-to-trough ratios to improve tolerability, thereby facilitating higher dosing and greater potential efficacy.

Our platform

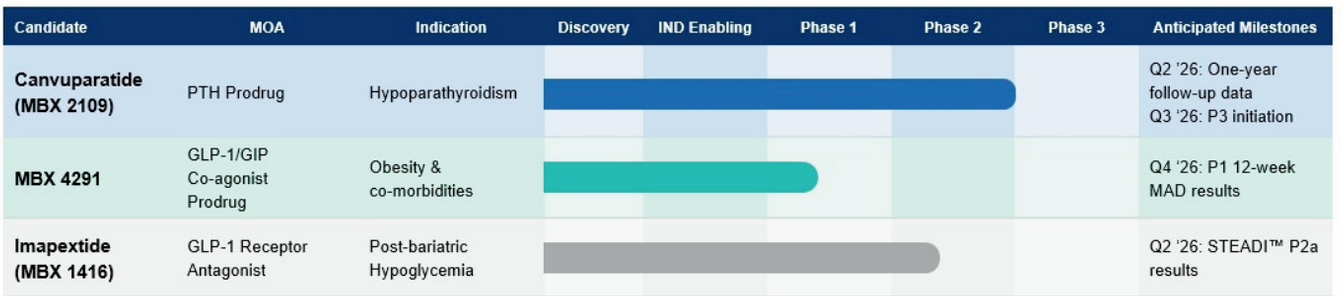
We have built our proprietary PEP™ platform to develop innovative precision peptide therapies that are designed to overcome key limitations of current peptide therapies. We were founded by leaders in the field of peptide discovery and development with the goal of transforming the treatment landscape for endocrine and metabolic diseases with novel, efficacious, safe and convenient treatments. Our PEP™ platform builds upon the expertise and chemical technologies originally discovered at the Indiana University laboratory of our scientific co-founder, Dr. Richard DiMarchi, who is globally recognized for translational breakthroughs in endocrine pharmacology, including the discovery of the first GLP-1/GIP co-agonist as well as other dual and triple incretin agonists. We have developed a proprietary platform of tools that we believe will allow us to continually design transformative therapies. These proprietary tools and know-how include:

- **Innovative peptide design** with a goal to provide enhanced physical properties including stability and solubility, increased potency, and multiple mechanisms of action in a single peptide
- **Programmable prodrug technologies** that are designed to precisely time the chemical conversion of the prodrug into an active form to reduce peak-to-trough ratios and improve clinical outcomes
- **Fatty acylation** that aims to increase duration of action for more convenient dosing regimens and compatibility with non-injectable formulations

Our PEP™ platform is designed to improve clinical outcomes and simplify disease management for patients. Our PEPs are engineered to potentially optimize pharmaceutical properties yielding peptides with extended time-action profiles, convenient dosing regimens and the potential to enhance compliance and improve treatment effectiveness in a real-world setting. PEPs may improve efficacy and reduce adverse events by providing a more continuous, infusion-like exposure to the peptide. We believe that our PEP™ technology, along with our significant know-how in the synergistic application of these tools, provides the opportunity to discover novel, highly selective and efficacious peptides with extended time-action profiles and low peak-to-trough ratios that may improve on the shortcomings of existing peptide therapies.

Our pipeline

We are leveraging our PEP™ platform to advance a pipeline of programs to treat both endocrine and metabolic disorders with clinically validated targets, established endpoints for regulatory approval, significant unmet needs and large potential market opportunities.



MBX expects to nominate two additional obesity development candidates in Q2 2026 and Q3 2026

GLP-1=glucagon-like peptide-1; GIP=glucose-dependent insulinotropic polypeptide; PTH=parathyroid hormone

Beyond MBX 4291, we have a robust discovery pipeline including multiple programs in the lead optimization stage of development, and we expect to nominate two additional candidates in the second and third quarters of 2026.

Canvuparatide for the treatment of chronic hypoparathyroidism

Our lead product candidate, canvuparatide, is a parathyroid hormone peptide prodrug that is designed as a potential long-acting hormone replacement therapy for the treatment of HP. HP is a rare endocrine disease where parathyroid glands fail to produce sufficient amounts of PTH, which is a hormone that regulates calcium levels in the blood through its effects on bone, kidneys and intestines. Leveraging our proprietary PEP™ platform, we designed canvuparatide to treat the underlying pathophysiology of HP by providing a continuous, infusion-like exposure to PTH with a convenient once-weekly injection. In a Phase 1 clinical trial in healthy adults, canvuparatide demonstrated a low peak-to-trough ratio, which is consistent with a continuous, infusion-like profile, and an extended half-life potentially enabling the first once-weekly PTH dosing regimen for patients with HP. Canvuparatide was generally well-tolerated with no drug-related severe or serious adverse effects. The FDA and the European Commission have granted orphan drug designation to canvuparatide for the treatment of HP. Orphan drug designation does not shorten the development time or regulatory review time of a product candidate and does not provide any guarantee of approval in the regulatory review or approval process. In September 2025, we announced canvuparatide achieved the primary endpoint in our Phase 2 trial with a statistically significant responder rate at Week 12 and further demonstrated positive six-month responder results from the open-label extension portion of the trial. All patients completed the 12-week trial, and canvuparatide was generally well-tolerated, with no treatment-related serious adverse events or discontinuations. We intend to present results from the Phase 2 clinical trial and one-year follow-up data from our ongoing open-label extension study at a medical meeting in the second quarter of 2026; and initiate a Phase 3 clinical trial of canvuparatide in the third quarter of 2026.

Overview of chronic hypoparathyroidism

HP is a rare endocrine disease caused by a deficiency of PTH released by parathyroid glands that results in decreased calcium levels in the blood leading to hypocalcemia. Hypocalcemia can result in a variety of acute symptoms, such as muscle cramping or spasm, tingling, and neurological symptoms such as depression, confusion and cognitive impairment. More serious complications can occur, including seizures and cardiac arrhythmias. As a result, HP can interfere with daily activities,

negatively impacting the quality of life for patients. We estimate that HP affects approximately 120,000 people in the United States and more than 250,000 in the United States and Europe. The most common cause for HP, in approximately 75% of cases, is inadvertent removal or damage to the parathyroid glands during neck surgery. It can also be caused by certain autoimmune processes and genetic conditions.

Current treatments and limitations

The current standard of care for HP does not address the PTH deficiency, which is the underlying cause of the disease. To avoid hypocalcemia and its symptoms due to PTH deficiency, the current standard of care consists primarily of high doses of oral calcium supplements and active vitamin D. Patients are treated with high dose calcium supplements (approximately 1.8 grams per day, compared to 250 to 500 mg in a multivitamin) and prescription strength active vitamin D therapy, which can require the daily ingestion of approximately seven or more pills taken at multiple times throughout the day. Despite this therapy, symptom relief can be suboptimal and does not address PTH deficiency. In addition, treatment with large doses of calcium and active vitamin D are associated with long-term complications such as cardiovascular disease, vascular calcification and increased urinary calcium excretion, which can result in chronic kidney disease and kidney stones.

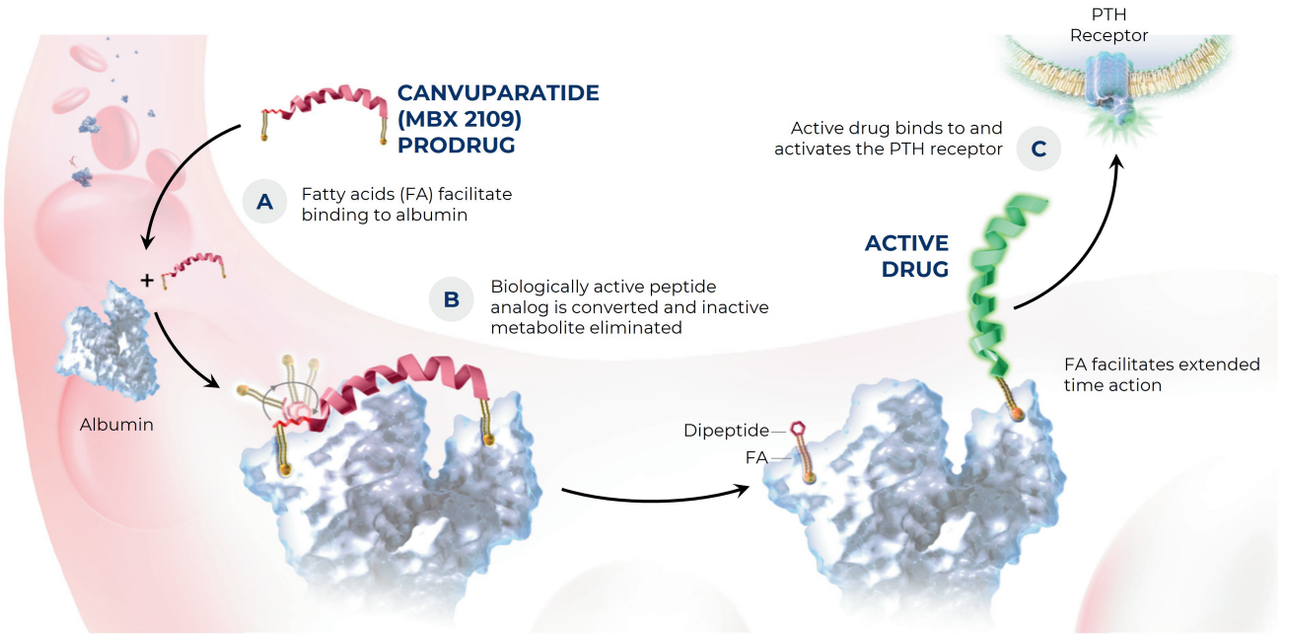
As the underlying pathophysiology of HP is a deficiency in PTH, clinicians have used Natpara®, a once-daily, unmodified PTH peptide replacement therapy to treat HP. However, Natpara has a short half-life and does not provide PTH exposure over a full 24-hour period. The inability to provide continuous blood exposure to PTH leads to suboptimal efficacy as patients are unable to stop active vitamin D and calcium supplements. After the recall of Natpara in 2019, Takeda announced in 2022 that it decided to discontinue manufacturing of Natpara on a voluntary basis at the end of 2024 due to unresolved supply issues that are specific to the product and has indicated that it will not re-commercialize the product. Palopegteriparatide, manufactured by Ascendis Pharma, is a once-daily PTH replacement therapy that is approved in the United States and European Union, marketed as Yorvipath® (palopegteriparatide), for the treatment of HP in adults. In Phase 3 trials, palopegteriparatide treatment rendered the majority of patients independent of active vitamin D and calcium supplements (which reduced pill burden), reduced urinary calcium excretion and, by patient-reported-outcome assessments, improved quality of life. We believe there is a need for a more effective therapy, which can ultimately normalize serum and urine calcium levels with a sustained PTH pharmacology, with a more convenient, once-weekly dosing regimen for patients with HP.

Our solution: Canvuparatide

Canvuparatide is designed to treat the underlying pathophysiology of HP by providing a continuous, infusion-like exposure to PTH with a convenient once-weekly injection. Utilizing our PEP™ platform, we designed canvuparatide to address the narrow therapeutic window of PTH by delivering a consistent exposure to the hormone, thereby maintaining normal serum and urinary calcium levels and reducing the need for vitamin D and calcium supplements. The FDA and European Commission have granted orphan drug designation to canvuparatide for the treatment of HP.

Canvuparatide is a fatty acylated prodrug engineered to be biologically inactive at the time of subcutaneous injection and convert to an active PTH peptide in an intrinsically controlled, time-dependent fashion to enable once-weekly administration with reduced fluctuations in peptide concentration. As shown in “A” in the graphic below, canvuparatide features fatty acids at both termini which facilitate binding to plasma proteins like albumin, extending time in circulation. Under physiologic conditions, as depicted in “B”, the prodrug is converted at a precisely controlled rate to the active peptide and an inactive fatty acylated two amino acid metabolite. This conversion step is essential for achieving the desired pharmacokinetic profile. Finally, in “C,” the fatty acylated active drug slowly diffuses from albumin and engages the PTH receptor, increasing calcium levels in the blood. canvuparatide incorporates two independent mechanisms utilizing our PEP™ technologies — programmable prodrug and fatty acylation — to provide sustained, predictable PTH peptide levels and convenient, once-weekly dosing.

Canvuparatide: Prodrug chemically converts to active drug at a precisely controlled rate



The once-weekly canvuparatide dosing regimen may improve compliance relative to daily PTH dosing regimens, which we believe has the potential to improve effectiveness in a real-world setting. The prodrug design and the fatty acylation are meant to provide an extended time-action profile that allows a once-weekly administration and provides a continuous, infusion-like PTH exposure with a lower daily peak-to-trough ratios than observed with daily PTH dosing regimens. This continuous, infusion-like exposure to canvuparatide may reduce the frequency and severity of events of hypercalcemia and hypocalcemia. Our goal is to simplify and improve the treatment of HP by providing a convenient, once-weekly therapy that addresses the underlying pathophysiology of HP and thereby eliminating the need for complicated treatment regimens with oral calcium supplements and active vitamin D and their long-term complications. By maintaining normal serum calcium levels, canvuparatide aims to reduce episodes of hypercalcemia and hypocalcemia and thereby potentially improve the quality of life of patients living with HP.

Canvuparatide Phase 3 clinical trial development

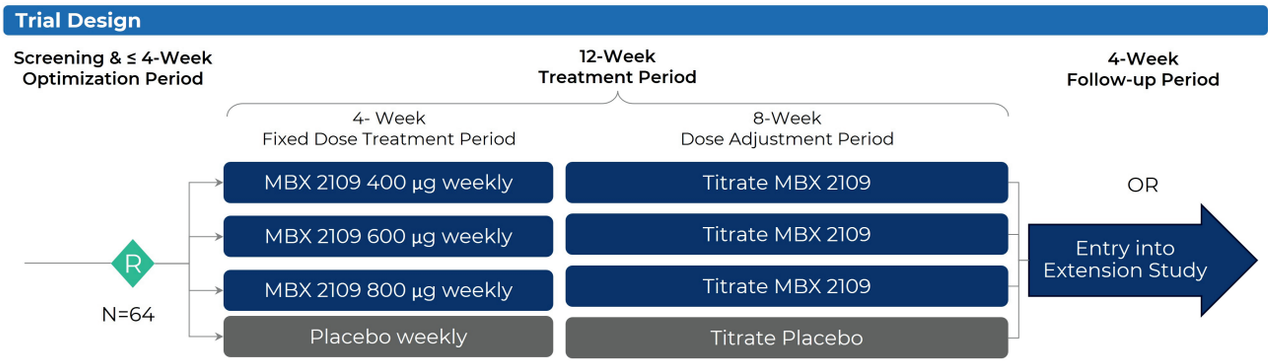
The Company plans to advance once-weekly canvuparatide into a Phase 3 trial for the treatment of chronic hypoparathyroidism ("HP") in the third quarter of 2026.

The Phase 3, double-blind, placebo-controlled trial will enroll approximately 160 patients randomized in a 3:1 ratio to receive canvuparatide or placebo. Following randomization, there will be a four-week fixed dose period of 600 ug canvuparatide (or placebo), followed by an eighteen-week dose titration period, and a four-week maintenance period. The Phase 3 trial will evaluate the primary endpoint, proportion of participants who achieve normal serum calcium and independence from conventional therapy, as well as secondary endpoints, including normalization of urinary calcium. The primary endpoint will be assessed at week 26, followed by an open label extension.

Avail™ Phase 2 clinical development and results

In March 2025, we completed a randomized double-blind, placebo controlled Phase 2 clinical trial in adult patients with HP (the "Avail trial"), and we announced topline data in September 2025. The Avail trial evaluated the safety, tolerability and efficacy of canvuparatide over a 12-week period in 64 patients. The primary endpoint of the Phase 2 clinical trial was the proportion of patients who could discontinue active vitamin D and reduce calcium supplements to less than or equal to 600 mg per day after 12 weeks of treatment while maintaining normal serum calcium levels. Secondary endpoints included safety and tolerability of canvuparatide and characterization of the pharmacokinetics and pharmacodynamics activity (including urine calcium, serum phosphorus, 1,25 dihydroxyvitamin D and bone biomarkers) and the impact on quality of life using patient-reported outcome tools.

In the Avail trial, patients were randomized (1:1:1:1) to weekly subcutaneous injections of placebo or 400 µg, 600 µg, and 800 µg of canvuparatide. The 12-week treatment period was comprised of a 4-week fixed dose period and an 8-week titration period. During the titration period, patients who had not been able to discontinue active vitamin D and/or reduce calcium supplements may have been able to up-titrate the study drug using a protocol-specified algorithm. Patients who completing the 12-week treatment period were eligible to participate in a 104-week long-term extension study in which all patients received canvuparatide.



In the Avail trial, canvuparatide achieved the primary endpoint with a statistically significant responder rate at Week 12 and further demonstrated positive six-month responder results from the open-label extension ("OLE") portion of the trial. All patients completed the 12-week trial, and canvuparatide was generally well-tolerated, with no treatment-related serious adverse events or discontinuations during the 12-week trial.

Primary Endpoint:

- **At 12 Weeks:** The primary composite endpoint (maintaining albumin-adjusted serum calcium levels in the normal range (8.2–10.6 mg/dL) and independence from conventional therapy (defined as independence from active vitamin D and receiving no more than 600 mg/day of calcium supplements)) was achieved in 63% of canvuparatide-treated patients (30/48) compared with 31% in placebo-treated patients (5/16) (p=0.042) at Week 12.
- **At 6 Months:** In the OLE, 79% of patients (44/56 evaluable) who received treatment achieved responder status at six months, including patients initially randomized to placebo.

Select Secondary and Exploratory Endpoints:

- **Pharmacokinetics:** Pharmacokinetic findings were consistent with the Phase 1 results, supporting a once-weekly dosing schedule.
- **Bone Activity:** Bone turnover and formation markers (BSAP, CTx and P1NP) increased over 12 weeks compared to placebo, consistent with enhanced bone remodeling.
- **Kidney Activity:** In patients with elevated urine calcium at screening that normalized at Week 12, mean urine calcium was reduced by 48% in patients treated with once-weekly canvuparatide compared with 33% on placebo.

We completed an End of Phase 2 meeting with the FDA and expect to receive Scientific Advice with the European Medicines Agency in the first half of 2026. We also intend to present results from our Phase 2 clinical trial and report one-year follow-up data from our ongoing open-label extension study at a medical meeting in the second quarter of 2026; and initiate a Phase 3 clinical trial of canvuparatide in the third quarter of 2026.

Phase 1 clinical development and results

We evaluated the safety, tolerability, pharmacokinetics and pharmacodynamics of canvuparatide in our completed first-in-human, randomized double-blind, placebo controlled, single and multiple ascending dose Phase 1 clinical trial in healthy adults. The primary endpoint of the Phase 1 clinical trial was safety and tolerability and secondary endpoints were pharmacokinetics and pharmacodynamic activity of canvuparatide. The key pharmacokinetic endpoints for the active drug were half-life, peak-to-trough ratios and time to reach steady-state. The key pharmacodynamic endpoints for the active drug were changes in albumin-adjusted serum calcium levels and suppression of endogenous PTH secreted by the parathyroid gland.

Canvuparatide was generally well-tolerated with no drug-related severe or serious adverse effects being observed. No dose-limiting toxicities or off-target adverse effects were noted. Adverse events were generally mild in nature. Injection site adverse events were the most common treatment-related adverse event, with the most common reaction being a non-raised, painless and non-pruritic red area generally less than 50 mm in diameter, which resolved without intervention. Hypercalcemia was observed in three subjects each in the single and multiple ascending parts of the trial. These events occurred at the higher dose levels, resolved without intervention and were asymptomatic laboratory findings.

Single and multiple weekly doses of canvuparatide had dose-proportional and time-dependent increases in exposure to the active drug, with low to moderate intersubject variability. We believe these findings support use of a reliable titration regimen across subjects. The half-life of the canvuparatide active drug across all doses was approximately 7.7 to 8.9 days, which we believe supports a once-weekly dosing regimen. Mean peak-to-trough ratios of the active drug following the last dose ranged from 1.47 to 1.79, indicating a continuous, infusion-like profile over a seven-day period.

Once-weekly canvuparatide increased serum calcium levels assessed by either the maximal increase in serum calcium (Emax,adj) or the total serum calcium levels between injections (AUEC0-t adj) in a dose- and time-dependent fashion. Maximal increases in albumin-adjusted serum calcium ("adj-Ca") were seen approximately 48 hours after injection. At the higher doses, increases in serum calcium were apparent after the first injection, with the effect being nearly maximal after the third weekly injection. These results have demonstrated a dose- and time-dependent effect of canvuparatide in increasing serum calcium levels with an initial effect within days after the first dose and nearly maximal after the third dose.

Obesity portfolio

Obesity is widely recognized as a global epidemic which imposes a substantial health care burden and is associated with significant co-morbidities. We believe that we are well positioned to deliver an array of differentiated obesity candidates offering treatment flexibility to improve patient outcomes. Based on the significant unmet need, we see a potentially large commercial opportunity for our obesity portfolio.

Leveraging our PEP™ platform, we are discovering and developing candidates with optimized pharmacokinetic profiles and pharmacologic attributes to potentially improve on the current treatments for obesity and related co-morbidities. We are engineering our candidates to extend the time-action profile and to potentially improve tolerability, thereby providing the potential for higher doses leading to greater weight loss than can be achieved with existing therapies. We are prioritizing candidates targeting clinically validated mechanisms for weight loss and are focusing on discovering peptides that target multiple unique receptors. Our obesity portfolio currently includes one product candidate, MBX 4291, for which we have completed IND-enabling studies, and a robust discovery pipeline with multiple development programs in the lead optimization stage of development, and we expect to nominate two additional candidates in the second and third quarters of 2026.

MBX 4291 for the treatment of obesity

Our lead obesity product candidate, MBX 4291, is designed to be a long-acting and highly potent PEP™ GLP-1 and glucose-dependent insulinotropic polypeptide ("GIP") receptor co-agonist prodrug with the goal of potential once monthly dosing frequency and improved efficacy and tolerability relative to existing standards of care. In our preclinical studies, the active component of MBX 4291 demonstrated a similar activity profile and body weight loss in mice as tirzepatide, an approved weekly GLP-1/GIP co-agonist. In additional preclinical evaluation, MBX 4291 demonstrated an extended duration of action of the active component of MBX 4291, supporting the potential for once-monthly administration. We are conducting a randomized, double-blind, placebo controlled Phase 1 clinical trial designed to evaluate safety, tolerability, pharmacokinetics, and pharmacodynamics of SAD and MAD doses in adults with obesity. Following the SAD and four-week MAD portions of the trial, we plan to evaluate multiple ascending doses of MBX 4291, or matching placebo, administered over 12 weeks in up to two cohorts consisting of thirty participants. Results from the planned 12-week MAD portion are expected in the fourth quarter of 2026. Beyond MBX 4291, we have a robust discovery pipeline including multiple programs in the lead optimization stage of development.

Obesity

Obesity is a common and costly chronic condition leading to significant morbidity and mortality. According to the CDC, an estimated 42% of U.S. adults aged 20 and over have obesity (BMI≥30 kg/m2) as of 2018, including 9% of adults with severe obesity (BMI≥40 kg/m2), and another 31% of adults who are overweight (BMI between 25.0 and 29.9 kg/m2). Based on the CDC’s 2018 prevalence rates, we estimate that at least 190 million adults in the United States are obese or overweight.

Obesity leads to co-morbidities that have a significant impact on the health. Obesity associated co-morbidities include illnesses such as type 2 diabetes, hypertension, dyslipidemia, sleep apnea, osteoarthritis, metabolic dysfunction associated steatohepatitis, infertility, heart failure, stroke, coronary artery disease, venous thromboembolic disease, gall stones, disease, depression and certain types of cancer. These co-morbidities have a negative impact on the quality and quantity of life, reduce productivity and impose a substantial economic cost on society.

Current treatments and limitations

Initial treatment options for people with obesity focus on a combination of diet, exercise and lifestyle modifications. The American College of Cardiology (the "ACC") and American Association of Clinical Endocrinologists (the "AACE") recommend people with obesity should initially be prescribed aerobic exercise and resistance training, a reduced calorie diet, and behavioral intervention. Behavioral modification therapy typically results in only modest weight loss that is often not sustained. Therefore, surgery and pharmacological treatment are often required.

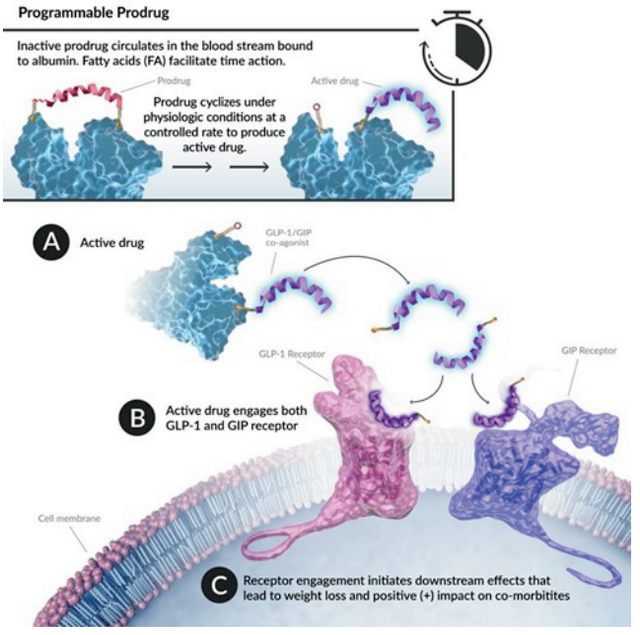
The AACE guidelines recommend that pharmacotherapy combined with lifestyle modifications be considered in individuals with a BMI of at least 27 kg/m2. GLP-1 receptor mono-agonists have been approved by the FDA and EMA for obesity, such as Wegovy® (semaglutide) and Saxenda® (liraglutide). Zepbound® (tirzepatide) was the first GLP-1/GIP receptor co-agonist approved for obesity. In a head-to-head study in overweight and obese subjects with type 2 diabetes, tirzepatide, the GLP-1/GIP receptor co-agonist, provided statistically and clinically meaningful greater weight loss, relative to semaglutide, the GLP-1 receptor mono- agonist. Based on demonstrating reductions in the risk of heart attack, stroke, or cardiovascular disease-related death, a weight loss drug (Wegovy) has been approved by the FDA to reduce the risk of major cardiovascular events in overweight or obese individuals with cardiovascular disease and no prior history of type 2 diabetes. Additionally, the FDA has approved an oral tablet version of Wegovy for treatment.

While the current GLP-1-based agonists represent significant and clinically meaningful advances in the treatment of obesity, they require weekly injections and can be associated with significant GI side effects such as nausea, diarrhea, constipation, and vomiting. These side effects often lead to reduced adherence and increased discontinuation, thereby limiting a patient's ability to lose weight. The availability of better tolerated agents with weight loss equal to or exceeding the approved GLP-1 receptor mono-agonist therapies or more efficacious GLP-1/GIP receptor co-agonist therapies would be a clinically meaningful therapeutic advance for people with obesity and its co-morbidities. We believe that our PEP™ technology can improve on the shortcomings of existing pharmacologic weight loss therapies through the discovery of novel, highly selective and efficacious peptides with extended time-action profiles and the flexibility to utilize dosing regimens that may improve efficacy and tolerability.

Our solution: MBX 4291

Leveraging our PEP™ technology, we have engineered MBX 4291, a long-acting and highly potent PEP™ GLP-1 and GIP receptor co-agonist prodrug with the goal of potential once monthly dosing frequency and improved efficacy and tolerability relative to existing standards of care, and have advanced this product candidate into Phase 1 development for the treatment of obesity. In our preclinical studies, the active component of MBX 4291 demonstrated a similar activity profile and body weight loss in mice as tirzepatide, an approved weekly GLP-1/GIP co-agonist. In additional preclinical evaluation, MBX 4291 demonstrated an extended duration of action of the active component of MBX 4291, supporting the potential for once-monthly administration. MBX 4291 has demonstrated the desired pharmacokinetic profile by utilizing two independent mechanisms – programmable prodrug and fatty acylation. When injected subcutaneously, MBX 4291 is an inactive prodrug that at physiological conditions will slowly and precisely convert in an intrinsically controlled, time-dependent fashion to the active drug. Additionally, we incorporated fatty acylation into the peptide to enhance binding to albumin from which the active peptide is slowly released to interact with its cognate receptors. The combination of the prodrug and fatty acylation approaches to MBX 4291 provides the potential for a once-monthly dosing regimen. We believe that our proprietary PEP™ platform and know-how provide significant optionality in devising dosing regimens that could lead to clinically meaningful improvements in tolerability and increase the maximally attained weight loss, relative to existing, approved GLP-1-based therapies.

The graphic below illustrates the use of our PEP™ technology in the design of MBX 4291. The helix represents the active drug's ability to bind both the GLP-1 and GIP receptors. The "tails" at each end of the molecule represent lipids, or fatty acylations. The "zig-zag" at the N-terminus represents our prodrug sequence, which activates the drug at a precise rate under physiological conditions, and without requiring enzymatic intervention. We believe activity over one month at GLP-1 and GIP receptors will be enabled by the combination of the prodrug and fatty acylation utilizing our PEP™ platform.



While the design of MBX 4291 utilized similar, clinically validated mechanisms to prolong half-life as those used in designing canvuparatide, including prodrug and fatty acylation, with its extended half-life, additional prodrug modifications were made to extend the time-action profile beyond that seen with canvuparatide potentially allowing for a once-monthly dosing regimen. We believe MBX 4291 has the potential to be a safe and efficacious therapy that will help people achieve their weight loss goals and improve their overall health.

MBX 4291 Phase 1 development

We are currently evaluating MBX 4291 in a randomized, double-blind, placebo controlled first-in-human Phase 1 trial to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of single and multiple ascending doses of MBX 4291 in adult participants with obesity. The trial includes:

Part A SAD: single ascending doses of MBX 4291 or matching placebo are administered in five cohorts consisting of eight participants each. Participants will be randomized to receive MBX 4291 or matching placebo in a 3:1 ratio. Participants in each cohort will be followed for 63 days after the single study intervention administration.

Part B MAD (4 weeks): multiple ascending doses of MBX 4291 or matching placebo are administered in three cohorts consisting of eight participants each. Participants are randomized to receive MBX 4291 or matching placebo in a 3:1 ratio. Participants in each cohort will receive a total of four study intervention administrations one week apart and will be followed for 71 days after the first study intervention administration.

Following completion of Parts A and B, we plan to evaluate multiple ascending doses of MBX 4291, or matching placebo, administered over 12 weeks in up to two cohorts consisting of 30 participants each in a 2:1 randomization ratio. Participants are expected to receive up to a total of 12 study intervention administrations one week or one week and one month apart with increasing doses of MBX 4291 and will be followed for 120 days after the first dose. Topline results of the Phase 1 clinical trial of MBX 4291 are anticipated in 2027.

Preclinical studies

The active component of MBX 4291 has demonstrated a similar activity profile and body weight loss in mice as the clinically-validated and approved weight-loss drug, tirzepatide, in *in vitro* studies. In the *in vitro* study in cells expressing the human GLP-1 or GIP receptors, MBX 4291 active drug binds to GLP-1 and GIP receptors with similar activity to tirzepatide.

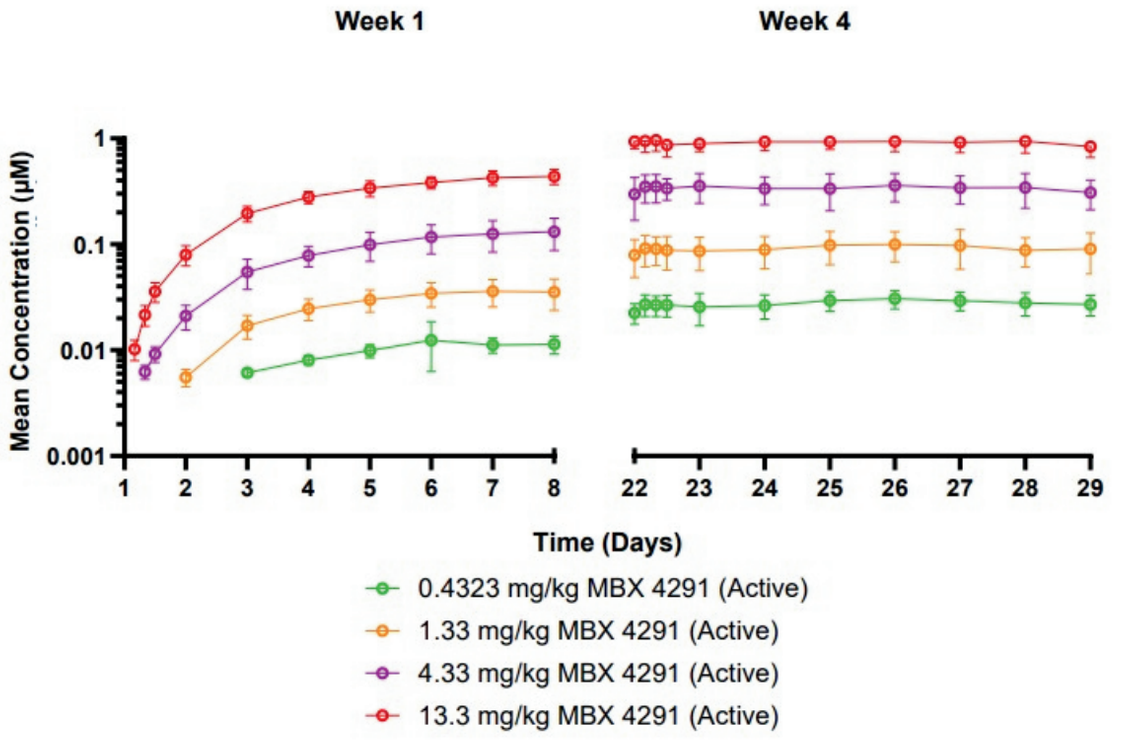
We also compared MBX 4291 active drug to tirzepatide in diet-induced obesity ("DIO") rodent models, which are commonly used to assess weight loss of agents being evaluated as clinical development candidates. In this study, eight mice were subcutaneously dosed daily with the MBX 4291 active drug and eight with tirzepatide for ten days and weight and food

intake were assessed each day. The MBX 4291 active drug produced similar reductions in body weight and food intake as tirzepatide.

As metabolism and albumin turnover rates in non-human primates more closely resemble humans than do rodents, non-human primates were used to assess the conversion of MBX 4291 to the active drug and overall pharmacokinetic profile. After a single, subcutaneous MBX 4291 injection, peak exposure to the biologically active component of MBX 4291 occurred 4-5 days later. This reflects the prodrug design, in which the biologically inactive prodrug converts into the active peptide in a time-dependent fashion, allowing an extended duration of action for the biologically active component of the compound. In contrast, peak exposure to tirzepatide, which is itself the active compound, occurred within 24 hours of injection. In addition, the decline in exposure to the active component of MBX 4291 was flatter than the more rapid reduction in tirzepatide exposures. Based on this observed pharmacokinetic profile, which illustrates the prodrug and fatty acylation mechanisms, we believe MBX 4291 has the potential to be dosed less frequently than the once weekly dosing required for tirzepatide in humans. The mean concentration of tirzepatide ranged from a maximum of 387 nM at 12 hours to 50.0 nM at 168 hours, whereas the mean concentration of the active component of MBX 4291 ranged from a maximum of 5.05 nM at 96 hours to 3.96 nM at 168 hours and 0.615 nM at the final measurable concentration at 456 hours.

We also observed a concentration plateau when MBX 4291 was dosed once weekly in non-human primates. The figure below shows the pharmacokinetic profile observed in a preclinical study of non-human primates dosed with MBX 4291 at various doses weekly over four weeks. After a single, subcutaneous MBX 4291 injection, exposure to the biologically active component of MBX 4291 rose gradually over the week. After the fourth dose of MBX 4291, the mean concentration of the active component was observed to reach a plateau. Based on the findings in the figure below, we believe MBX 4291 may allow for a flat steady exposure over time. We believe the observed slower flatter decline in mean active drug concentration, as well as the observed plateau following regular dosing, may allow us to find a dosage for MBX 4291 that can maintain an appropriate active concentration of MBX 4291 within the therapeutic window for longer with less than weekly dosing.

MBX 4291 Proof of Concept: Flattened and Steady Exposure



Imapextide (MBX 1416) for the treatment of post-bariatric surgery hypoglycemia

We are developing imapextide (MBX 1416), a long-acting GLP-1 receptor antagonist, as a potential treatment for PBH. Imapextide is designed to block pathologic increases in GLP-1 released following a meal, which increases lead to hyperinsulinemia and may result in hypoglycemia. By inhibiting GLP-1-induced hyperinsulinemia in patients with PBH, imapextide is designed as a potential once-weekly therapy to reduce insulin secretion and increase blood glucose to reduce the

frequency and severity of hypoglycemic events. In a Phase 1 clinical trial, weekly subcutaneous injections resulted in dose-proportional increases in imapextide exposure and a half-life supporting a once-weekly dosing regimen. Imapextide was generally well-tolerated with a favorable safety profile and no treatment-related serious adverse events. We are currently conducting the STEADI™ Phase 2a, an open-label clinical trial evaluating primary efficacy of subcutaneous imapextide in adult patients with PBH. Topline results are expected in the second quarter of 2026.

Post-bariatric surgery hypoglycemia

PBH is a rare, serious and chronic complication of bariatric surgery typically occurring six months or later after surgery. We estimate PBH affects more than 90,000 people in the United States. In PBH, pathologic increases in GLP-1 are released following a meal leading to hyperinsulinemia, or excessive levels of insulin, that may result in hypoglycemia, or low blood glucose. Hypoglycemic symptoms may include confusion, weakness, dizziness, blurred vision, loss of consciousness and seizures. The unpredictable onset of hypoglycemia and anxiety due to fear of hypoglycemia significantly negatively impact the quality of life in patients with PBH.

While GLP-1-based therapies have been recently approved to treat obesity and its co-morbidities, people with severe obesity, defined as a BMI ≥40 kg/m2, often can require a greater degree of weight loss than these current therapies can achieve. According to the CDC, the prevalence of severe obesity in the United States in adults over 20 years increased from 4.7% in 2000 to 9.2% in 2018. Bariatric surgery still remains the most efficacious means of treating severe obesity. Bariatric surgeries have increased by approximately 23% since 2017 to approximately 280,000 in the United States in 2022, according to the American Society for Metabolic and Bariatric Surgery. Further, the use of bariatric surgery to address severe obesity and related comorbidities has increased by more than 50% over the past decade from 2011 to 2022, according to the Journal of the American Heart Association, with further increases expected due to the use of bariatric surgery to treat severe obesity and its co-morbidity of type 2 diabetes. The most commonly employed bariatric procedures are Roux-en-Y gastric bypass ("RYGB") and sleeve gastrectomy ("SG") which represent approximately 75% of bariatric surgeries performed annually. We estimate that PBH impacts up to approximately 13% and approximately 2% of patients who undergo RYGB and SG, respectively.

Following a meal, nutrients are absorbed from the upper small intestine causing blood glucose levels to increase. In response to increasing glucose levels, GLP-1 is released from intestinal L-cells which augments insulin release from the pancreas to maintain euglycemia, or normalized blood glucose levels. Following RYGB and SG, the transit of nutrients from the stomach to the upper small intestine is markedly increased, which requires more rapid GLP-1 and insulin secretion to maintain euglycemia. In PBH, GLP-1 release following a meal is excessive which results in a pathologic increase in insulin release from the pancreas leading to hyperinsulinemia and hypoglycemia. Both peak GLP-1 and peak insulin levels are higher and the lowest blood glucose levels are lower in patients with PBH than in patients without hypoglycemia following bariatric surgery.

Patients with PBH can experience symptomatic hypoglycemia sometimes multiple times a day. Hypoglycemia also causes a shortage of glucose in the brain, or neuroglycopenia. Neuroglycopenic symptoms, such as confusion, weakness, dizziness, blurred vision, loss of consciousness and/or seizures may develop, which can result in emotional and physical trauma to the individual.

The unpredictable nature and severity of hypoglycemic episodes can meaningfully hinder daily activities. As a result, the patient burden is substantial with some patients unable to drive, work, or live alone, leading to a significant negative impact on a patient’s quality of life.

Current treatments and limitations

There are currently no FDA-approved pharmacologic therapies for PBH. The current treatment options to reduce the frequency and severity of hypoglycemic episodes focus on dietary interventions and secondarily on the use of off-label medications with unproven effectiveness for patients with PBH and significant effect profiles. While glucagon is used as a rescue therapy to treat severe hypoglycemic events, it does not prevent hypoglycemia from occurring. In certain patients with severe, intractable hypoglycemia, surgical reversal of the bariatric procedure may be considered.

GLP-1 antagonism as a clinically validated solution for PBH

Use of a GLP-1 inhibition-based mechanism has been clinically validated as a potential therapy to reduce the frequency and severity of hypoglycemic episodes in patients with PBH. When administered to patients with PBH, exendin (9-39), a short-acting, unmodified GLP-1 receptor antagonist, prevents hyperinsulinemia and blood glucose levels from decreasing into the

hypoglycemic range. In a study in patients with PBH, patients who received treatment with exendin (9-39) did not experience hyperinsulinemia and blood glucose levels remained in the euglycemic range after a meal. On the other hand, without treatment with exendin (9-39), blood glucose levels in patients can decrease into the hypoglycemic range and rescue therapy was needed to avert symptomatic hypoglycemia after a meal.

Our solution: Imapextide

Imapextide is a long-acting GLP-1 receptor antagonist that is designed to prevent GLP-1 from augmenting insulin release to cause hyperinsulinemia following a meal and thereby prevent the occurrence of severe hypoglycemia in patients with PBH. Imapextide binds to the GLP-1 receptor but lacks the ability to activate the receptor, acting as a competitive antagonist of GLP-1. Leveraging our PEP™ platform, we aim to improve the pharmaceutical properties of the GLP-1 sequence required to inhibit GLP-1 action by chemically modifying the amino acid backbone to achieve enhanced potency, stability and solubility, relative to the corresponding, unmodified GLP-1 sequence. Leveraging the clinically validated GLP-1 antagonist approach, imapextide has the potential to be the first pharmacologic therapy to prevent and reduce the severity of hypoglycemia in patients with PBH with convenient once-weekly administration.

Our goal is for imapextide to improve the quality of life in patients with PBH by reducing the burden of living with the unpredictable nature of hypoglycemia and anxiety from fear of suffering the potentially severe adverse clinical outcomes from hypoglycemia. We aim to do this by reducing the frequency and decreasing the severity of hypoglycemic episodes.

STEADI™ Phase 2a clinical development

We are conducting the STEADI™ Phase 2a, an open-label clinical trial evaluating primary efficacy of subcutaneous imapextide in adult patients with PBH. Patients with a history of hypoglycemia following Roux-en-Y or sleeve gastrectomy will undergo three mixed-meal tolerance tests after each imapextide administration, to evaluate the pharmacodynamic effect of imapextide. Topline results are expected in the second quarter of 2026.

Phase 1 clinical development and results

We evaluated the safety, tolerability, pharmacokinetics and pharmacodynamics of imapextide in a randomized, double-blind, placebo controlled, single- and multiple- ascending dose, first-in-human Phase 1 clinical trial in healthy adults. The primary endpoint of the Phase 1 clinical trial was to evaluate the safety and tolerability of imapextide. Secondary endpoints were to evaluate the pharmacokinetic profile of imapextide to establish the time-action profile to support a once-weekly dosing regimen and to utilize pharmacodynamic parameters (e.g., blood glucose, insulin, c-peptide levels) obtained during a mixed meal tolerance test to select a range of imapextide doses to advance into the next phase of development.

The single ascending dose portion of this Phase 1 trial evaluated subcutaneous imapextide doses of 10 mg, 30 mg, 100 mg and 200 mg, in eight healthy adults per cohort randomized 3:1 (six imapextide; two placebo in each cohort). The multiple ascending dose portion of the trial evaluated four weekly subcutaneous doses of placebo and doses of imapextide at 10 mg, 30 mg in two 15 mg injections, and 30 mg in a single injection in four cohorts in eight healthy adults per cohort (six imapextide; two placebo in each cohort). An additional cohort assessed potential drug-drug interaction of imapextide on rosuvastatin exposure and on gastric emptying.

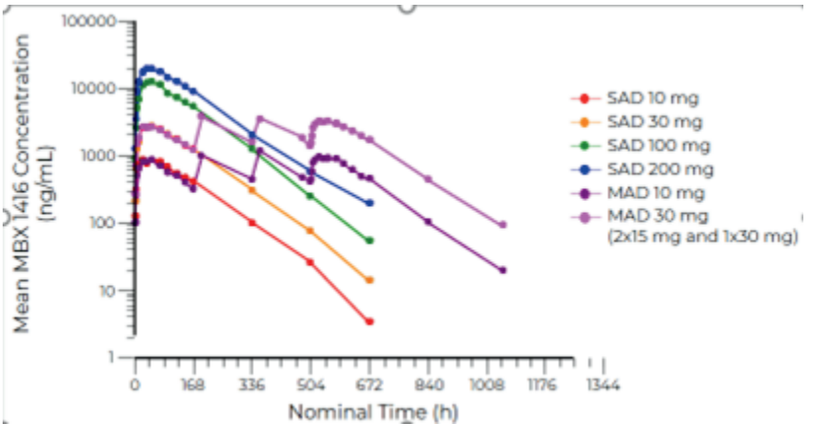
Imapextide was generally well-tolerated with a favorable safety profile and no dose-related serious adverse events. Injection site adverse events were the most common treatment-related adverse event, with the most common reaction being a non-raised and non-pruritic red area, which resolved generally within about seven days and with little or no pain. Similar injection site reactions have been observed with other peptide therapeutics. Except for adverse events related to the injection site reactions, no pattern or imbalance between imapextide and placebo were observed for any adverse event. No clinically meaningful changes were observed in laboratory values, including glucose and hematology values, in vital signs or body weight, or in electrocardiogram findings.

Pharmacokinetic data from our Phase 1 clinical trial showed that weekly subcutaneous injections resulted in dose-proportional increases in imapextide exposure over the 10mg to 200mg dose range, with low intersubject variability. In the multiple ascending dose cohort, the median half-life of imapextide was approximately 90 hours, supporting once-weekly

administration. Steady state was achieved by the third dose, and at steady state, the median Tmax was between 36 and 48 hours.

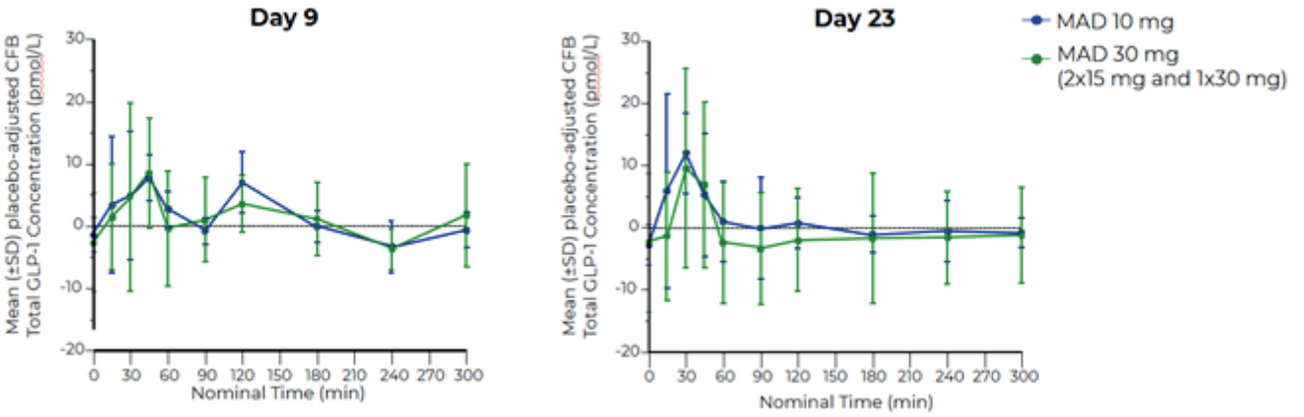
The graph below shows the mean serum concentration of imapextide over time following dosing, from the single- and multiple-ascending dose cohorts of the Phase 1 trial, illustrating the dose-proportionality and half-life of imapextide.

Dose-proportional increases in mean imapextide concentrations with increasing doses



In the mixed meal tolerance test portion of the trial, we observed an increase in GLP-1 within 60 minutes following the meal in patients dosed with imapextide, suggesting a pharmacodynamic effect in healthy volunteers that could potentially translate into a therapeutic benefit in PBH patients. No meaningful changes were observed in other parameters such as glucose, insulin, and c-peptide, as expected in healthy volunteers. The graph below shows the increase in placebo-adjusted GLP-1 peak from baseline following a mixed-meal tolerance test, conducted one day after the second and fourth doses of imapextide.

Change from baseline (CFB) in placebo-adjusted GLP-1 serum concentration following mixed-meal tolerance test



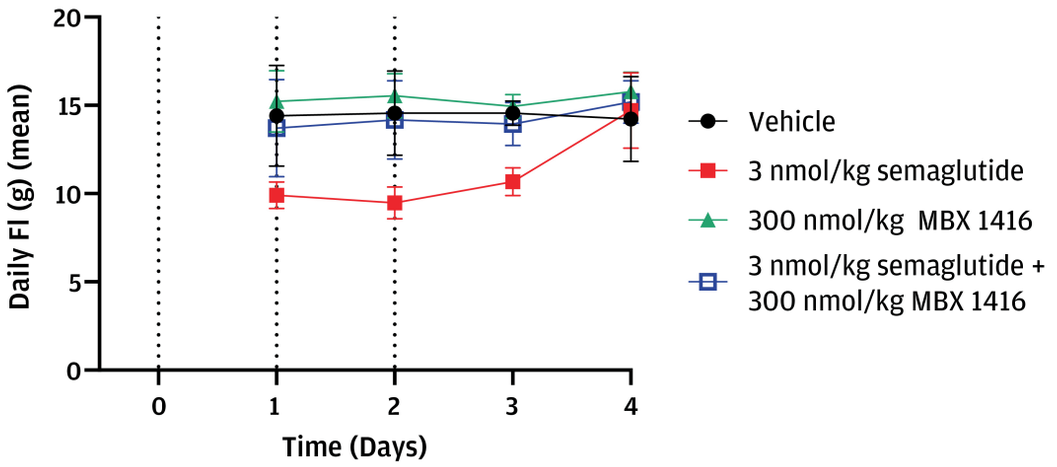
In our drug-drug interaction cohort, imapextide had no meaningful effect on rosuvastatin exposure, a commonly prescribed statin.

Preclinical studies

In *in vitro* studies, imapextide inhibited GLP-1 receptor activation and was approximately a six to nine times more potent inhibitor than exendin (9-39). By blocking GLP-1 action, GLP-1-induced augmentation of insulin release is blocked. The ability of imapextide and exendin (9-39) to block GLP-1 receptor activation were evaluated in an *in vitro* GLP-1 receptor assay. In *in vitro* receptor assays, the concentration required to inhibit 50% of GLP-1 action was 54 nM and 503 nM for imapextide and exendin (9-39), respectively.

In a diet-induced obesity mouse model, we evaluated whether imapextide could block the ability of semaglutide, a GLP-1 agonist, to reduce food intake. In this study, on days 0, 1 and 2, rodents were administered semaglutide alone, imapextide alone or semaglutide in combination with imapextide. Semaglutide was observed to inhibit food intake. However, this inhibition was blocked by the administration of imapextide with semaglutide. Imapextide administered alone did not affect food intake. These data provide *in vivo* evidence for the clinical potential of imapextide-induced inhibition of GLP-1 action.

Imapextide (MBX 1416) induces inhibition of GLP-1 action when administered in combination with semaglutide in an *in vivo* model



In rodent and non-human primate toxicology studies of up to four weeks in duration, no clinical signs of toxicity were observed.

License agreement

Below is a summary of the key terms for our license agreement.

Indiana University Research and Technology Corporation Exclusive License Agreement

In June 2020, we entered into an Exclusive License Agreement with Indiana University Research and Technology Corporation ("IURTC"), a non-profit corporation organized under the laws of the State of Indiana, represented by The Trustees of Indiana University ("IU") pursuant to which we have been granted an exclusive, royalty-bearing license to certain IURTC patent rights ("the Licensed Intellectual Property") developed by Dr. DiMarchi and other collaborators to further scientific research, for new product development, and for other applications in public interest, such license, the IURTC License Agreement. In particular, we have been granted an exclusive, royalty-bearing license to make, have made, use, have used, offer to sell, have offered for sale, sell, have sold, import and have imported products that are covered by the Licensed Intellectual Property ("Licensed Products") with the right to sublicense to third parties. IURTC and IU have retained the right to (i) practice and use the Licensed Intellectual Property for non-commercial educational, research, and patient care and treatment purposes, and (ii) permit other non-profit and academic entities to practice and use the Licensed Intellectual Property for the same non-commercial purposes. Under the IURTC License Agreement, we agreed to use commercially reasonable efforts to develop, promote and sell Licensed Products in accordance with the IURTC License Agreement and any applicable laws. The IURTC License Agreement leverages IURTC's expertise in peptide therapies as well as our scientific, clinical, and regulatory capabilities to accelerate the development of peptide treatments for people with endocrine and metabolic disorders. Canvuparatide (MBX 2109), imapextide (MBX1416) and MBX 4291 are Licensed Products under the IURTC License Agreement. Any future product candidates developed pursuant to our sponsored research agreement with IU or otherwise covered by the Licensed Intellectual Property may be subject to the IURTC License Agreement.

As initial consideration for the license, we paid IURTC an immaterial issue fee. As additional consideration for the license, we are required to pay IURTC: (i) royalties with a rate based on net sales per calendar year; (ii) an annual maintenance fee of up to $0.1 million beginning in the first year in which the first commercial sale occurs; (iii) a mid-single digits percentage of any sublicensing revenue; and (iv) milestone payments in the event of successful achievement of specified development milestones up to an aggregate of $0.4 million. IURTC is also entitled to receive reimbursement for all patent prosecution and maintenance related expenses. Our tiered royalties are in the low single-digits on annual net sales of the Licensed Products. In the event that we are required to pay a non-affiliate third party consideration for intellectual property owned or controlled by such non-affiliate third party that we or a sublicensee licensed for the development of Licensed Products, we can deduct such amounts from the royalty payments up to a certain amount of the running royalties owed that year. The royalty term will terminate on a country-by-country basis as to each Licensed Product, until the expiration or termination of the last valid claim within the patent rights covering such Licensed Product in that country.

On January 5, 2024, we and IURTC entered into a fourth amendment to the IURTC License Agreement ("the Fourth Amendment"). The Fourth Amendment specifies IURTC is entitled to the receipt of additional clinical and regulatory milestones, as defined in the Fourth Amendment, up to an aggregate of $9.0 million. Following the execution of the Fourth Amendment, future remaining clinical and regulatory milestone payments in the IURTC License Agreement and all amendments totaled up to $9.3 million. In 2025, we paid a $1.0 million milestone payment to IURTC related to the initiation of the Phase 1 clinical trial of MBX 4291. At December 31, 2025, future remaining clinical and regulatory milestone payments in the IURTC License Agreement and all amendments totaled up to $8.3 million.

The IURTC License Agreement will expire at the expiration of the last of the patent rights covered in the IURTC License Agreement, unless terminated earlier by mutual agreement or by one of the parties. We may terminate the IURTC License Agreement with or without cause upon ninety (90) days prior written notice to IURTC. IURTC may terminate the IURTC License Agreement if we commit a material breach of the IURTC License Agreement and fail to cure the breach within the respective cure period after receipt of the notice of material breach or upon our failure to undertake certain activities in furtherance of commercial development goals. Upon termination of the IURTC License Agreement, all rights granted by IURTC will terminate and automatically revert to IURTC.

Manufacturing

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacturing of our product candidates for preclinical and clinical testing, as well as for commercial manufacturing if our product candidates receive marketing approval. As a key part of our product development approach, we aim to complete formulation work at an early stage of development, such that our clinical studies are conducted with a formulation that has the potential for eventual scale-up. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

Commercial strategy

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We intend to build a commercial infrastructure to support sales of any of our approved future drugs if and when we believe a regulatory approval of the first of such product candidates in a particular geographic market appears imminent. We expect to manage sales, marketing and distribution through a combination of internal resources and third-party relationships. In addition, we will opportunistically explore commercialization partnerships, particularly with entities that have strong capabilities in geographies outside the United States and depending on the specific development path pursued. For more specialized indications, we would consider commercializing our product candidates independently. For example, we believe the patient and prescriber populations for HP and PBH are relatively concentrated, with significant overlap, and can be addressed with a focused sales team. We also do not believe any existing pharmaceutical companies have significant expertise in the commercialization of therapies in the PBH specific area. We will, however, continuously review our partnering strategy in the light of new clinical data and market understanding. As our current and future drug candidates progress through clinical development, our commercial plans may change. Clinical data, the size of the development programs, the size of our target markets, the size of the requisite commercial infrastructure and manufacturing needs may all influence our commercialization strategies.

Competition

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, intense competition and a strong emphasis on intellectual property. We face substantial

competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future that are approved to treat the same diseases for which we may obtain approval for our product candidates. This may include other peptide companies using similar approaches or other types of therapies, such as small molecule, antibody, and/or protein therapies.

In addition, many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials and approved products than we do today. 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 or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We also compete with these companies in recruiting, hiring, and retaining qualified scientific and management talent, establishing clinical trial sites and patient registration for clinical trials, obtaining manufacturing slots at contract manufacturing organizations. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, particularly if they represent cures, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be their potential efficacy, safety, convenience, and availability of reimbursement.

Our most direct competitors with respect to HP include:

- Ascendis Pharma has Yorvipath approved in the United States, EU, Australia, and Japan for the treatment of HP in adults.
- AstraZeneca is developing eneboparatide, an investigational once-daily injectable PTH1R agonist, for the treatment of HP in adults. Eneboparatide has successfully completed its Phase 3 clinical trial, but an NDA has yet to be filed with the FDA.
- Extend Biosciences announced results in May 2023 from a Phase 1 clinical trial investigating injectable EXT608, a long-acting PTH (1-34) using D-VITylation technology. Extend initiated a Phase 2 trial in May 2025, which is expected to complete in May 2027.
- Septerna, Inc. was previously investigating a daily oral PTH1R, agonist (SEP-786) in a Phase 1 clinical trial in healthy volunteers in Australia. In February 2025, Septerna announced the discontinuation of the Phase 1 clinical trial due to unanticipated severe (Grade 3) events of elevated unconjugated bilirubin levels. Septerna selected SEP-479 for development, also an oral PTH1R agonist, and expects to initiate a Phase 1 trial in Australia in the first half of 2026.
- BridgeBio/Calcilytix is developing CLTX-305, a small molecule targeting CaSR ("calcium sensing receptor") for the treatment of ADH1 (autosomal dominant hypocalcemia type 1). BridgeBio/Calcilytix announced positive topline results in October 2025 with a planned NDA submission (for ADH1) in the first half of 2026, and plans to initiate registrational studies for HP in 2026.

Our most direct competitors with respect to obesity include:

- Eli Lilly and Company has several obesity compounds approved and under development, including: tirzepatide—expanding indications and labeling of Zepbound (tirzepatide) via the potential addition of long-term usage data, as well as data showing long-term reductions in cardiovascular-related mortality. Orforglipron, an oral (non-peptide) GLP-1 receptor agonist currently in pre‑registration in the U.S. with expected FDA review in the second quarter of 2026. Retatrutide, a tri-agonist targeting GLP-1, GIP and glucagon currently in Phase 3 clinical development.
- Novo Nordisk has several obesity compounds approved and under development, including: semaglutide – expanding indications and labeling of Wegovy (semaglutide). Novo received FDA approval in December 2025 for an oral (pill) formulation of Wegovy 25mg for chronic weight management, with U.S. availability in January 2026. In March 2024, Novo received FDA approval for reducing the risk of heart attacks, strokes and cardiovascular-related death in patients with heart disease and who are overweight or obese. Amycretin, a fusion peptide, that acts on GLP-1 as well as amylin receptors expected to enter Phase 3 clinical trials in the first half of 2026 with both

injectable (weekly) and oral (daily) formulations being evaluated. CagriSema, a combination of semaglutide and cagrilinitide, a dual amylin and calcitonin receptor agonist, administered as a single, once-weekly injection has completed Phase 3 clinical development and has been submitted to the FDA. NN9541 a potential once-weekly oral GLP-1/GIP receptor co-agonist has completed Phase 1 clinical development and is currently in Phase 2 clinical development as an injectable. NNC0480-0389, a potential once-weekly injectable GIP receptor agonist to be co-administered with semaglutide is currently in Phase 2 clinical development. INV-202 (NN9441 - monlunabant) a potential once-daily, oral cannabinoid receptor-1 (CB1R) inverse agonist is currently in Phase 2 clinical development. INV 202 (NN9441) was acquired by Novo in late 2023 through their acquisition of Inversago Pharma.

- Amgen is developing MariTide/AMG-133 (maridebart cagraglutide), a fused/conjugated molecule combining a GLP-1 receptor agonist with a GIP receptor antagonist, as a potential once-monthly injectable. Phase 2 results were released in 2025 and Phase 3 MARITIME trials have been initiated and are currently enrolling.
- Roche is developing CT-868, CT-388, and CT-996 for obesity (with or without type 1 or type 2 diabetes). CT-388 is a potential weekly, injectable GLP-1/GIP receptor co-agonist. CT-388 phase 2 results were announced in January 2026, and Roche plans to start Phase 3 trials in early 2026. CT-868 is being targeted for obesity with type 1 diabetes and is a once-daily injectable. CT-996 is a potential once-daily oral for type 2 diabetes and obesity. Phase 1 results for CT-996 were announced in 2025 and is currently advancing to Phase 2.
- Viking Therapeutics is developing VK-2735, a potential once-weekly subcutaneous injectable GLP-1/GIP receptor co-agonist currently in Phase 2 clinical development. Viking is also developing an oral formulation of VK-2735, which completed Phase 2 clinical development in 2025. Viking announced it will advance VK2735 to Phase 3.
- Zealand Pharma is developing three obesity compounds. Petrelintide, a long-acting, once-weekly amylin analog currently in Phase 2b clinical development, is being jointly developed in collaboration with Roche. Topline data is expected in the first half of 2026. Petrelintide is being developed both as a standalone therapy and in combination with Roche's incretin candidate, CT-388. Dapiglutide, a long-acting GLP-1/GLP-2R receptor co-agonist is currently in Phase 2 clinical development. Survodutide, a long-acting once-weekly injectable GLP-1/glucagon receptor co-agonist is currently in Phase 3 clinical development with data expected in the first half of 2026. Survodutide was co-invented by Boehringer Ingelheim who is leading development of the candidate.

Our most direct competitors with respect to PBH include:

- In July 2024, Amylyx Pharmaceuticals Inc. ("Amylyx") announced its acquisition of avexitide (exendin 9-39) from Eiger BioPharmaceuticals, Inc. ("Eiger") as a once or twice daily subcutaneous injection of a selective GLP-1 antagonist, which has received Breakthrough Therapy and orphan drug designation from the FDA. Eiger previously completed Phase 2 clinical trials for avexitide in 2021. Amylyx is currently conducting a Phase 3 trial (LUCIDITY) in patients with PBH and expects top line results in the second half of 2026.
- Vogenx is developing mizagliflozin for treatment of PBH. Mizagliflozin is designed to inhibit sodium dependent glucose cotransporter. In June 2023, Vogenx announced results from a Phase 2 single ascending dose trial evaluating mizagliflozin in patients with PBH. In June 2024, Vogenx announced the successful completion of their second Phase 2 clinical trial. A Phase 3 program has not yet been announced/initiated.
- Recordati is developing Signifor (pasireotide injection) for the treatment of PBH. A Phase 2 trial (PASIPHY) is currently in progress and results are expected in the first half of 2026.

Intellectual property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to the development of our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. We also rely on trademarks, copyrights and trade secrets relating to our proprietary technology platform and on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary and intellectual property position. We additionally may rely on regulatory and other protections afforded through data exclusivity, market exclusivity and patent term extensions, where available.

Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and trade secrets related to our business, defend and enforce our intellectual property rights, particularly our patent rights, preserve the confidentiality of our trade secrets and operate without

infringing valid and enforceable intellectual property rights of others. A discussion of risks relating to intellectual property is provided under the section titled “Risk factors—Risks related to our intellectual property”

The patent positions for biotechnology and pharmaceutical companies like us are generally uncertain and can involve complex legal, scientific, and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Our patent portfolio includes issued patents and pending patent applications exclusively in-licensed from IURTC relating to our PEP™ technology and product candidates. We also have company-owned patent applications directed to our product candidates.

With respect to our PEP™ technology, as of February 2026, we exclusively in-license from IURTC two issued patents, in Japan and Mexico, with claims directed to composition of matter relating to peptide prodrugs with fatty acylation linked via a non-enzymatic self-cleaving dipeptide, each with an expected expiration date of 2029, not including any patent term adjustments or patent term extensions.

With respect to our canvuparatide product candidate, as of February 2026, we exclusively in-license from IURTC two pending U.S. non-provisional patent applications and 12 foreign patent applications pending in Australia, Brazil, Canada, China, Europe, Israel, Japan, South Korea, Mexico, New Zealand, Russia, and Singapore, with claims directed to composition of matter, pharmaceutical composition, and method of treatment relating to canvuparatide. Any patents that issue from these applications are expected to expire in 2041, not including any patent term adjustment or patent term extensions that may be available. We also own a pending international patent application and a pending U.S. provisional patent application with claims directed to dosage regimen relating to canvuparatide and analogs of canvuparatide, respectively. Patent applications claiming priority to these pending applications, if issued, are expected to expire no earlier than 2044, not including any patent term adjustment or patent term extensions that may be available.

With regard to our obesity portfolio including our MBX 4291 product candidate, as of February 2026, we exclusively in-license from IURTC three pending international patent applications, including one with claims directed to composition of matter, pharmaceutical composition, and method of treatment relating to MBX 4291. Patent applications relating to these international patent applications, if issued, are expected to expire in 2045, not including any patent term adjustment or patent term extensions that may be available. We also own a pending U.S. provisional patent application with claims directed to analogs of MBX 4291. Patent applications claiming priority to this provisional application, if issued, are expected to expire in 2047, not including any patent term adjustment or patent term extensions that may be available.

With regard to our imapextide product candidate, as of February 2026, we exclusively in-license from IURTC two pending U.S. non-provisional patent applications, and a total of 29 foreign patent applications pending in Australia, Brazil, Canada, China, Europe, Israel, Japan, South Korea, Mexico, New Zealand, Russia, Saudi Arabia, Taiwan, Hong Kong, and Singapore, with claims directed to composition of matter, pharmaceutical composition, and method of treatment relating to imapextide. Any patents that issue from these patent applications are expected to expire no earlier than 2042, not including any patent term adjustment or patent term extensions that may be available.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application.

In the United States, the term of a patent covering an FDA-approved drug may be eligible for a patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years beyond the expiration of the patent, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended, and only those claims covering an approved product, a method for using it or a method of manufacturing it may be extended. Moreover, a given patent may only be extended once. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. If our product candidates receive FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved product candidates. We also intend to seek patent term extensions in any jurisdictions where they are available, however, there is no guarantee that the applicable

authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

In addition to patent protection, we also rely on know-how and trade secret protection for our proprietary information to develop and maintain our proprietary position. However, trade secrets can be difficult to protect. Although we take steps to protect our proprietary information, including restricting access to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors and potential collaborators, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our know-how, trade secrets, and other proprietary information.

In addition, we plan to rely on regulatory protection based on orphan drug exclusivities, data exclusivities, and market exclusivities. See "—Government regulation" for additional information.

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, 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 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, including risk evaluation and mitigation strategies ("REMS") and 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 events ("AEs") 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.

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 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 are meant to be reviewed within 10 months from the date of filing, and applications for "priority review" products containing new molecular entities are meant to be reviewed within six months of filing. 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 a 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 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.

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.

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 specific 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. 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.

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 adverse events 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.

From time to time, legislation is drafted, introduced, passed in Congress and signed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidances, and policies are often revised or reinterpreted by the agency in ways that may significantly affect the manner in which pharmaceutical products are regulated and marketed.

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.

Rest of the world regulation

For other countries outside of the United States, such as those in Europe, Latin America or Asia, the requirements governing product development, the conduct of clinical trials, product marketing, product licensing, pricing and reimbursement can vary from country to country. Failure to comply with applicable foreign regulatory requirements may subject sponsors, manufacturers or marketers of pharmaceutical products to, among other things, fines, suspension or withdrawal of regulatory authorizations and approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Review and Approval of Medicinal Products in the European Union

The process governing approval of medicinal products in the European Union ("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 a submission to the relevant competent authorities of a marketing authorization application 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 authorization through the Clinical Trials Information System, coordinated by a reporting Member State, with assessment by the concerned EU Member States in which the clinical trial is to be conducted, and approval by the national competent authorities of those Member States. 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 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 and a harmonized procedure for the assessment of applications; and simplified reporting procedures for clinical trial sponsors.

Marketing Authorization

To obtain a marketing authorization for a product in the EU, an applicant must submit a marketing authorization application, 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 in 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 a marketing authorization application 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 a marketing authorization application 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 marketing authorization application.

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.

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.

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 marketing authorization application 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 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 a marketing authorization application 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 and (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 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 orphan product, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the authorized orphan product consents to a second medicinal product application; or (iii) the marketing authorization holder for the authorized orphan 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 medicinal product 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").

All of 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). In April 2024, the European Parliament adopted its position on the legislative proposals and, in June 2025, the Council of the European Union adopted its position. A common position on the text has been agreed upon on December 11, 2025, and in the context of the subsequent inter-institutional trilogue negotiations. The proposed revisions remain to be adopted, and are not expected to become applicable before 2028.

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 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 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 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, 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 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.

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.

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 European Union, 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 European Union 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 European Union. 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. For example, in 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. For example, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent point-of-sale discount off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell “branded prescription drugs” to specified federal government programs.

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. President Biden previously issued multiple executive orders that sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that included a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway.

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 Inflation Reduction Act of 2022 ("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 2031.
- The U.S. American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- The American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers were further reduced starting on January 1, 2025. These laws and regulations may result in additional reductions in Medicare and other healthcare funding available for healthcare providers and may 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.

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.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices, which has resulted in several U.S. Congressional inquiries and federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs, and review the relationship between pricing and manufacturer patient programs. The IRA, for example, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries to $2,000 starting in 2025, eliminating the prescription drug coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of an HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs were previously exempted from the Medicare drug price negotiation program; however, this exemption was restricted to drugs with only one orphan designation and for which the only approved indication is for that disease or condition. If a product received multiple orphan designations or had multiple approved indications, it would not qualify for the orphan drug exemption. Under the OBBBA, this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs,

regardless of the number of orphan designations or indications, are exempt from the Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

At a federal level, President Trump reversed some of President Biden's executive orders including rescinding Executive Order 14087 entitled "Lowering Prescription Drug Costs for Americans." President Trump may issue new executive orders designed to impact drug pricing. A number of these and other proposed measures may require authorization through additional legislation to become effective. Congress and the Trump administration have indicated that they will continue to seek new legislative measures to control drug costs.

On April 15, 2025, the Trump Administration published Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the federal government to take measures to reduce drug prices, including eliminating the so-called "pill penalty" under the IRA that creates a distinction between small molecule and large molecule products for purposes of determining when a drug may be eligible for drug price negotiation. On May 12, 2025, the Trump Administration published Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" which generally, among other things, directs the federal government to establish and communicate most-favored-nation ("MFN") price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the Administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the MFN lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . . including by suppressing the price of pharmaceutical products below fair market value in foreign countries." Notably, a similar "Most Favored Nation" pricing rule enacted under the first Trump Administration was subject to an injunction resulting from judicial challenges to the rule, which was formally rescinded by the former Biden Administration in August 2021.

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. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards ("PDABs") and similar entities. While many PDABs have been granted authority to promote drug price transparency and reporting, some states have granted PDABs more expansive authority, including to set Upper Payment Limits ("UPLs") on select, high price drugs. The adoption and implementation of UPLs may put downward pressure on drug prices and impact our company's future revenues. 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.

Human capital resources

As of December 31, 2025, we had 63 full-time employees, of which thirteen have M.D. or Ph.D. degrees. Within our workforce, 45 employees are engaged in research and development and 18 are engaged in general and administrative. We have

never had a work stoppage, and none of our employees is represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of equity-based compensation awards in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate information

We were founded as MBX Biosciences LLC, an Indiana limited liability company, in August 2018. We converted to a Delaware corporation in April 2019 and incorporated under the name MBX Biosciences, Inc. Our principal executive offices are located at 11711 N. Meridian Street, Suite 300, Carmel, Indiana 46032, and our telephone number is (317) 659-0200. Our website address is https://www.mbxbio.com. The information contained in or accessible from our website is not incorporated into this Annual Report on Form 10-K, and you should not consider it part of this Annual Report on Form 10-K. We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference.

Available information

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings at the SEC's website at www.sec.gov. We also maintain a website at https://www.mbxbio.com and 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 any amendments to those reports, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. Investors and others should note that we announce material information to our investors using our investor relations website (https://*investors.mbxbio.com*), SEC filings, press releases, public conference calls and webcasts. We use these channels as well as social media, including LinkedIn and our X (formerly Twitter) (@MBXBio), to communicate with the public about our company, our business, our product candidates and other matters. It is possible that the information we post on social media could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our company to review the information we post on the social media channels listed on our investor relations website. Information that is contained in and can be accessed through our website or our social media posts are not incorporated into, and does not form a part of, this Annual Report on Form 10-K.

Item 1A. Risk Factors.

Our business involves significant risks. Stockholders should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K (this "Annual Report") and in the other documents that we file with the SEC, including our audited financial statements and related notes appearing in this Annual Report, before deciding to invest in our common stock. If any of the events or developments described below were to occur, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Risks related to financial position and need for capital

We have incurred significant losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was $87.0 million and $61.9 million for the years ended December 31, 2025 and December 31, 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $224.5 million. We have financed our operations primarily through our issuance and sale of our common stock, including through the sale of common stock in our initial and secondary public offerings and sales of our common stock from time to time in "at-the-market" offerings, convertible preferred stock and convertible promissory notes. Substantially all of our losses have resulted from expenses incurred in connection with our research and development and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our ability to generate revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of our current product candidates and potential future product candidates. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially for the foreseeable future if and as we:

- advance our current research activities and further develop our platform;
- continue preclinical development and progress clinical trials for our product candidates and any future product candidates we may identify;
- seek regulatory approval for any product candidates for which we successfully complete clinical trials;
- establish our manufacturing capacity capabilities to supply our clinical trials in our pipeline and eventually for commercialization;
- commercialize our product candidates, if approved, which will require significant marketing, sales, and distribution infrastructure expenses;
- hire additional research and development, clinical, commercial, and general and administration personnel;
- develop, maintain, expand, protect, and enforce our intellectual property portfolio;
- acquire or in-license product candidates, intellectual property and technologies;
- confirm, maintain or obtain freedom to operate for any of our owned or licensed technologies and product candidates;
- establish and maintain collaborations; or
- add operational, financial and management information systems and personnel.

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 the sale of equity, debt financings, or other capital sources, which may include collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of our platform, product candidates or delay our pursuit of potential in-licenses or acquisitions.

We have not yet demonstrated an ability to successfully complete any pivotal clinical trials, advance any product candidate beyond Phase 2, obtain regulatory approvals, manufacture our product candidates at commercial scale, or arrange for

a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. To become and remain profitable, we must develop and, either directly or through collaborators, eventually commercialize a therapy or therapies with market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of product candidates, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling those therapies for which we may obtain regulatory approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability.

Because of the numerous risks and uncertainties associated with developing our technology, platform and our product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if at all. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have never generated revenue from product sales and may never become profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. We may not generate revenues from product sales for many years, if ever. Our ability to generate future revenues from product sales depends heavily on our or our collaborators' ability to successfully:

- complete research and development of our product candidates;
- identify new product candidates;
- seek and obtain regulatory approvals for any product candidates for which we successfully complete clinical trials;
- launch and commercialize any product candidates for which we may obtain regulatory approval by establishing a sales force, marketing and distribution infrastructure, or alternatively, collaborating with a commercialization partner;
- qualify for adequate coverage and reimbursement by government and third-party payors for any product candidates for which we may obtain regulatory approval;
- establish and maintain supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for any product candidates for which we obtain regulatory approval;
- develop, maintain and enhance a sustainable, scalable, reproducible and transferable manufacturing process for the product candidates we may develop;
- address competing technological and market developments;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- receive market acceptance by physicians, patients, healthcare payors, and others in the medical community;
- maintain, protect, enforce, defend and expand our portfolio of intellectual property and other proprietary rights, including patents, trade secrets and know-how;
- defend against third-party intellectual property claims of infringement, misappropriation or other violation; and
- attract, hire and retain qualified personnel.

Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration ("FDA") or other regulatory authorities to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Even if one or more of our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Additionally, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives. Even if we are able to generate revenues from the sale of any approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations.

We will need substantial additional funding. If we are unable to raise additional capital when needed on acceptable terms, or at all, we may be forced to delay, reduce, or terminate certain of our research and product development programs, future commercialization efforts or other operations.

Developing product candidates, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue, initiate and conduct clinical trials of, and seek regulatory approval for, our product candidates. In addition, if we obtain regulatory approval for our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution to the extent that such sales, marketing, manufacturing, and distribution are not the responsibility of a collaborator. Other unanticipated costs may also arise. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce, or eliminate our research and product development programs, future commercialization efforts or other operations.

As of December 31, 2025, our cash, cash equivalents and marketable securities were $373.7 million. We expect that our existing cash, cash equivalents, and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into 2029. However, our operating plan may change as a result of factors currently unknown to us, and we may need to seek funding sooner than planned. Our future capital requirements will depend on many factors, including:

- the timing and progress of research and development, preclinical and clinical development activities;
- the number, scope and duration of clinical trials required for regulatory approval of our product candidates;
- the costs, timing, and outcome of regulatory review of any of our product candidates;
- the costs and timing of manufacturing clinical and commercial supplies of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive regulatory approval;
- the costs of preparing, filing and prosecuting our patent applications, maintaining and enforcing our patents and other intellectual property rights and defending intellectual property-related claims;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements, and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the extent to which we acquire or in-license other product candidates and technologies;
- any product liability or other lawsuits related to our product candidates;
- our implementation of various computerized informational systems and efforts to enhance operational systems;
- expenses incurred to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payers;
- the extent to which we acquire or invest in businesses, products, and technologies;
- the effect of competing technological and market developments; and

- the impact of economic uncertainty, global health crises and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

Identifying potential product candidates and conducting preclinical testing 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 regulatory 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 at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or 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. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, and possibly other restrictions.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. We have no committed sources of additional capital and, if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our future product candidates or other research and development initiatives. Without sufficient funding, our license agreements and any future collaboration agreements may also be terminated if we are unable to meet the payment or other obligations under such agreements.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Additionally, if we raise funds through additional collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates, or we may have to grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock.

Our short operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are an early-stage company. We commenced our operations in August 2018. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, and research and development activities such as developing our platform and technology and identifying and beginning to advance preclinical and clinical testing of our product candidates. Three of our product candidates, canvuparatide, imapextide and MBX 4291 are in clinical development, and our other development programs remain in the research or lead optimization stage of development. We have not yet demonstrated an ability to complete any large-scale, pivotal clinical trials, advance any product candidate beyond Phase 2, obtain regulatory approvals, manufacture our product candidates at commercial scale, arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful commercialization.

Our limited operating history, particularly in light of the evolving field of peptide therapies, may make it difficult to evaluate our platform, technology and industry and predict our future performance. Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by very early stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

In addition, as a new business that is rapidly growing, we may encounter other unforeseen expenses, difficulties, complications, and delays in our product development. We will need to transition from a company with a focus on research and conducting clinical trials to a company capable of supporting commercial activities if any of our product candidates are approved. We may not be successful in such a transition.

Our future ability to utilize our net operating loss 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 net operating loss carryforwards of $128.3 million which are not subject to expiration and state net operating loss carryforwards of $219.7 million which begin to expire in various amounts in 2039, and $18.5 million of U.S. federal research

and development carryforwards which begin to expire in various amounts in 2039, and $2.7 million of research credit carryforwards for state income tax purposes which begin to expire in various amounts in 2029. To the extent that we continue to generate taxable losses, under current law, our unused U.S. federal net operating losses ("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 or groups of shareholders who own at least 5 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. To date, we have not completed an analysis under Section 382 or Section 383 of the Code. It is possible that our prior equity offerings and other changes in our stock ownership could have resulted in such ownership changes in the past. In addition, we may experience ownership changes in the future 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 owed. 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 and the U.S. Treasury Department. For example, the One Big Beautiful Bill Act (the "OBBBA") was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. Key corporate tax provisions include the restoration of 100% bonus depreciation, immediate expensing for domestic research and experimental expenditures under Section 174, changes to Section 163(j) interest limitations, updates to "GILTI" and "FDII" rules, amendments to energy credits, and expanded Section 162(m) aggregation requirements. We are still evaluating the impact of the OBBBA; however, given the scope of our operations, it is difficult to assess how any changes in tax laws arising from OBBBA would impact our income tax expense. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time and any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. 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 or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize any adverse effects of changes in tax laws or in the interpretation thereof. Future changes in tax law could have a material adverse effect on our business, cash flow, financial condition or results of operations.

The U.S. Congress, the Trump administration, or any new administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business

In 2017, the U.S. Congress and the Trump administration made substantial changes to U.S. policies, which included comprehensive corporate and individual tax reform. In addition, the Trump administration called for significant changes to U.S. trade, healthcare, immigration and government regulatory policy. With the transition to the Biden administration in early 2021, changes to U. S. policy occurred and since the start of the Trump Administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Risks related to our business and industry

Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.

We have three product candidates, canvuparatide (MBX 2109), imapextide (MBX 1416), and MBX 4291 in clinical development, and our other development programs remain in the research or lead optimization stage of development. To date, as an organization, we have not completed the development of any product candidates. Our future success and ability to generate revenue from our product candidates is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our product candidates. All of our product candidates will require substantial additional investment for clinical development, regulatory review and approval in one or more jurisdictions. If any of our product candidates encounters safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed.

We may not have the financial resources to continue development of our product candidates if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- our inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective;
- insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- product-related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results or drug-drug interactions, or by individuals using drugs or therapeutic biologics similar to our product candidates;
- delays in submitting an Investigational New Drug ("IND"), application or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- poor effectiveness of our product candidates during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- delays in enrolling or inability to enroll subjects in our clinical trials;
- high drop-out rates of subjects from our clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- higher than anticipated clinical trial or manufacturing costs;
- our inability to timely or adequately finalize the design or formulation of any product candidate or demonstrate that a formulation of any product candidate will be stable for commercially reasonable time periods;
- unfavorable FDA or comparable regulatory authority inspection and review of our clinical trial sites;
- failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all;
- failure to acquire patent rights over our product candidates;
- delays and changes in regulatory requirements, policies and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or
- varying interpretations of data by the FDA and comparable foreign regulatory authorities.

If we fail to discover, develop and commercialize other product candidates, or successfully build out our own internal discovery capacities, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

Although the development and commercialization of canvuparatide, imapextide and MBX 4291 and the other development candidates in our obesity portfolio are our initial focus, as part of our longer-term growth strategy, we plan to continue to develop additional assets in earlier stages of development and to build fully functional internal discovery capabilities to develop other product candidates. We intend to evaluate internal opportunities from our existing product candidates or other potential product candidates. We have historically relied on the discovery capabilities of our co-founder, Dr. Richard DiMarchi. Dr. DiMarchi is a current consultant to the Company, as well as the principal investigator under our research agreement with the Trustees of Indiana University, under which we retain intellectual property developed on our behalf by Dr. DiMarchi, but the consulting agreement and research agreement are both terminable by either party. We are continuing to expand our laboratory capabilities and expect to continue to enhance our internal discovery efforts. If we are unable to complete this internalization, we may not be able to add internally-developed product candidates to our pipeline and will have to rely on our existing product candidates, additional product candidates we may in-license, or additional candidates we may develop through third-party research partners.

We also may choose to in-license or acquire other product candidates to treat patients suffering from other disorders with significant unmet medical needs and limited treatment options. These in-licensed or internally developed potential product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical 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, we cannot be certain 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.

These research programs to discover and identify additional product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified, and all efforts are as of now completed externally as we continue our efforts to internalize certain of our discovery capabilities. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects, interactions with other drugs, or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be sufficiently differentiated or offer substantial improvement over the currently available treatment options or standard of care in a given therapeutic category;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

In the future, we may also seek to in-license or acquire product candidates or the underlying technology. The process of proposing, negotiating and implementing a license or acquisition is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;

- disruption of our business and diversion of management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty assimilating or integrating acquired or licensed technologies, products, employees or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- increased amortization expenses;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

If we are unsuccessful in identifying and developing additional product candidates, either through internal development or licensing or acquisition from third parties, our potential for growth and achieving our strategic objectives may be impaired and we may not be able to increase our revenues in future periods, which could harm our business, results of operations and prospects, and the value of our shares.

The successful development of pharmaceutical products is highly uncertain.

Successful development of pharmaceutical products is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- clinical trial results may show the product candidates to be less effective than expected (for example, a clinical trial could fail to meet its primary or key secondary endpoint(s)) or have an unacceptable safety or tolerability profile or may not show an appropriate dose to fit a target profile, or may not be consistent with our pharmacokinetic modeling;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals, which, among other things, may be caused by patients who fail the trial screening process, slow enrollment in clinical trials, patients dropping out of trials, patients lost to follow-up, length of time to achieve trial endpoints, additional time requirements for data analysis or New Drug Application ("NDA"), preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data (such as long-term toxicology studies) or unexpected safety or manufacturing issues;
- preclinical study results may show the product candidate to be less effective than desired or to have harmful side effects;
- post-marketing approval requirements; or
- the proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized.

The length of time necessary to complete clinical trials and submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product candidate to the next and from one country or jurisdiction to the next and may be difficult to predict.

Even if we are successful in obtaining marketing approval, 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 managed care organizations in the United States or country-specific governmental organizations in foreign countries, 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 were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced.

In addition, if any of our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue 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 adversely affect our business, financial condition and results of operations.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an IND, or not approving or delaying approval for any clinical trial grant or similar approval we need to initiate a clinical trial. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators, institutional review boards ("IRBs") or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- 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, including because of the small number of patients for certain of our rare disease indications, 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;
- 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;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes to incorporate adjustments in our planned analysis or in regulatory requirements or guidance, which may be required to resubmit to an IRB and regulatory authorities for re-examination;
- regulators or other reviewing bodies may find deficiencies with, fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies, 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; and
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Regulators or IRBs of the institutions in which clinical trials are being conducted may suspend, limit or terminate a clinical trial, or data monitoring committees may recommend that we suspend or terminate a clinical trial, 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 the FDA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Negative or inconclusive results

from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of our product candidates in such other indications. We do not know whether any clinical trials that we conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates for the indications that we are pursuing. If later-stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates will be adversely impacted.

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 product candidate development costs will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. We cannot be certain 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. For instance, we previously adjusted our protocol for our Phase 2 trial to take into account feedback from our CRO. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our 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 and results of operations. 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.

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 our product candidates.

Any product candidate we develop and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval.

We have no experience in submitting and supporting the applications necessary to gain marketing approvals and expect to rely on third-party 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 its 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, if approval is obtained at all, 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. The FDA and comparable authorities in other countries 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 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 that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.

Undesirable side effects caused by any of our product candidates 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 the FDA or comparable foreign regulatory authorities. Certain side effects have been observed in our product candidates to date. For example, injection site reactions were commonly observed in subjects dosed with imapextide in the single and multiple ascending dose cohorts of our Phase 1 trial of imapextide. Although imapextide was generally well-tolerated, these ISRs were mostly mild to moderate, and PBH is a severe orphan disease with no FDA approved treatment options, if we are unable to identify a dose of imapextide with a tolerable side-effect profile, the commercial success of imapextide, if approved, could be limited. In addition, in our Phase 1 clinical trial of canvuparatide, the most common treatment-related adverse events observed were injection site reactions, though these were infrequent, less than 5 cm in size, and similar to those seen in other PTH agents, and we observed events of hypercalcemia at the top doses in three subjects each in the single and multiple ascending dose cohort. In our Avail trial in patients with HP, because patients are randomized into three dose levels while study investigators are reducing active vitamin D and calcium supplements and identifying an appropriate dose level based on a titration algorithm, we also observed incidents of hypocalcemia in four patients and hypercalcemia in nine patients. If we are unable to identify a dose of canvuparatide, or any of our other potential candidates with a tolerable side-effect profile, or are limited in our ability for our product candidates to be used with certain other drugs, the commercial success of such product candidates, if approved, could be limited.

We may also observe additional safety or tolerability issues with our product candidates in ongoing or future clinical trials. Many compounds that initially showed promise in clinical or earlier-stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Results of future clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier-stage testing.

If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. 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 our product candidates could result in harm to patients that are administered our product candidates. Any of these occurrences may adversely affect our business, financial condition and prospects significantly.

Moreover, clinical trials of our product candidates 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.

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 our product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from such preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as other product candidates that we believe may have similar profiles. For example, our future preclinical or clinical trials for our existing and future product candidates may not continue to demonstrate the extended half lives and low peak-to-trough ratios that we have seen so far in our product candidates.

In addition, in our planned future clinical trials, we may utilize clinical trial designs or dosing regimens 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 any of our 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, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events.

Additionally, we may utilize an "open-label" clinical trial design. 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 FDA or comparable foreign regulatory authority approval.

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

From time to time, we may publish interim, topline or preliminary data from our 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 patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

We may find it difficult to enroll patients in our future clinical trials given the limited number of patients who have the diseases some of our product candidates are intended to target. Additionally, we also compete for trial participants with other clinical trials for product candidates or commercially available products that are in the same areas as our product candidates. If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical development activities and our receipt of necessary regulatory approvals could be delayed or prevented.

As we progress our programs, we may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other comparable regulatory authorities outside the United States, or as needed to provide appropriate statistical power for a given trial. Enrollment may be particularly challenging for some of the rare diseases we are targeting in our programs such as canvuparatide and imapextide. For instance, in our Phase 1 trial of canvuparatide, we added one new site to the trial following slow enrollment at the originally selected sites, in order to meet our enrollment requirements. Enrollment may also be challenging for product candidates targeting prevalent diseases, such as MBX 4291 or other product candidates in our obesity portfolio, due to the intense competition in the field. In addition, if patients are unwilling to participate in our trials because of negative publicity from adverse events, competitive clinical trials for similar patient populations, clinical trials in competing product candidates, commercially available competing products or for other reasons, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of our product candidates may be delayed. Moreover, some of our competitors may have commercially available products, such as Yorvipath, or ongoing clinical trials for product candidates, such as AstraZeneca's PTH analog, AZP-3601, that would treat the same indications as our product candidates, and patients who would otherwise be eligible for our future clinical trials may instead utilize competitors' approved products or enroll in clinical trials of our competitors' product candidates.

Patient enrollment is also affected by other factors, some of which may include:

- severity of the disease under investigation;

- size of the patient population and process for identifying patients, including proximity and availability of clinical trial sites for prospective patients with conditions that have small patient pools;
- effects of global health crises on enrollment and/or completion of a trial;
- design of the trial protocol, including efforts to facilitate timely enrollment in clinical trials;
- availability and efficacy of approved medications for the disease under investigation;
- ability to monitor patients adequately during and after treatment;
- ability to obtain and maintain patient informed consent;
- risk that enrolled patients will drop out before completion of the trial;
- eligibility and exclusion criteria for the trial in question;
- perceived risks and benefits of the product candidate; and
- patient referral practices of physicians.

In addition, we expect to enroll in sites outside of the United States. Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, some of which may include:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials;
- different standard-of-care for patients with a particular disease;
- difficulty in locating qualified local consultants, physicians and partners; and
- potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. If we or our collaborators have difficulty enrolling a sufficient number of patients to conduct our clinical trials, we may need to delay, limit or terminate ongoing or planned clinical trials or entire clinical programs, any of which would have an adverse effect on our business, financial condition, results of operations and prospects.

The number of patients with the diseases and disorders for which we are developing our product candidates has not been established with precision. If the actual number of patients with the diseases or disorders we elect to pursue with our product candidates is smaller than we anticipate, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. Even if such product candidates are successfully developed and approved, the markets for our products may be smaller than we expect and our revenue potential and ability to achieve profitability may be materially adversely affected.

Our pipeline includes product candidates for both endocrine and metabolic diseases, with our lead product candidates targeting HP, PBH, and obesity. There is no precise method of establishing the actual number of patients with any of these disorders in any geography over any time period. With respect to many of the indications in which we have developed, are developing, or plan to develop our product candidates, we have estimates of the prevalence of the disease or disorder. The process we have used in developing an estimated incidence and prevalence for the indications we are targeting has involved collating limited data from multiple sources. Our estimates as to prevalence may not be accurate, and the actual prevalence or addressable patient population for some or all of those indications, or any other indication that we elect to pursue, may be significantly smaller than our estimates. For example, the estimated patient population for HP, a rare endocrine disease, already tends to be small, and may be even smaller than our current estimates. Moreover, the patient population for PBH may decrease due to the development of novel treatments for obesity, reducing the potential need for bariatric surgery, and the patient population for obesity may decrease as novel treatments for obesity are introduced. In estimating the potential prevalence of indications we are pursuing, or may in the future pursue, including our estimates as to the prevalence of HP, PBH and obesity, we apply assumptions to available information that may not prove to be accurate. In each case, there is a range of estimates in the published literature and in marketing studies, which include estimates within the range that are lower than our estimates. The actual number of patients with these disease indications may, however, be significantly lower than we believe. Even if our

prevalence estimates are correct, our product candidates may be developed for only a subset of patients with the relevant disease or disorder or our products, if approved, may be indicated for or used by only a subset. In the event the number of patients with the diseases and disorders we are studying is significantly lower than we expect, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. If any of our product candidates are approved and our prevalence estimates with respect to any indication or our other market assumptions are not accurate, the markets for our product candidates for these indications may be smaller than we anticipate, which could limit our revenues and our ability to achieve profitability or to meet our expectations with respect to revenues or profits.

Even if any of our product candidates receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

We have never commercialized a product, and even if any of our product candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to achieve sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Many of the indications for our product candidates have well-established standards of care that physicians, patients and payors are familiar with. Even if our product candidates are successful in registrational clinical trials, they may not be successful in displacing these current standards of care if we are unable to demonstrate superior efficacy, safety, ease of administration and/or cost-effectiveness. For example, physicians may be reluctant to take their patients off their current medications and switch their treatment regimen to our product candidates. Further, patients often acclimate to the treatment regimen that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch due to lack of coverage and adequate reimbursement. Even if we are able to demonstrate our product candidates' safety and efficacy to the FDA and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. If any product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we 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 efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including interactions with other drugs or distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Any failure by one or more of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects.

We face significant competition in an environment of rapid change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, or that we are unable to compete with existing entities that have made substantial investment into novel treatments for disease, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.

The development and commercialization of new drug products is highly competitive. We will face competition with respect to our product candidates and any product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent or other intellectual property protection and establish collaborative arrangements for research, development, manufacturing and commercialization. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we have research programs. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, while others are based on entirely different approaches.

Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future that are approved to treat the same diseases for which we may obtain approval for any product candidates we may develop. This may include other types of therapies, such as small molecule, antibody and/or protein therapies.

Many of our current or potential competitors, either alone or with their collaboration partners, may have significantly greater financial resources and expertise in research and development, manufacturing, conducting preclinical studies and clinical trials, obtaining regulatory approvals and marketing approved products than we do. 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 or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any product candidates that we may develop or that would render any product candidates that we may develop obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, as a result of the expiration or successful challenge of our patent or other intellectual property rights, we could face risks relating to our ability to successfully prevent or delay launch of competitors' products. The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidates that we may develop and commercialize.

Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.

We currently have three product candidates as well as several other programs at various stages of discovery and development. We seek to advance discovery and development for product candidates with an initial focus on both endocrine and metabolic disorders with high unmet need.

Due to the significant resources required for the development of our product candidates, we must decide which product candidates and indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates, therapeutic areas or indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. For instance, we have elected to evaluate imapextide as a treatment for PBH, but there may be better indications for which to evaluate imapextide, and this decision may divert resources away from better opportunities for imapextide. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, in particular for the rare diseases we are pursuing, our business, financial

condition and results of operations 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 such 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.

We currently have no commercial marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we expect to establish a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may also choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. 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, 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 ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other regulatory authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used to manufacture our product candidates;
- the efforts of our collaborators with respect to the 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.

If we fail to achieve announced milestones in the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

Risks related to regulatory, legal, and clinical trials

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Jurisdictions outside of the United States, such as the European Union or Japan, may have different requirements for regulatory approval, which may require us to conduct additional clinical, nonclinical or chemistry, manufacturing and control studies. To date, we have not submitted an NDA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any product candidate. We must complete additional preclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

In addition, a product known as Yorvipath has received orphan medicine designation for hypoparathyroidism in the EU and was granted a marketing authorization in November 2023. In the EU, orphan medicines benefit from 10 years of market exclusivity once they receive a marketing authorization in the EU (which may be extended by two additional years when the results of specific studies are reflected in the summary of product characteristics ("SmPC") addressing the pediatric population and completed in accordance with a fully compliant pediatric investigation plan). This market exclusivity prevents the EMA and all EU Member States from accepting an application or granting a marketing authorization for a "similar medicinal product" for the same therapeutic indication as the authorized orphan medicine, subject to certain specific derogations. Regulation (EC) 847/2000 defines a "similar medicinal product" as one which contains a similar active substance or substances as contained in an authorized orphan medicinal product and which is intended for the same therapeutic indication. A "similar active substance" is defined in the same Regulation as an identical active substance, or an active substance with the same principal molecular structural features (but not necessarily all of the same molecular structural features) and which acts via the same mechanism. There are some limited derogations to the market exclusivity granted to orphan medicinal products in the EU. Specifically, a company may be able to market a similar medicinal product to an authorized orphan product if: (i) the marketing authorization holder for the authorized orphan product consents to the grant of a marketing authorization for the similar product; (ii) the marketing authorization holder for the authorized orphan product is unable to supply sufficient quantities of its product; or (iii) the later applicant can establish that its product, although similar to the authorized orphan product, is safer, more effective or otherwise clinically superior. Regulation (EC) 847/2000 provides details on what would constitute clinical superiority in this context, including that direct comparative clinical trials may be required to demonstrate greater efficacy or safety to the authorized orphan product. As a result, while we have secured orphan drug designation in Europe, this still needs to be converted to orphan drug status at the time of a marketing authorization application, and we may not be able to gain approval for canvuparatide in the EU until expiry of the market exclusivity period for Yorvipath (palopegteriparatide) (which could run until 2035 at the latest), unless we can demonstrate that canvuparatide is either not a similar medicinal product to Yorvipath (i.e. the active substance in canvuparatide, if not identical to Yorvipath, does not have the same principal molecular structural features and act via the same mechanism as Yorvipath) or, if it is, that canvuparatide is safer, more effective or otherwise clinically superior. Any comparative studies required to demonstrate clinical superiority could be costly and time-consuming, and there is no certainty that we would succeed in adequately demonstrating that our product is clinically superior to Yorvipath.

Yorvipath is also approved in the United States for the treatment of HP in adults. In Phase 3 trials, palopegteriparatide treatment rendered the majority of patients independent of active vitamin D and calcium supplements (which reduced pill burden), reduced urinary calcium excretion and, by patient-reported-outcome assessments, improved quality of life.

Our current and future product candidates could fail to receive, or be significantly delayed in receiving, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign 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 or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- another company may benefit from market exclusivity for their product which prevents us from obtaining marketing authorization for our product in the same indication during such exclusivity period (as described above).

This lengthy approval process as well as the unpredictability of clinical trial results and market exclusivity issues described above may result in our failing to obtain regulatory approval to market any product candidate we develop, which would substantially harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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.

Our product candidates are sensitive to temperature, storage and handling conditions. They must be stored at low temperatures in specialized freezers, refrigerators or specialized shipping containers until immediately prior to use. The handling and administration of the therapy product, if approved, may need to be performed according to specific instructions and in some steps within specific time periods. Failure to correctly handle our product could negatively impact the efficacy and or safety of our product, or cause a loss of product. In addition, if approved, certain of our products may need to be frozen or refrigerated using specialized equipment and maintained following specific procedures in order to be stored without damage in a cost-efficient manner and without degradation. 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 commercial supply. 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 are able to manufacture and distribute the product candidates, if our products require specific procedures to maintain and use them, we may be limited in commercial opportunity.

Any drug delivery device that we potentially use to deliver our product candidates may have its own regulatory, development, supply and other risks.

We expect to deliver our product candidates via a drug delivery device, such as an injector or other delivery system. There may be unforeseen technical complications related to the development activities required to bring such a product to market, including primary container compatibility and/or dose volume requirements. Our product candidates may not be approved or may be substantially delayed in receiving approval if the devices that we choose to utilize or develop do not gain and/or maintain their own regulatory approvals or clearances, if required. Where approval of the drug product and device is

sought under a single application, the increased complexity of the review process may delay approval. In addition, some drug delivery devices are provided by single-source unaffiliated third-party companies. We may be dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. Even if approval is obtained, we may also be dependent on those third-party companies continuing to maintain such approvals or clearances once they have been received. Failure of third-party companies to supply the devices, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications.

The FDA or comparable foreign regulatory authorities may disagree with our regulatory plan for our product candidates.

The general approach for FDA approval of a new drug, at least until recently, has been dispositive data from two or more adequate and well-controlled clinical trials of the product candidate in the relevant patient population. While the FDA has recently announced one adequate and controlled trial may be acceptable to support an NDA, these trials typically involve a large number of patients, have significant costs and take years to complete and will still need to be supported by other appropriate data as part of any future NDA. The FDA or other 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. 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 agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals.

Our clinical trial results may not support approval of our product candidates. In addition, our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may not file or accept our NDA or marketing application for substantive review;
- the FDA or comparable foreign regulatory authorities may disagree with the dosing regimen, design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of our clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from our preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We may in the future conduct clinical trials for drug candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more additional clinical trials outside the United States, including, among other places, in the EU, South America, Australia and/or Asia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority 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 regulatory approval in the United States, the FDA will generally not approve the application based on foreign data alone unless: (i) the data is applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by

clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does 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 drug candidates that we may develop not receiving approval for commercialization in such jurisdiction. Additionally, recent policy proposals in the U.S., if enacted in the future, may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates 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, comparable foreign regulatory authorities must also approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements 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.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries.

While we may in the future seek designations for our product candidates with the FDA and comparable foreign regulatory authorities that are intended to confer benefits such as a faster development process, an accelerated regulatory pathway or regulatory exclusivity, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The FDA and comparable foreign 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 conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review. However, there can be no assurance that we will successfully obtain such designations for our product candidates. 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, we may seek a Fast Track Designation for future product candidates we develop. 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. 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, we cannot be certain that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development activities.

We may seek Breakthrough Therapy Designation for any product candidate that we develop. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval and priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate we develop meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if any product candidate we develop qualifies as a breakthrough therapy, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Even in the absence of obtaining Fast Track and/or Breakthrough Therapy Designations, a sponsor can seek priority review at the time of submitting a marketing application. The FDA may designate a product for priority review if it is a product that treats 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 taking action 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.

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.

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 generally defined as a patient population of fewer than 200,000 individuals annually in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the U.S., 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 July 2022, the FDA granted canvuparatide Orphan Drug Designation for the treatment of hypoparathyroidism.

Similarly, in the EU, the European Commission ("EC") grants orphan medicinal product designation after receiving the opinion of the EMA's Committee for Orphan Medicinal Products on an orphan medicinal product designation application. Orphan medicinal product designation may be granted in respect of medicinal products that are intended for the diagnosis, prevention or treatment of life threatening or chronically debilitating conditions affecting not more than five (5) in ten thousand (10,000) persons in the EU or for products intended for the diagnosis, prevention, or treatment of a life threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the product in the EU would generate sufficient return to justify the necessary investment in developing the product. In each case, there must be no satisfactory method of diagnosis, prevention, or treatment authorized for marketing in the EU (or, if such a method exists, the product would be of significant benefit to those affected by the condition). In the EU, orphan medicinal product designation entitles a party to financial incentives such as reduction of fees or fee waivers.

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 EC or the competent authorities of the EU member states, or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the U.S. and ten years in the EU. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan medicinal product designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the designated drug from competition because different drugs can be approved for the same condition. 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.

Where appropriate, we plan to pursue approval from the FDA or comparable foreign regulatory authorities through the use of expedited approval pathways, such as accelerated approval. If we are unable to obtain such approvals, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA or comparable regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or such other 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 therapeutic candidates from the FDA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a therapeutic candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the therapeutic 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 ("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 or biologic 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 take action, 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, we would seek feedback from the FDA or comparable foreign regulatory authorities and would otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA or BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, or comparable foreign 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 submit an application for accelerated approval, 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. The FDA or other comparable foreign 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 and subsequently converted by FDA to full approval. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our therapeutic candidate would result in a longer time period to commercialization of such therapeutic candidate, could increase the cost of development of such therapeutic candidate and could harm our competitive position in the marketplace.

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and would sell, market and distribute our products. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations that

may affect our ability to operate may apply. See the section titled, “Business–Government regulation–Other healthcare laws” included in this annual report on Form 10-K.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare and privacy laws, as well as responding to possible investigations by government authorities, can be time and resource-consuming and can divert a company’s attention from the business.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop. See the section titled, “Business–Government regulation–Coverage and reimbursement” included in this annual report on Form 10-K.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

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. In addition, many pharmaceutical 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.

Moreover, increasing efforts by governmental and other third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted 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.

At the state level, legislatures have increasingly passed legislation and implemented 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.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. 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. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals or clearances of our product candidates, if any, may be.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union 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 any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, (1) changes to our manufacturing arrangements, (2) additions or modifications to product labeling, (3) the recall or discontinuation of our products or (4) 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–Current and future U.S. healthcare reform” included in this annual report on Form 10-K.

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. 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. Even if we do receive a favorable coverage determination for our 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, 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. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our approved products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

These laws, and future 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 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.

In addition, the U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. 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, our business could be materially harmed.

Off-label use or misuse of our product candidates may harm our reputation in the marketplace or result in injuries that lead to costly product liability suits.

If our product candidates are approved by the FDA, we may only promote or market our product candidates in a manner consistent with their FDA-approved labeling. We will train our marketing and sales force against promoting our product candidates for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our product candidates off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. Furthermore, the use of our product candidates for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our product candidates for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation.

Changes in the FDA, other government agencies or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA or comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies or comparable foreign regulatory authorities on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, other government agencies or comparable foreign regulatory authorities may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, including as a result of reaching the debt ceiling, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, government shutdowns could impact our ability to access the public markets and obtain additional capital in the future.

In addition, with the change in the U.S. presidential administration in 2025, there is substantial uncertainty as to the extent and manner in which the U.S. government will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our product candidates. Additionally, the current administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates. Also, state governments may seek to address or react to changes at the federal level with changes to their regulatory frameworks in a manner that could impact our operations.

Inadequate funding for the FDA or other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA or other government agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business.

Without appropriation of necessary funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, adequate staffing, furloughs, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, leadership and policy changes. Average review times at the agency have fluctuated in recent years as a result. For example, in 2025, changes and cuts in FDA staffing have been reported as resulting in delays in the FDA's responsiveness or in its ability to review IND submissions or marketing applications.

Failure to access or a significant delay in accessing animal research models may materially adversely affect our ability to advance our preclinical programs and successfully develop any product candidates, which could result in significant harm to our business.

Consistent with various rules, regulations and cGMP, our ability to advance our preclinical and clinical programs for our product candidates requires access to animal research models sufficient to assess safety and in some cases to establish the rationale for therapeutic use. Failure to access or a significant delay in accessing animal research models that meet our needs or that fulfill regulatory requirements may materially adversely affect our ability to advance our preclinical programs and successfully develop any product candidates and this could result in significant harm to our business. During the COVID-19

pandemic, researchers and CROs (including those engaged by us) experienced significant limitations in their access to animal research models, specifically including a sharp reduction in the availability of non-human primates ("NHPs") originating from breeding farms in Southeast Asia and limited access to the generation of genetically-modified rodent models used in efficacy evaluations. Prior to the pandemic, China was the leading exporter of NHPs employed in basic and applied research; however, early in 2020, China ceased exportation of cynomolgus monkeys, the species most commonly involved in pharmaceutical product development. This change in the world supply of a critical research model has resulted in increased demand from breeding farms principally located in Cambodia, Vietnam, and Mauritius Island, with a resultant marked increase in unit pricing. Consequently, this has further exacerbated an already constrained NHP supply for research purposes. If we are unable to obtain NHPs in sufficient quantities and in a timely manner to meet the needs of our preclinical research programs, if the price of NHPs that are available increases significantly, or if our suppliers are unable to ship the NHPs in their possession that are reserved for us, our ability to advance our preclinical programs and successfully develop any additional preclinical candidates we may identify may be materially adversely affected or significantly delayed.

Even if we receive regulatory approval of any product candidates, 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.

If any of 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.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

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 strategies ("REMS") program 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. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw 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 third-party manufacturers 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. 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 the FDA to approve pending applications or supplements to approved applications filed by us or suspension or withdrawal of approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

Additionally, under FDORA, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. The FDA strictly regulates 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 the FDA and comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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. In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. 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 are and will continue to be subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control, the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. We cannot eliminate the risk of contamination or injury from hazardous materials, including chemical and biological materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws, regulations, and permitting requirements. These current or future laws, regulations, and permitting requirements may impair our research, development, or production efforts. Failure to comply with these laws, regulations, and permitting requirements also may result in substantial fines, penalties, or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Any third-party contract manufacturers and suppliers we engage will also be subject to these and other environmental, health, and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our employees, principal investigators, consultants and commercial partners 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, consultants and commercial partners, and, if we commence clinical trials, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations and other jurisdictions, provide accurate information to the FDA and other 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. In particular, 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. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. We have adopted a code of conduct and an insider trading policy applicable to all of our employees, but 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.

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

We will face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell such product candidates. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any of our product candidates;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any of our product candidates.

We anticipate that we will need to increase our insurance coverage when we begin clinical trials and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our internal computer and information technology systems, or those of our third-party vendors, collaborators, contractors, consultants or other third parties, may fail, become unavailable, or suffer cybersecurity incidents, compromises, or data breaches, loss or leakage of data and other disruptions, which could result in a material disruption of our product development programs, compromise confidential, sensitive or personal information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

Our internal computer and information technology systems and those of our current and any future third-party vendors, collaborators, contractors, consultants or other third parties, are vulnerable to damage or interruption from, among other things, computer viruses, computer hackers, social engineering (including phishing attacks), attacks enhanced or facilitated by AI, ransomware, malware, social engineering, service interruptions, system malfunction, malicious code, employee theft, fraud, misconduct or misuse, wrongful conduct by insider employees or vendors, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, data breaches, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we seek to protect our information technology systems from system failure, accident and security breach, we have in the past and may in the future experience phishing and other security incidents which could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other

proprietary, personal or confidential information or other disruptions. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

While we have implemented cybersecurity measures designed to protect our information technology systems as well as the confidential and sensitive data in our possession, there can be no assurance that these measures will be adequate to detect, prevent, or adequately address any cybersecurity incident or data breach that we may face. Controls employed by our information technology department and other third parties could prove inadequate, and our ability to monitor such third parties' data security practices is limited. Due to applicable laws, rules, regulations and standards or contractual obligations, we may be held responsible for any information security failure or cybersecurity incident or compromise attributed to our third-party vendors as they relate to the information we share with them.

If we were to experience a cybersecurity incident, breach, compromise or other security event relating to our information systems or data, the costs, time and effort associated with the investigation, remediation and potential notification of the breach to counterparties, regulators and data subjects could be material. We may incur significant costs in an effort to detect and prevent security incidents or compromises, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security incident or compromise. In addition, techniques used to sabotage or to obtain unauthorized access to networks in which data is stored or through which data is transmitted change frequently, become more complex over time and generally are not recognized until launched against a target. The risk of a cybersecurity breach, incident, compromise or disruption, particularly through cyberattacks including supply chain attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Attempts to disrupt or gain unauthorized access to our and our third-party service providers' information systems from malicious third parties or insider threats may incorporate widely varying and frequently changing tactics, which may be enhanced or facilitated by AI. As a result, we and our third-party vendors may be unable to anticipate these techniques or implement adequate preventative measures quickly enough to prevent either an electronic intrusion into our systems or services or a compromise of critical information. We cannot guarantee that we will be able to detect or prevent any such incidents, and, our remediation efforts may not be successful or timely. Our efforts to improve our cybersecurity and protect data from compromise may also identify previously undiscovered instances of data breaches, compromises or other cybersecurity incidents. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary, personal or confidential information. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Although we currently maintain cybersecurity insurance, the insurance we maintain against the risk of this type of loss may not be sufficient to cover actual losses, or may not apply to the circumstances relating to any particular loss.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our or our third-party vendors', collaborators', contractors', employees', consultants' or other third parties' data, including personal data, or applications or inappropriate disclosure, loss, destruction or alteration of, or access to, confidential, personal or proprietary information, we could incur significant liability including litigation exposure, substantial penalties and fines, we could become the subject of regulatory action, inquiry or investigation, our competitive position could be harmed, we could incur significant reputational damage and the further development and commercialization of any product candidates we may develop could be delayed.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates we may identify outside of the United States and require us to develop and implement costly compliance programs.

We will be subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate in the future. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including

international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Similarly, the U.K. Bribery Act 2010 has extra-territorial effect for companies and individuals having a connection with the United Kingdom. The U.K. Bribery Act prohibits inducements both to public officials and private individuals and organizations. Compliance with the FCPA and the U.K. Bribery Act is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the United States has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain drugs and drug candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to stringent and often unsettled laws, rules, regulations, policies, standards and contractual obligations related to data privacy and security and changes in such laws, rules, regulations, policies, standards and contractual obligations could adversely affect our business.

We are subject to data privacy and protection laws, rules, regulations, policies, standards and contractual obligations that apply to the collection, transmission, storage, use, disclosure, transfer, maintenance and other processing of sensitive, personal and personally-identifying information, which, among other things, impose certain requirements relating to the privacy, security, transmission and other processing of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Additionally, we rely on certain third-party vendors to process certain confidential, sensitive or personal information on our behalf. Failure by us or our third-party vendors to comply with any of these laws, rules, regulations, contractual obligations or standards could result in notification obligations, enforcement actions, regulatory investigations or inquiries, significant fines, imprisonment of company officials and public censure, litigation and claims for damages by affected individuals, customers or business partners, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws, rules and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. The Genetic Information Nondiscrimination Act of 2008 ("GINA") clarified that genetic information is protected under HIPAA and restricts the use and disclosure of genetic information. 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. The FTC's current guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA security regulations, but this guidance may change in the future, resulting in increased complexity and the need to expend additional resources to ensure we are complying with the FTC Act.

Additionally, laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a cybersecurity incident or data breach. These laws are not consistent, and compliance in the event of a widespread cybersecurity incident or data breach is difficult and may be costly. Moreover, states

have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify patients or other counterparties of a cybersecurity incident, data breach or compromise. Although we may have contractual protections with our service providers, any actual or perceived data breach, cybersecurity incident, or other information system compromise could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived data breach, cybersecurity incident, or compromise. Any contractual protections we may have from our service providers may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory information technology system standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. Determining whether personal information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation.

If we are unable to properly protect the privacy and security of personal information, we could be alleged or actually found to have breached our contracts. Furthermore, if we fail to comply with applicable privacy laws, we could face significant administrative, civil and criminal penalties. We cannot be sure how these laws, rules and regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws, rules and regulations at the international, federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

We make public statements about our use, collection, disclosure and other processing of personal information through our privacy policies and information provided on our website. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices.

Data privacy remains an evolving landscape at both the domestic and international level, with new laws, rules and regulations coming into effect and continued legal challenges. At the state level, numerous states have enacted or are in the process of enacting or considering comprehensive data privacy and security laws, rules and regulations while other states have focused on more narrow aspects of privacy. For example, in California, the California Consumer Privacy Act, or CCPA, which came into effect on January 1, 2020, established a comprehensive privacy framework for covered businesses by creating an expanded definition of personal information, providing data privacy rights for consumers and imposing operational requirements for companies. The CCPA requires covered companies to provide certain disclosures to consumers about their data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. In particular, the CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and to receive detailed information about how their personal information is used. Laws similar to the CCPA have been passed or proposed in numerous other states, adding complexity, varying requirements, restrictions and potential legal risk, and requiring additional investment of resources in compliance programs. The introduction of these laws across the country may impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies.

Several states are also specifically regulating health information. For example, Washington state passed a health privacy law that will regulate the collection and sharing of consumer health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a number of states, including Illinois and Texas, have passed laws that regulate biometric data specifically. These various privacy and 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. State laws are changing rapidly and there have been discussions in the U.S. Congress of comprehensive federal data privacy laws to which we could become subject, if enacted. The existence of different privacy laws in various jurisdictions in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. Although many of the existing state privacy laws exempt clinical trial information and health information governed by HIPAA, future privacy and data protection laws may be broader in scope.

Regulators and legislators in the U.S. are also increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Department of Justice's January 8, 2025, rule on "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," prohibits data brokerage and data sharing transactions involving certain sensitive personal data categories, including health data, genetic data,

and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions, and may result in exclusion from participation in federal and state programs.

To the extent that these laws are or become applicable, all of these evolving compliance and operational requirements may impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Our efforts to comply with these evolving data protection laws, rules and regulations may be unsuccessful. It is possible that these laws, rules and regulations may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. The laws are not consistent, and compliance in the event of a widespread cybersecurity incident or data breach is costly and time-consuming. States are also frequently amending existing laws, requiring attention to frequently changing regulatory requirements. We must devote significant resources to understanding and complying with this changing landscape

Any failure or perceived failure by us or our third-party vendors to comply with laws, rules and regulations regarding data privacy and protection could result in damage to our reputation or expose us to risk of enforcement actions taken by data protection authorities and/or other third parties, including class action privacy litigation in certain jurisdictions, which carry the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws, rules and regulations in the United States regarding privacy and security of personal information could expose us to penalties under such laws, rules and regulations. Any such failure, or perceived failure, by us or our third-party vendors to comply with data protection and privacy laws, rules and regulations could result in significant government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, rules or regulations, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

The use of new and evolving technologies, such as artificial intelligence ("AI") in our operations may require us to expend material resources and may present risks and challenges that can impact our business including by posing security and other risks to our confidential information, proprietary information and personal information, any of which may result in reputational harm and liability, or otherwise adversely affect our business.

We may choose to integrate AI into our operations both in our own development and implementation of AI and through the adoption of commercially available tools, and this innovation presents risks and challenges that could affect its adoption, and therefore our business. There are significant risks involved in utilizing AI and no assurance can be provided that the usage of AI will enhance our business or assist our business in becoming more efficient or profitable. The use of certain AI technology can give rise to intellectual property risks, including by disclosing or otherwise compromising our confidential or proprietary intellectual property and intellectual property infringement and misappropriation, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of AI tools. Development, use, and deployment of these technologies could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational, and other risks and challenges that could affect our business. Specifically, risks related to bias, AI hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks such as model poisoning or data poisoning, surveillance, data leakage, loss of consensus reality, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies. In addition, AI may have errors or inadequacies that are not easily detectable. AI may also be subject to data herding and interconnectedness (i.e., multiple market participants utilizing the same data), which may adversely impact our business. 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, overbroad or biased, our business, financial condition, and results of operations may be adversely affected.

A growing number of legislators 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 artificial intelligence 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 began implementing the Artificial Intelligence Act (the "AI Act") on August 1, 2024, with a significant part of the law scheduled to come into effect in August 2026. As currently enacted, the AI Act, which may be amended as part of the EU's Digital Omnibus, imposes significant obligations on providers and deployers of high risk AI

systems, and encourages providers and deployers of AI systems to account for certain ethical principles in their design, development and use of these systems. 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.

In the U.S., the AI regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, 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. If we develop or use AI systems governed by these laws or regulations, we will 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.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our technology and products to help ensure that AI is implemented in accordance with applicable laws and regulations and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. The legal landscape and subsequent legal protection for the use of AI remains uncertain, and development of the law in this area could impact our ability to enforce our proprietary rights or protect against infringing uses. If we do not have sufficient rights to use the data on which AI relies or to the outputs produced by AI applications, we may incur liability through the violation of certain laws, third-party privacy or other rights or contracts to which we are a party. Our use of AI applications may also, in the future, result in cybersecurity incidents or data breaches that implicate the personal data of customers or patients. Any such cybersecurity incidents or data breach related to our use of AI applications could adversely affect our reputation and results of operations.

Our vendors may also incorporate AI tools into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to intellectual property, privacy and data security. 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. In addition, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Significant political, trade, regulatory developments, and other circumstances beyond our control, could have a material adverse effect on our financial condition or results of operations.

We may in the future operate beyond the United States and, if approved, we may sell our products in countries throughout the world. Significant political, trade, or regulatory developments in the jurisdictions in which we may sell our products, such as those stemming from the change in U.S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, in 2025, the United States imposed tariffs on imports on its trading partners, including Canada, Mexico, the EU and China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations.

Risks related to third-party relationships

We are reliant on a license agreement with Indiana University Research and Technology Corporation.

We are reliant on a License Agreement (the "IURTC License Agreement") with Indiana University Research and Technology Corporation ("IURTC") pursuant to which we have been granted an exclusive, royalty-bearing license to certain IURTC patent rights (the "Licensed Intellectual Property") developed by Dr. DiMarchi and other collaborators to further scientific research, for new product development, and for other applications in public interest. In particular, we have been granted an exclusive, royalty-bearing license to make, have made, use, have used, offer to sell, have offered for sale, sell, have sold, import and have imported products that are covered by the Licensed Intellectual Property. Termination of our IURTC License Agreement or reduction or elimination of our licensed rights may require us to negotiate new or reinstated licenses with less favorable terms or to cease all development and commercialization of our current product candidates. In addition, delay in appointing or finding a suitable replacement provider, if one exists, could make it difficult for us to operate our

business for that period. If any such events were to occur, they could have a material adverse effect on our business prospects, financial condition and results of operations. For more information, see "Business—License agreement".

We are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical studies and clinical trials that were previously conducted for our product candidates.

We have relied on third parties, including Indiana University, to conduct certain preclinical studies and clinical trials. Therefore, we are dependent on these third parties having conducted their research and development in accordance with the applicable protocols, legal and regulatory requirements, and scientific standards; having accurately reported the results of all preclinical studies and clinical trials conducted with respect to such product candidates and having correctly collected and interpreted the data from these studies and trials. These risks also apply to any additional product candidates that we may acquire or in-license in the future. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of our product candidates will be adversely affected.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our collaborators and corporate or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Some of our collaborators and strategic partners are conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the product candidates we may develop that are the subject of these collaborations with us. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for any product candidates we may develop.

Additionally, some of our collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, prevent us from obtaining timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the collaboration efforts, including development, delivery, manufacturing and commercialization of products. Any of these developments could harm our company and product development efforts.

We may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with other pharmaceutical and biotechnology companies with respect to development and potential commercialization. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies, and academic research centers. In addition, if we are able to obtain regulatory approval for product candidates from foreign regulatory authorities, we may enter into collaborations with international biotechnology or pharmaceutical companies for the commercialization of such product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may 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 product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of

potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

We rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

We have relied upon and plan to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. Our ability to complete clinical trials in a timely fashion depends on a number of key factors. These factors include protocol design, regulatory and IRB approval, patient enrollment rates and compliance with GCPs. We have opened clinical trial sites and may in the future enroll patients in a number of countries where our experience is limited. In most cases, we use the services of third parties, including CROs, to carry out our clinical trial-related activities and rely on such parties to accurately report their results. Our reliance on third parties for clinical development activities may impact or limit our control over the timing, conduct, expense and quality of our clinical trials. 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. The FDA enforces these GCPs through periodic inspections of clinical trial sponsors, principal investigators, clinical trial sites and IRBs. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States.

We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. Our failure or the failure of third parties to comply with the applicable protocol, legal and regulatory requirements and scientific standards can result in rejection of our clinical trial data or other sanctions. If we or our third-party clinical trial providers or third-party CROs do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or be unsuccessful. Additionally, if we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, or other applicable regulatory agencies, may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with GCPs. We are also required to register certain 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.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. Moreover, many CROs, including some of those that we have engaged to conduct our clinical trials, are experiencing enrollment challenges as a result of, among other things, high employee turnover driven by the post-COVID macroeconomic environment and the inexperience of new employees. Furthermore, at clinical trial sites, the availability of staff and trial participants has been limited due to a decrease in the number of clinical investigative sites across the globe. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or regulatory approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue.

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 and prospects.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As 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. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. Moreover, if the formulation of our product candidates requires the use of delivery methods such as cold-chain distribution provided by third parties, whereby the product must be maintained between specified temperatures, we will be subject to reliance on our distribution partners to maintain the temperature of the formulation or else risk it being adulterated and rendered unusable. Any of the above 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.

Our use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, raw materials, active pharmaceutical ingredients ("APIs"), or drug products when needed or at an acceptable cost.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. Our current strategy is to outsource all manufacturing of our product candidates to third parties.

We currently rely on and engage third-party manufacturers to provide all of the API and the final drug product formulation of all of our product candidates that are being used in our clinical trials and preclinical studies. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement. In addition, we typically order raw materials, API and drug product and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. We may not be able to timely secure needed supply arrangements on satisfactory 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. We may be unable to conclude agreements for commercial supply with third-party manufacturers or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of our product candidates, and the costs of manufacturing could be prohibitive.

If our manufacturers have difficulty or suffer delays in successfully manufacturing material that meets our specifications, it may limit supply of our product candidates and could delay our clinical trials. Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third-party manufacturer to comply with applicable regulatory requirements and reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform 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 third parties because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our product candidates. If we do find replacement manufacturers, 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 FDA and other foreign regulatory authorities.

Additionally, if any third-party manufacturer 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 manufacturer. 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 manufacturer 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 third-party manufacturers for any reason, we will be required to verify that the new manufacturer 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 candidate according to the specifications previously submitted to the FDA or another regulatory authority. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. Regional or single-source dependencies may in some cases accentuate these risks. For example, the pharmaceutical industry generally, and in some instances our Company or our collaborators or other third-parties on which we rely, depend on China-based suppliers or services providers for certain raw materials, products and services, or other activities. Our ability or the ability of our collaborators or such other third-parties to continue to engage these China-based suppliers or services providers for certain preclinical research programs and clinical development programs could be restricted due to geopolitical developments between the United States and China, including as a result of the escalation of tariffs or other trade restrictions or as a result of recently enacted legislation like the BIOSECURE Act (described below). On December 18, 2025, the National Defense Authorization Act for Fiscal Year 2026 ("NDAA") was enacted, which includes Section 851, commonly referred to as the "BIOSECURE ACT." The BIOSECURE Act restricts U.S. government agencies from procuring biotechnology equipment or services from, or entering into contracts contracting with, entities that use biotechnology equipment or services from, designated "biotechnology companies of concern" ("BCCs"), and from expending federal loans or grant funds for such equipment or services. The enacted version of the BIOSECURE Act does not identify any specific companies by name in the legislative text, but provides for automatic designation as a BCC if a company is included on the Department of Defense's Section 1260H list of "Chinese military companies." Companies can also be designated as a BCC through a criteria-based pathway administered through an interagency process led by the Office of Management and Budget ("OMB").

Although the BIOSECURE Act includes certain exceptions, waivers, and safe harbors, including a transition period for existing contracts following the issuance of implementing regulations, these provisions may be limited in scope, subject to agency interpretation, or unavailable particular circumstances. In addition, the BIOSECURE Act has not yet been fully implemented through final regulations, and the manner in which U.S. government agencies will interpret and enforce these restrictions remains uncertain.

If any of our current vendors or future vendors with which we work are designated as BCCs, or if our collaborators, customers, investors, or future commercial partners become subject to BIOSECURE-related restrictions as a result of their relationships with such vendors, we could be required to terminate or restructure existing arrangements, transition manufacturing or other services to alternative suppliers, or delay or suspend development activities. Any such transition could involve significant cost, operational complexity, regulatory risks, and delays, and alternative suppliers may not be available on acceptable terms or at all. In addition, BIOSECURE-related restrictions could adversely affect our ability to obtain U.S. government funding, enter into collaborations with parties that receive federal funds, attract investment, or ultimately commercialize any product candidates, which could materially harm our business, financial condition and prospects.

Any delays associated with the verification of a new third-party manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidate that such third party owns

independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such third-party manufacturer in order to have another third party manufacture our product candidates.

If any of our product candidates is approved by any regulatory agency, we intend to utilize arrangements with third-party contract manufacturers for the commercial production of those products. This process is difficult and time consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay our commercialization.

Some of our manufacturers may be located outside of the United States. 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. Increased tariffs (including tariffs that have been or may in the future be imposed by the United States or other countries) could potentially disrupt our existing supply chains and impose additional costs on our business. Additionally, it is possible further tariffs may be imposed that could affect imports of APIs 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, regulatory changes or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business and financial condition.

Our failure, or the failure of our third-party manufacturers, 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, seizures or voluntary recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be evaluated by the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we may not be able to secure and/or maintain regulatory approval for our product candidates manufactured at these facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA finds deficiencies or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with cGMPs.

Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval, if obtained.

If any third-party manufacturer of our product candidates is unable to increase the scale of its production of our product candidates or increase the product yield of its manufacturing, then our manufacturing costs may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of our product candidates. The transition to larger scale production could prove difficult. In addition, 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 decrease our ability to generate profits and have a material adverse impact on our business and results of operations.

We may need to maintain licenses for APIs from third parties to develop and commercialize some of our product candidates, which could increase our development costs and delay our ability to commercialize those product candidates.

Should we decide to use any APIs in any of our product candidates that are proprietary to one or more third parties, we would need to maintain licenses to those APIs from those third parties. If we are unable to gain or continue to access rights to these APIs prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate APIs, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to gain or maintain continued access rights to the desired APIs on commercially reasonable terms or develop suitable alternate APIs, we may not be able to commercialize product candidates from these programs.

Risks related to personnel, operations, and growth

We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, including our President and Chief Executive Officer, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to continue to significantly increase the size of our organization and we may have difficulties in managing our growth and expanding our operations successfully.

As of December 31, 2025, we had 63 full-time employees. As we advance our products and product candidates through the development and commercialization process, we will need to expand managerial, operational, financial, sales and marketing and other resources to manage our operations, preclinical and clinical trials, research and development activities, regulatory filings, manufacturing and supply activities, and any marketing and commercialization activities or contract with other organizations to provide these capabilities for us. As operations expand, we expect that we will need to manage additional relationships with various suppliers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our operational, financial and management controls, reporting systems and procedures across a global organization. Such growth could place a strain on our administrative and operational infrastructure.

Further, we may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among pharmaceutical, biotechnology and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years.

Additionally, we may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we either internally, together with collaboration partners or through third-party contractors, as applicable:

- expand our general and administrative functions;
- identify, recruit, screen, retain, incentivize and integrate additional employees;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties;
- establish and build a marketing and commercial organization; and

- continue to improve our operational, legal, financial, compliance and management controls, reporting systems and procedures.

If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Risks related to our intellectual property

Our commercial success depends on our ability to obtain, maintain, enforce, and otherwise protect our intellectual property and proprietary technology, and if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products and product candidates similar to ours and our ability to successfully develop and commercialize our product candidates may be adversely affected.

Our commercial success depends, in large part, on our ability to obtain and maintain intellectual property rights protection through patents, trademarks, and trade secrets in the United States and other countries with respect to our technology and product candidates. If we do not adequately protect our intellectual property rights, competitors or other third parties may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we have filed patent applications and may file other patent applications in the United States or abroad related to our product candidates that are important to our business; we also license and may purchase patents or patent applications filed by others. In particular, we are heavily reliant on patent rights we have exclusively in-licensed from IURTC pursuant to the IURTC License Agreement. The patent application process is expensive, time-consuming and complex. We may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Our owned and in-licensed patent portfolio is generally at a very early stage. In particular, we do not currently own or in-license any issued patents relating to any of our product candidates and we also do not own or in-license any issued U.S. patents relating to our PEP™ technology or otherwise. Further, the only pending patent applications we currently own are two U.S. provisional patent applications relating to one of our product candidates.

We may not be able to obtain patents on certain inventions if those inventions are publicly disclosed prior to our filing a patent application covering them. We enter into nondisclosure and confidentiality agreements with parties who have access to confidential information, including confidential information regarding inventions not yet disclosed in patent applications. We cannot guarantee that any of these parties will not breach these confidentiality agreements and publicly disclose any of our inventions before a patent application is filed covering such inventions. If such confidential information is publicly disclosed, we may not be able to successfully patent it and consequently, we may not be able to prevent third parties from using such inventions.

Composition of matter patents for pharmaceutical and biological product candidates can provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our or our licensors' pending patent applications directed to the composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office ("USPTO") or by patent offices in foreign countries, or that the claims in any of the issued patents we may own or license will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe such products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

If the scope of the patent protection we obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our in-licensed patents have, or that any of our owned or in-licensed pending patent applications that mature into issued patents will include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. Other parties have developed or may develop technologies that may be related or competitive with our approach, and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or conflict with our patent portfolio, either by claiming the same compounds, formulations or methods or by claiming subject matter that could dominate our patent position. In addition, the laws of foreign countries may not protect our rights to the same

extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to ours.

Even if they are unchallenged, our owned and in-licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patent portfolio by developing similar or alternative product candidates in a non-infringing manner. For example, a third party may develop a product candidate that provides benefits similar to one of our product candidates but falls outside the scope of our patent protection or license rights. If the patent protection provided by the patent and patent applications we hold or pursue with respect to such product candidate is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidate could be negatively affected, which would harm our business.

We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patent portfolio may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, or licensees whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patent portfolio, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and patent applications. We rely on our outside counsel or our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Non-compliant events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent position of biotechnology and pharmaceutical companies carries uncertainty. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are characterized by uncertainty.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patent portfolio, or that we were the first to file for patent protection of such inventions. If third parties have filed prior patent applications on inventions claimed in our patent portfolio that were filed on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by our patent portfolio. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, any patents we may own or license may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all the potentially relevant prior art relating to our patent portfolio has been found. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know

with certainty whether we were the first to make the inventions claimed in our patent portfolio, or that we were the first to file for patent protection of such inventions. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party submission of prior art to the USPTO, or to other patent offices around the world. Alternately or additionally, we may become involved in post-grant review procedures, oppositions, derivation proceedings, ex parte reexaminations, inter partes review, supplemental examinations, or interference proceedings or challenges before the USPTO or in district court in the United States, or similar proceedings in various foreign jurisdictions, including both national and regional, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of the patent or claims in the patent portfolio being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent portfolio, any of 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 products.

Our or our licensors' pending and future patent applications may not result in patents being issued that protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. For example, our or our licensors' provisional applications may never result in issued patents. A provisional patent application is not eligible to become an issued patent until, among other things, we or our licensors file a non-provisional patent application within 12 months of filing the related provisional patent application. If we or our licensors do not timely file non-provisional patent applications, we or our licensors may lose the priority dates with respect to such provisional patent applications and any patent protection on the inventions disclosed in such provisional patent applications. While we intend to timely file non-provisional patent applications relating to our current and future provisional patent applications, we cannot predict whether any of our or our licensors' patent applications for our technology and product candidates will result in the issuance of patents that effectively protect our technology and product candidates. Further, competitors may be able to design around our patents. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries also may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including jurisdiction covering significant commercial markets, such as the European Patent Office, China, and Japan, restrict the patentability of methods of treatment of the human body more than United States law does. If these developments were to occur, they could have a material adverse effect on our ability to generate revenue.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance, whether intentional or not, can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- company-owned or in-licensed patents that have been issued or may be issued in the future may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our product candidates, if approved;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products; and
- countries other than the U.S. may, under certain circumstances, force us to grant a license under our patents to a competitor, thus allowing the competitor to compete with us in that jurisdiction or forcing us to lower the price of our drug in that jurisdiction.

Issued patents that we may own or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors do not infringe our patents. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

We maintain certain information as company trade secrets. This information may relate to inventions that are not patentable or not optimally protected with patents. We use commercially acceptable practices to protect this information, including, for example, limiting access to the information and requiring passwords for our computers. Additionally, we execute confidentiality agreements with any third parties to whom we may provide access to the information and with our employees, consultants, scientific advisors, collaborators, vendors, contractors, and advisors. We cannot provide any assurances that all such agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. It is possible that technology relevant to our business will be independently developed by a person who is not a party to such a confidentiality or invention assignment agreement. If any of our trade secrets were to be independently developed by a competitor or other third party, we would have no right to prevent such competitor or third party, or those to whom they communicate such independently developed information, from using that information to compete with us. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by contract manufacturers, consultants, collaborators, vendors, advisors, former employees and current employees. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Furthermore, if the parties to our confidentiality agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a consequence of such breaches or violations. Our trade secrets could otherwise become known or be independently discovered by our competitors. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. If any of these events occurs or if we otherwise lose protection for our trade secrets, our business, financial condition, results of operation and prospects may be materially and adversely harmed.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our current and future licensors, we could lose license rights that are important to our business.

We are heavily reliant upon the IURTC License Agreement pursuant to which we have been granted an exclusive, royalty-bearing license to certain patent rights that are important or necessary to the development of our proprietary technology and product candidates. Termination of the IURTC License Agreement or reduction or elimination of our licensed rights could lead to the loss of our ability to develop and commercialize our proprietary technology and product candidates. Further development of our proprietary technology and product candidates may require us to enter into additional license or collaboration agreements. Our future licenses may not provide us with exclusive rights to use the licensed intellectual property and technology, or may not provide us with exclusive 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 and proprietary technology in the future. Additionally, the IURTC License Agreement imposes, and future agreements may impose, various development, diligence, commercialization and other obligations on us and require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses.

Disputes may arise between us and our current or future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;

- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license 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 intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Despite our best efforts, our current or future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products, if approved, and technology covered by these license agreements. As a result, we may be required to cease our development and commercialization of our product candidates and use of our proprietary technologies covered by the patent rights owned by the licensors. Furthermore, if the in-licensed patent rights fail to provide the intended exclusivity, competitors will have the freedom to seek regulatory approval of, and to market, products identical to ours. These events could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for our product candidates, as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved and have in recent years been the subject of much litigation. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Over the past decade, U.S. federal courts have increasingly invalidated pharmaceutical and biotechnology patents during litigation often based on changing interpretations of patent law. Further, the determination that a patent application or patent claim meets all the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third-party publications, patents and other information that may affect the patentability of claims in our patent portfolio, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our own patent portfolio.

Although we exclusively in-license pending patent applications relating to our canvuparatide, imapextide, and MBX 4291 product candidates and we own pending provisional patent applications relating to our various product candidates, we cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art publications or patent literature, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patent portfolio in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our product candidates and/or materially harm our business.

In addition to challenges during litigation, third parties can challenge the validity of our patents in the United States using post-grant review and inter partes review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent filed March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for inter partes review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of

invalidity, whereas inter partes review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or inter partes review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we will be successful in defending the patent, which may result in a loss of the challenged patent right to us.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent claims will not have sufficient scope to protect our technology, provide us with commercially viable patent protection or provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as invalid or unenforceable under United States or foreign laws;
- we may not successfully commercialize our product candidates, if approved, before our relevant patents expire;
- we may not be the first to file patent applications for the inventions covered by our patent portfolio; or
- we may not develop additional proprietary technologies that are separately patentable.

In addition, to the extent that we are unable to obtain and maintain patent protection for our product candidates, or in the event that such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of any of our product candidates for follow-on indications.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. The patent term of a U.S. patent may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over another patent having an earlier expiration date.

Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a Patent Term Extension ("PTE") of up to five years beyond the normal expiration of the patent to compensate patent owners for loss of enforceable patent term due to the lengthy regulatory approval process. A PTE grant cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product approval. Further, PTE may only be applied once per product, and only with respect to an approved indication—in other words, only one patent (for example, covering the product itself, an approved use of said product, or a method of manufacturing said product) can be extended by PTE. Moreover, the scope of protection during the period of the PTE does not extend to the full scope of the claim, but instead only to the scope of the product as approved. We anticipate applying for PTE in the United States. Similar extensions may be available in other countries where we are prosecuting patents and we likewise anticipate applying for such extensions.

The granting of such patent term extensions is not guaranteed and is subject to numerous requirements. We might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents, failure to exercise due diligence during the testing phase or regulatory review process or any other failure to satisfy any of the numerous applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of

competing products following our patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate revenue.

Changes in the interpretation of patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States Congress is responsible for passing laws establishing patentability standards. As with any laws, implementation is left to federal agencies and the federal courts based on their interpretations of the laws. Interpretation of patent standards can vary significantly within the USPTO, and across the various federal courts, including the U.S. Supreme Court. Recently, the Supreme Court has ruled on several patent cases, generally limiting the types of inventions that can be patented. Further, there are open questions regarding interpretation of patentability standards that the Supreme Court has yet to decisively address. Absent clear guidance from the Supreme Court, the USPTO has become increasingly conservative in its interpretation of patent laws and standards.

In addition to increasing uncertainty with regard to our ability to obtain patents in the future, the legal landscape in the U.S. has created uncertainty with respect to the value of patents. Depending on any actions by Congress, and future decisions by the lower federal courts and the U.S. Supreme Court, along with interpretations by the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the "Leahy-Smith Act") signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts 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 invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, 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 future issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

After March 16, 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether this inventor was the first to invent the claimed invention. As a result, a third party that files a patent application in the USPTO on or after March 16 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing until publication or issuance, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates and other proprietary technologies we may develop. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date. Accordingly, 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 future issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. The U.S. Supreme Court has ruled on several patent cases in recent years; these cases often narrow the scope of patent protection available to inventions in the biotechnology and pharmaceutical spaces. For example, in Amgen Inc. v. Sanofi ("Amgen"), the U.S. Supreme Court held that certain of Amgen’s patent claims defined a class of antibodies by their function of binding to a particular antigen. The

U.S. Supreme Court further wrote that because the patent claims defined the claimed class of antibodies only by their function of binding to a particular antigen, a skilled artisan would have to use significant trial and error to identify and make all of the molecules in that class. The U.S. Supreme Court ultimately held that Amgen failed to properly enable its patent claims. In the 2013 case Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. In 2023, the Federal Circuit issued a decision in In re Cellect, LLC involving the interaction of patent term adjustment ("PTA"), terminal disclaimers, and obviousness-type double patenting which may affect the patent term of any issued patents that rely on any PTA. In 2022, Congress passed the Inflation Reduction Act ("IRA"), which authorizes the Secretary of the Department of Health and Human Services ("HHS") to negotiate prices directly with participating manufacturers for selected medicines covered by Medicare even if these medicines are protected by an existing patent. For small molecule medicines, the process begins seven years after initial approval by the FDA. While we do not believe that the IRA or its effects will impact our ability to obtain patents in the near future, we cannot be certain that it will not affect our patent strategy in the long run.

Further, a new court system recently became operational in the European Union. The Unified Patent Court ("UPC") began accepting patent cases on June 1, 2023. The UPC is a common patent court with jurisdiction over patent infringement and revocation proceedings effective for multiple member states of the European Union. The broad geographic reach of the UPC could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the individual European Union member states in which the European patent is validated. Under the UPC, a successful revocation proceeding for a European Patent under the UPC would result in loss of patent protection in those European Union countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection in numerous European Union countries. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations. Moreover, the controlling laws and regulations of the UPC will develop over time and we cannot predict what the outcomes of cases tried before the UPC will be. The case law of the UPC may adversely affect our ability to enforce or defend the validity of our European patents. Patent owners have the option to opt-out their European Patents from the jurisdiction of the UPC, defaulting to pre-UPC enforcement mechanisms. We have decided to opt out certain European patents and patent applications from the UPC. However, if certain formalities and requirements are not met, our European patents could be subject to the jurisdiction of the UPC. We cannot be certain that our European patents will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

We may not be able to seek or obtain patent protection throughout the world or enforce such patent protection once obtained.

Filing, prosecuting, enforcing, and defending patents protecting our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe or from selling or importing products made from our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights, whether successful or not, could result in substantial costs and divert our efforts and resources from other aspects of our business. Further, such proceedings could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly; put our pending patent applications at risk of not issuing; and provoke third parties to assert claims 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.

Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products, if approved. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to the military conflict in Ukraine and Russia may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies, products and product candidates. While we will endeavor to try to protect our technologies, products and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and unpredictable.

In order to protect our competitive position around our product candidates, we may become involved in lawsuits to enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful and which may result in our patents being found invalid or unenforceable.

Competitors may seek to commercialize competitive products to our product candidates. In order to protect our competitive position, we may become involved in lawsuits asserting infringement of our patents, or misappropriation or other violations of other of our intellectual property rights. Litigation is expensive and time consuming and would likely divert the time and attention of our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

If we file a patent infringement lawsuit against a perceived infringer, such a lawsuit could provoke the defendant to counterclaim that we infringe their patents and/or that our patents are invalid and/or unenforceable. In patent litigation in the United States, it is commonplace for a defendant to counterclaim alleging invalidity and/or unenforceability. In any patent litigation there is a risk that a court will decide that the asserted patents are invalid or unenforceable, in whole or in part, and that we do not have the right to stop the defendant from using the invention at issue. With respect to a counterclaim of invalidity, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent 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. If any of our patents are found invalid or unenforceable, or construed narrowly, our ability to stop the other party from launching a competitive product would be materially impaired. Further, such adverse outcomes could limit our ability to assert those patents against future competitors. Loss of patent protection would have a material adverse impact on our business.

Even if we establish infringement of any of our patents by a competitive product, a court may decide not to grant an injunction against further infringing activity, thus allowing the competitive product to continue to be marketed by the competitor. It is difficult to obtain an injunction in U.S. litigation and a court could decide that the competitor should instead pay us a “reasonable royalty” as determined by the court, and/or other monetary damages. A reasonable royalty or other monetary damages may or may not be an adequate remedy. Loss of exclusivity and/or competition from a related product would have a material adverse impact on our business.

Litigation often involves significant amounts of public disclosures. Such disclosures could have a materially adverse impact on our competitive position or our stock prices. During U.S. litigation we would be required to produce voluminous records related to our patents and our research and development activities in a process called discovery. The discovery process may result in the disclosure of some of our confidential information. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of our common shares.

Litigation is inherently expensive, and the outcome is often uncertain. Any litigation likely would substantially increase our operating costs and reduce our resources available for development activities. Further, we may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. As a result, we may conclude that even if a competitor is infringing any of our patents, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

If in the future, we in-license any patent rights, we may not have the right to file a lawsuit for infringement and may have to rely on a licensor to enforce these rights for us. If we are not able to directly assert our licensed patent rights against infringers or if a licensor does not vigorously prosecute any infringement claims on our behalf, we may have difficulty competing in certain markets where such potential infringers conduct their business, and our commercialization efforts may suffer as a result.

Concurrently with an infringement litigation, third parties may also be able to challenge the validity of our patents before administrative bodies in the United States or abroad. Such mechanisms include re-examination, post grant review 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 products, potentially negatively impacting any concurrent litigation.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to compounds, methods of manufacturing compounds and/or methods of use for the treatment of the disease indications for which we are developing our product candidates. If any third-party patents or patent applications are found to cover our product candidates, or their methods of use or manufacture, we may not be free to manufacture or market such product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates, including patent infringement lawsuits in the U.S. or abroad. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the composition, use or manufacture of our product candidates. Third parties may assert infringement claims against us based on existing patents that they own or in-license or patents that may grant to them (or which they may in-license) in the future, regardless of the merit of such patents or infringement claims. If our defenses to such assertions of infringement were unsuccessful, we could be liable for a court-determined reasonable royalty on our existing sales and further damages to the patent owner (or licensee), such as lost profits. Such royalties and damages could be significant. If we are found to have willfully infringed the claims of a third party's patent, the third party could be awarded treble damages and attorney's fees. Further, unless we obtain a license to such patent, we may be precluded from commercializing the infringing product candidate. Any of the aforementioned could have a material adverse effect on our business, financial condition, results of operations and prospects.

While we perform periodic searches for relevant patents and patent applications with respect to our product candidates, including canvuparatide, imapextide, and MBX 4291, we cannot guarantee the completeness or thoroughness of any of our patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, nor can we be certain that we have identified each and every patent and pending application in

the United States and abroad that is relevant to or necessary for the commercialization of any of our product candidates in any jurisdiction. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. As a result, we may be unable to identify such patents or patent applications despite our best efforts. In addition, patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that any of our product candidates may be accused of infringing. Generative AI resources that are publicly available also present a risk that a company may inadvertently obtain, incorporate or use a third party's intellectual property. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that the relevant product or methods of using the product either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources, and we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe, misappropriate or otherwise violate a third party’s intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product. If we were required to obtain a license to continue to manufacture or market the affected product, we may be required to pay substantial royalties or grant cross-licenses to our patents. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. We cannot be certain that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights, Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Furthermore, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. 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 patent. A finding of infringement could prevent us from commercializing a product or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. There could also 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 adversely affect the price of our common shares. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Others may challenge inventorship or claim an ownership interest in our intellectual property which could expose it to litigation and have a significant adverse effect on its prospects.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors or the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent. Furthermore, ownership disputes may arise from alleged contributions of

third parties involved in developing our product candidates and may result in joint ownership of our inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Any disagreement over inventorship could result in our being forced to defend our determination of inventorship in a legal action which could result in substantial costs and be a distraction to our senior management and scientific personnel. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, 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 effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

While we typically require employees, consultants and contractors who may develop intellectual property on our behalf to execute agreements assigning such intellectual property to us, we may be unsuccessful in obtaining execution of assignment agreements with each party who in fact develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached. In either case, we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we are unsuccessful in obtaining assignment agreements from an employee, consultant or contractor who develops intellectual property on our behalf, the employee, consultant or contractor may later claim ownership of the invention. Any disagreement over ownership of intellectual property could result in our losing ownership, or exclusive ownership, of the contested intellectual property, paying monetary damages and/or being enjoined from clinical testing, manufacturing and marketing of the affected product candidate(s). Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

We may be subject to claims that we have wrongfully hired an employee from a competitor or by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our current and former employees and our licensors' current and former employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Although we take commercially reasonable steps to ensure that our employees do not use the proprietary information, know-how or trade secrets of others in their work for us, including incorporating such intellectual property into our product candidates, we may be subject to claims that we or these employees have misappropriated the intellectual property of a third party.

If we or any of our employees are accused of misappropriating the proprietary information, know-how or trade secrets of a third party, we may be forced to defend such claims in litigation. If we are found to have misappropriated the intellectual property rights of a third party, we may be forced to pay monetary damages, sustain reputational damage, lose key personnel, or lose valuable intellectual property rights. Further, it may become necessary for us to obtain a license from such third party to commercialize any of our product candidates. Such a license may not be available on commercially reasonable terms or at all. Any of the aforementioned could materially affect the commercialization of any of our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

We may rely on trade secrets and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

We consider proprietary trade secrets or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. We expect to rely on third parties for future manufacturing of our product candidates. We also expect to collaborate with third parties on the development of our product candidates and as a result must, at times, share trade secrets with our collaborators. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements.

Trade secrets or confidential know-how can be difficult to maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or

former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information, including with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets and know-how. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators and we would have no right to prevent them from using that technology or information to compete with us. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We may need to acquire or license additional intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of one or more third parties to commercialize our current and future product candidates.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue 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 due to their size, cash resources and greater clinical development. If we are unable to acquire such intellectual property outright, or obtain licenses to such intellectual property from such third parties when needed or on commercially reasonable terms, our ability to commercialize our product candidates, if approved, would likely be delayed or we may have to abandon development of that product candidate and our business and financial condition could suffer.

If we in-license other product candidates in the future, we might become dependent on proprietary rights from third parties with respect to those product candidates. Any termination of such licenses could result in the loss of significant rights and would cause material adverse harm to our ability to develop and commercialize any product candidates subject to such licenses. Even if we are able to in-license any such necessary intellectual property, it could be on nonexclusive terms, including with respect to the use, field or territory of the licensed intellectual property, thereby giving our competitors and other third parties access to the same intellectual property licensed to us. In-licensing IP rights could require us to make substantial licensing and royalty payments. Patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings. If any in-licensed patents are invalidated or held unenforceable, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products.

We may not have the right to control the prosecution, maintenance, enforcement or defense of patents and patent applications that we license from third parties. In such cases, we would be reliant on the licensor to take any necessary actions. We cannot be certain that such licensor would act with our best interests in mind, or in compliance with applicable laws and regulations, or that their actions would result in valid and enforceable patents. For example, it is possible that a licensor's actions in enforcing and/or defending a patent licensed by us may be less vigorous than had we conducted them ourselves. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our present or future licensors may have relied upon or may rely upon third-party consultants or collaborators or on funds from third parties such that our present or future licensors may not be the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our present or future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing 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 licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

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

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we may own or in-license now or in the future, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have an adverse effect on our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and potential future licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our trademarks of interest and our business may be adversely affected.

We do not currently own any registered trademarks and we have not filed any trademark applications to date. While we may have common law protection for certain of our trademarks and trade names, it may be harder for us to rely on any such common law protection to prevent third parties from copying or using our trademarks or trade names without our permission. Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. We may not be able to protect our rights to our trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. 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. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to 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. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, 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 trademarks may not survive such proceedings. Moreover, any name we propose to use for our products in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Intellectual property rights do not necessarily address all potential threats to our business.

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. The following examples are illustrative:

- others may be able to make products that are competitive to our product candidates or any of our future product candidates that are not covered by the claims of our patent rights;
- others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our patent portfolio;
- we or any of our collaborators might not have been the first to invent the inventions covered by our patent portfolio;
- we or any of our collaborators might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;
- it is possible that our owned and in-licensed pending patent applications or those that we or our collaborators may file in the future will not lead to issued patents;
- others may have access to the same intellectual property rights licensed to us on a non-exclusive basis in the future;
- issued patents that we may own or in-license may not provide us with any competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our owned or in-licensed patent applications, including whether the patent applications that we may own or in-license will result in issued patents with claims that are directed to our product candidates or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our owned or in-licensed patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our owned or in-licensed patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- ownership of our patent portfolio may be challenged by third parties;
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business;
- patent enforcement is expensive and time-consuming and difficult to predict; thus, we may not be able to enforce any of our patents against a competitor;
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications; and
- we may choose not to file a patent application for certain inventions, instead choosing to rely on trade secret protection, and a third party may subsequently file a patent application covering such intellectual property.

Should any of these or similar events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be volatile, which could result in substantial losses for our shareholders.

The trading price of our common stock may be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and many others, some of which may include:

- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical studies and clinical trials for our current or future product candidates;
- failure or discontinuation of any of our development and research programs;
- results of any preclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- the results of efforts and level of expenses related to any of our research programs, clinical development programs or current or future product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts, if any, that cover our stock;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreements;
- 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 pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions, including the ongoing geopolitical conflict in Ukraine and the Israel-Hamas war, tensions in U.S.-China relations, rising interest rates, inflation and potential tariffs; and
- the other factors described in this "Risk Factors" section.

In recent years, the stock market in general and the market for pharmaceutical and biotechnology companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. In particular, in relation to uncertainty around inflation and the U.S. Federal Reserve's measures to slow inflation, the stock market has been exceptionally volatile. Market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

We incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002 ("SOX"), the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance and other personnel in

connection with our becoming, and our efforts to comply with the requirements of being, a public company. Our management and other personnel need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, the rules and regulations applicable to us as a public company make it more difficult and more expensive for us to obtain director and officer liability insurance, which make it more difficult for us to attract and retain qualified members of our board of directors. We continue to evaluate these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to SOX Section 404, we are required to furnish a report by our management on our internal control over financial reporting beginning with this Annual Report on Form 10-K with the SEC. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404 within the prescribed period, we have engaged and will continue to engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by SOX Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

An active trading market for our common stock may not be sustained.

An active or liquid market in our common stock may not be sustained. The lack of an active market may impair the value of our stockholders' shares, and our stockholders' ability to sell their shares at the desired time and price. An inactive market may also impair our ability to raise capital by selling our common stock and our ability to enter into strategic collaborations or acquire other companies, products, or technologies by using our common stock as consideration.

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 Nasdaq listing. 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. A 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.

If securities analysts do not continue to 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 relies in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. Similarly, 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.

A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of December 31, 2025, we have 44,927,953 shares of common stock outstanding. Holders of up to an aggregate 20,336,599 shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves

or other stockholders. We have also registered all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and lock-up agreements. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

In addition, certain of our employees, executive officers, and directors may enter into Rule 10b5-1 trading plans providing for sales of shares of our common stock from time to time. Under a Rule 10b5-1 trading plan, a broker executes trades pursuant to parameters established by the employee, director, or officer when entering into the plan, without further direction from the employee, officer, or director. A Rule 10b5-1 trading plan may be amended or terminated in some circumstances. Our employees, executive officers, and directors also may buy or sell additional shares outside of a Rule 10b5-1 trading plan when they are not in possession of material, nonpublic information.

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, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). We could be an emerging growth company until as late as December 31, 2029, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, or if we have total annual gross revenue of $1.235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. For so long as we remain an emerging growth company, we are permitted and plan 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 SOX Section 404, not being required to comply with any requirement for 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 nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies.

In addition, 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 are not subject to the 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 may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue is less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 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.

We cannot predict whether investors will find our common stock less attractive if we rely on 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.

Insiders own a significant percentage of our common stock and have the ability to exert significant control over matters subject to stockholder approval.

Our directors and executive officers and their affiliates collectively own a significant percentage of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

We do not expect to pay any dividends for the foreseeable future. Investors may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

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. We have undertaken the process of documenting, reviewing and improving our internal controls and procedures for compliance with SOX Section 404, which requires annual management assessment of the effectiveness of our internal control over financial reporting starting with this filing of our 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.

We are 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 amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is 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 or based on a breach of a fiduciary duty owed by any director, officer or other employee of ours to us or our stockholders; (iii) any action asserting a claim pursuant to any provision

of the Delaware General Corporation Law ("DGCL"), our fourth amended and restated certificate of incorporation or our amended and restated bylaws 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 (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"). 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 of action arising under the Securities Act, the Exchange Act, the respective rules and regulations promulgated thereunder or 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 capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; 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.

We recognize that 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, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. While the Delaware Supreme Court and other state courts have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, 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.

Provisions in our fourth amended and restated certificate of incorporation and Delaware law have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our fourth amended and restated certificate of incorporation and restated bylaws and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Our fourth amended and restated certificate of incorporation and our amended and restated bylaws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorized our board of directors to make, alter, amend or repeal our amended and restated bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits a person who owns in excess of 15 percent of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 percent of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our fourth amended and restated certificate of incorporation, 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.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that us, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry.

General risks

We may become involved in securities class action litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in or be concurrent with investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

Unfavorable 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, geopolitical tensions and in the global financial markets. A severe or prolonged economic downturn or additional global financial and political crises could result in a variety of risks to our business, including weakened demand for any product candidates we develop or our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers or other third parties and create import and export issues, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We face risks related to health epidemics, pandemics and other widespread outbreaks of contagious diseases, which could significantly disrupt our operations, impact our financial results or otherwise adversely impact our business.

Significant outbreaks of contagious diseases and other adverse public health developments could have a material impact on our business operations and operating results. For example, the spread of COVID-19 affected segments of the global economy and our operations. As a result of similar public health crises that may arise, we may experience disruptions that

could adversely impact our operations, research and development, and as we continue developing, any preclinical studies, clinical trials and manufacturing activities we may conduct, some of which may include:

- delays or disruptions in research programs, preclinical studies, clinical trials or IND-enabling studies that we or our collaborators may conduct;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- interruption of, or delays in receiving and distributing, supplies of drug substance and drug product from our contract development manufacturing organizations ("CDMOs") to preclinical or clinical research sites or delays or disruptions in any preclinical studies or clinical trials performed by CROs;
- limitations imposed on our business operations by local, state or federal authorities to address a pandemic or similar public health crises; and
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations, and cybersecurity and data accessibility or security issues.

In addition, the trading prices for biopharmaceutical companies have been highly volatile and we may face similar volatility in our stock price. We cannot predict the scope and severity of any economic recovery of health epidemics, pandemics and other widespread outbreaks of contagious diseases, including following any additional “waves” or other intensifying of a pandemic. If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, financial condition, our results of operations and prospects. Furthermore, such pandemics could exacerbate the other risks described in this section.

We or the third parties upon whom we depend may be adversely affected by climate change, earthquakes, outbreak of disease, or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Climate change, earthquakes, outbreak of disease, or other natural disasters, including extreme weather events and changing weather patterns such as storms, flooding, droughts, fires and temperature changes, which have become more common, could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, extreme weather risk, power outage, cybersecurity attack or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CDMOs, 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. For example, we may experience delays in the supply of drug product for our clinical trials as a result of disruptions to the operations of the manufacturing facilities of some of our third-party CDMOs. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. In addition, cybersecurity liability insurance is difficult to obtain and may not cover any damages we would sustain based on any breach or compromise 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, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Our ability to effectively monitor and respond to the rapid and ongoing developments and expectations relating to environmental, social and governance matters, including related social expectations and concerns, may impose unexpected costs on us or result in reputational or other harm to us that could have a material adverse effect on our business, financial condition and results of operations.

There is an increasing focus and rapid and ongoing developments and changing expectations from certain investors, customers, consumers, employees and other stakeholders concerning environmental, social and corporate governance ("ESG matters"). Additionally, public interest and legislative pressure related to public companies’ ESG practices continue to grow, which may result in increased regulatory, social or other scrutiny on us.

A variety of organizations measure the performance of companies on ESG topics, and the results of these assessments are widely publicized. In addition, investment in funds that specialize in companies that perform well in such assessments are increasingly popular, and major institutional investors have publicly emphasized the importance of such ESG measures to their investment decisions. Topics taken into account in such assessments include, among others, the company’s efforts and impacts

on climate change and human rights, ethics and compliance with law, and the role of the company's board of directors in supervising various sustainability issues.

We may be required to make investments in matters related to ESG, which could be significant. Our failure or perceived failure to meet the standards set by various constituencies could damage our reputation and our relationships with investors, governments, customers, employees, third parties and the communities in which we operate and expose us to increased regulatory risk, put us at a commercial disadvantage relative to our peers and materially adversely affect our business, financial condition, results of operations, ability to participate in debt and equity markets and the value of our shares.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We manage cybersecurity threats as part of our oversight, evaluation, and mitigation of enterprise-level risks. We have implemented a cybersecurity risk management program, in accordance with our risk profile and business size, that is designed to detect, identify, assess, and respond to current and emerging cybersecurity threats. Our cybersecurity risk management program is supported by third-party information technologies and vendors, including a managed services provider that assists us with, cybersecurity system monitoring, detection and alerting tools, and response support services. We also leverage third-party information technology service providers to monitor and evaluate our cybersecurity posture through cybersecurity risk reviews and assessments. Our cybersecurity risk assessments are informed by industry standards and frameworks and incorporate elements of the same, including elements of the National Institute of Standards and Technology ("NIST") cybersecurity framework.

We have adopted an incident response plan designed to coordinate the steps to identify, contain, eradicate, and recover from cybersecurity incidents. In addition, we provide security awareness training for all newly-hired employees and conduct annual cybersecurity training for all employees. We also have a process to review certain third-party information technology service providers and vendors, including through contractual requirements, due diligence and proactive threat intelligence monitoring, as appropriate.

To date, we have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, however, like other companies in our industry, we and our third-party information technology service providers and vendors have from time to time experienced threats that could affect our information or systems. For more information, please refer to Item 1A, "Risk Factors," in this Annual Report.

Governance

Our Senior Director of Information Technology coordinates with our Chief Financial Officer ("CFO") and relevant third parties, such as consultants and external legal advisors, to assess and manage material risks from cybersecurity threats. Our Senior Director of Information Technology has over fifteen years of experience in information technology, including over five years in cybersecurity and information security. Our Senior Director of Information Technology is also supported by a cross-functional security incident response team, which is responsible for identifying, reporting, investigating, documenting, and mitigating cybersecurity incidents pursuant to our incident response plan and policy.

Our board of directors has overall oversight responsibility for our risk management, and delegates its oversight of risk assessment and management guidelines to the audit committee of the board of directors. Members of the audit committee receive periodic updates from our CFO, who is briefed by our Senior Director of Information Technology, regarding matters of cybersecurity. These discussions may include updates on management's efforts to address and mitigate cybersecurity risks, cybersecurity incidents (if any), and the status of key information security initiatives. Executive management will promptly update our board of directors regarding significant threats and incidents as they arise.

Item 2. Properties.

Our principal executive offices are located in Carmel, Indiana. We lease our office space, which consists of 8,260 square feet. Our lease expires on December 31, 2028, with the option to renew for an additional three-year period. We also lease 810 square feet of laboratory space in Indianapolis, Indiana, under a lease that expires on November 30, 2026, and we previously leased 1,580 square feet of laboratory space in Indianapolis, Indiana, under a lease that expired on December 31, 2025. In

February 2026, we entered into a lease for an additional 13,642 square feet laboratory and office space in Burlington, Massachusetts, which is expected to commence in May 2026. We believe our current facilities are sufficient to meet our needs until the expiration of our leases. To meet the future needs of our business, we may lease additional or alternate space. We believe that suitable additional or substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or 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.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock trades on the Nasdaq Global Select Market under the symbol "MBX". Trading of our common stock commenced on September 13, 2024 in connection with our initial public offering. Prior to that time, there was no established public trading market for our common stock.

Holders

As of March 6, 2026, we had approximately twenty-one holders of record of our common stock. This number does not include beneficial owners whose shares were held in street name.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our results of operations, financial condition, capital requirements and other factors deemed relevant by our board of directors.

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Initial Public Offering of Common Stock

On September 12, 2024, our Registration Statement on Form S-1 (No. 333-281764) for our initial public offering (the "IPO") was declared effective by the SEC. Refer to the disclosure in our Quarterly Report on Form 10-Q, filed on November 7, 2024, which disclosure remains unchanged as of the date of this Annual Report.

Issuer Purchases of Equity Securities

None.

Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Item 6. [Reserved]

Item 7. 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 audited financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K (this "Annual Report"). This discussion and other parts of this Annual Report contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this Annual Report. You should carefully read the "Risk Factors" section of this Annual Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see "Special Note Regarding Forward-Looking Statements". Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel precision peptide therapies for the treatment of endocrine and metabolic disorders. Our company was founded by global leaders with a transformative approach to peptide drug design and development. Leveraging this expertise, we designed our

proprietary Precision Endocrine Peptide™ (the "PEP™") platform to overcome the key limitations of unmodified and modified peptide therapies and to improve clinical outcomes and simplify disease management for patients. Our PEPs are selectively engineered to have optimized pharmaceutical properties, including extended time-action profiles and consistent drug concentrations with low peak-to-trough concentration ratios, consistent exposure to target tissues, and less frequent dosing. We are advancing a pipeline of novel candidates for endocrine and metabolic disorders with clinically validated targets, established endpoints for regulatory approval, significant unmet medical needs and large potential market opportunities.

Our lead product candidate, canvuparatide (MBX 2109), is a parathyroid hormone ("PTH") peptide prodrug that is designed as a potential long-acting hormone replacement therapy for the treatment of chronic hypoparathyroidism ("HP"). Leveraging our proprietary PEP™ platform, we designed canvuparatide to treat the underlying pathophysiology of HP by providing a continuous, infusion-like exposure to PTH, with convenient once-weekly administration. In a Phase 1 clinical trial, canvuparatide demonstrated a low ratio between the highest concentration of active drug observed after a dose and the concentration of active drug observed immediately prior to the next dose ("peak-to-trough ratio"). This result is consistent with a continuous, infusion-like profile, and an extended half-life, potentially enabling the first once-weekly PTH dosing regimen for patients with HP. Canvuparatide was generally well-tolerated with no drug-related severe or serious adverse effects. In a Phase 2 clinical trial of 64 patients with HP, canvuparatide achieved the primary endpoint with a statistically significant responder rate at Week 12 and further demonstrated positive six-month responder results from the open-label extension portion of the trial. All patients completed the 12-week trial, and canvuparatide was generally well-tolerated, with no treatment-related serious adverse events or discontinuations. We completed an End of Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") and expect to receive Scientific Advice with the European Medicines Agency in the first half of 2026. We also intend to present results from our Phase 2 clinical trial and report one-year follow-up data from our ongoing open-label extension study at a medical meeting in the second quarter of 2026; and initiate a Phase 3 clinical trial of canvuparatide in the third quarter of 2026.

Our lead obesity product candidate, MBX 4291, is designed to be a long-acting and highly potent "PEP™ glucagon-like peptide 1 ("GLP-1") / glucose-dependent insulinotropic polypeptide ("GIP") co-agonist prodrug with the goal of potential once-monthly dosing frequency and improved efficacy and tolerability relative to existing standards of care. In our preclinical studies, the active component of MBX 4291 demonstrated a similar activity profile and body weight loss in mice as tirzepatide, an approved weekly GLP-1/GIP co-agonist, and an extended duration of action of the active component of MBX 4291, supporting the potential for once-monthly administration. The results observed from our preclinical studies may not necessarily be predictive of the results of later-stage clinical trials that we may conduct. We are conducting a randomized, double-blind, placebo controlled Phase 1 clinical trial designed to evaluate safety, tolerability, pharmacokinetics, and pharmacodynamics of SAD and MAD doses in adults with obesity. Following the SAD and four-week MAD portions of the trial, we plan to evaluate multiple ascending doses of MBX 4291, or matching placebo, administered over 12 weeks in up to two cohorts consisting of 30 participants. Results from the planned 12-week MAD portion are expected in the fourth quarter of 2026. Beyond MBX 4291, we have a robust discovery pipeline including multiple programs in the lead optimization stage of development, and we expect to nominate two additional candidates in the second and third quarters of 2026.

Our program, imapextide (MBX 1416), is designed to be a long-acting GLP-1 receptor antagonist as a potential therapy for post-bariatric hypoglycemia ("PBH"), a chronic complication of bariatric surgery. Imapextide is designed as a convenient once-weekly therapy to reduce insulin secretion and increase blood glucose to reduce the frequency and severity of hypoglycemic events. In January 2025, we announced positive topline results from our Phase 1 SAD and MAD clinical trial of imapextide in healthy adult volunteers. Results from the Phase 1 clinical trial demonstrated dose-proportional increases in imapextide exposure, a median half-life of 90 hours, which is supportive of a once-weekly dosing regimen, and, at steady state, the median T_{max} was between 36 and 48 hours. Imapextide was generally well-tolerated with a favorable safety profile and no treatment-related serious adverse events. We are conducting the STEADI™ Phase 2a, an open-label clinical trial evaluating primary efficacy of subcutaneous imapextide in adult patients with PBH. Topline results are expected in the second quarter of 2026.

Since our inception, we have devoted substantially all of our resources to drug discovery and development of our product candidates, canvuparatide, imapextide and MBX 4291, and other preclinical programs, building our intellectual property portfolio, organizing and staffing our company, business planning, raising capital and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. In September 2024, we completed our initial public offering (the "IPO"), pursuant to which we issued and sold 11,730,000 shares of common stock (inclusive of 1,530,000 shares of commons stock sold pursuant to the underwriters' exercise of their option to purchase additional shares). The aggregate net proceeds received by us from the IPO were $170.5 million, after deducting underwriting discounts and commissions and other offering costs of $17.2 million. In September 2025, we completed an underwritten public offering (the "September 2025 Offering") of 11,108,055 shares of our common stock, which generated approximately $187.4 million in aggregate net proceeds, after deducting underwriting discounts and commissions and other offering costs of $12.5 million. In February 2026, we closed on the sale and issuance of an aggregate of

2,250,986 shares of our common stock, which generated gross proceeds of approximately $87.1 million. The Shares were sold pursuant to the Company's Open Market Sale Agreement℠ with Jefferies, LLC dated November 6, 2025 and a shelf registration statement on Form S-3 (File No. 333-291308) previously filed by us and declared effective by the SEC in December 2025. We have historically funded our operations primarily from the issuance and sale of our common stock, convertible preferred stock and convertible notes, which have generated approximately $688.8 million in cumulative, aggregate gross proceeds to date.

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 revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Our net losses were $87.0 million and $61.9 million for the years ended December 31, 2025 and 2024, respectively. We had an accumulated deficit of $224.5 million and $137.5 million as of December 31, 2025 and December 31, 2024, respectively.

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

- advance the development of our lead product candidates, canvuparatide, imapextide and MBX 4291, and future product candidates;
- advance our current research activities and further develop our platform;
- continue preclinical development and discover and develop future product candidates we may identify;
- seek regulatory approval for any product candidates for which we successfully complete clinical trials;
- establish either internally or through contract manufacturing organizations manufacturing capacity capabilities to supply our clinical trials in our pipeline and eventually for commercialization;
- transition from a company with a research focus to a company capable of supporting commercial activities, including establishing sales, marketing, and distribution infrastructure;
- attract, hire and retain additional research and development, clinical, commercial, general and administrative personnel;
- develop, maintain, expand, protect and enforce our intellectual property portfolio;
- defend against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- acquire or in-license product candidates, intellectual property and technologies;
- confirm, maintain or obtain freedom to operate for any of our owned or licensed technologies and product candidates;
- establish and maintain collaborations; or
- add operational, financial and management information systems and personnel.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more product candidates. If we obtain regulatory approval for any product candidate 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, and distribution. 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 financings, 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. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of our platform or delay our pursuit of potential in-licenses or acquisitions.

We had cash, cash equivalents and marketable securities of $373.7 million and $262.1 million as of December 31, 2025 and December 31, 2024, respectively. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into 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. See “Liquidity and capital resources” herein and “Risk Factors—Risks related to financial position and need for capital.”

License agreement

Below is a summary of the key terms for our license agreement.

Indiana University Research And Technology Corporation Exclusive License Agreement

In June 2020, we entered into an Exclusive License Agreement with Indiana University Research and Technology Corporation ("IURTC"), a non-profit corporation organized under the laws of the State of Indiana, represented by The Trustees of Indiana University ("IU"), pursuant to which we have been granted an exclusive, royalty-bearing license to certain IURTC patent rights ("the Licensed Intellectual Property") developed by Dr. DiMarchi and other collaborators to further scientific research, for new product development, and for other applications in public interest, such license, the IURTC License Agreement. In particular, we have been granted an exclusive, royalty-bearing license to make, have made, use, have used, offer to sell, have offered for sale, sell, have sold, import and have imported products that are covered by the Licensed Intellectual Property ("Licensed Products"), with the right to sublicense to third parties. IURTC and IU have retained the right to (i) practice and use the Licensed Intellectual Property for non-commercial educational, research, and patient care and treatment purposes, and (ii) permit other non-profit and academic entities to practice and use the Licensed Intellectual Property for the same non-commercial purposes. Under the IURTC License Agreement, we agreed to use commercially reasonable efforts to develop, promote and sell Licensed Products in accordance with the IURTC License Agreement and any applicable laws. The IURTC License Agreement leverages IURTC's expertise in peptide therapies as well as our scientific, clinical, and regulatory capabilities to accelerate the development of peptide treatments for people with endocrine and metabolic disorders. Canvuparatide, imapextide, and MBX 4291 are Licensed Products under the IURTC License Agreement. Any future product candidates developed pursuant to our sponsored research agreement with IU or otherwise covered by the Licensed Intellectual Property may be subject to the IURTC License Agreement.

As initial consideration for the license, we paid IURTC an immaterial issue fee. As additional consideration for the license, we are required to pay IURTC: (i) royalties with a rate based on net sales per calendar year; (ii) an annual maintenance fee of up to $0.1 million beginning in the first year in which the first commercial sale occurs; (iii) a mid-single digits percentage of any sublicensing revenue; and (iv) milestone payments in the event of successful achievement of specified development milestones up to an aggregate of $0.4 million. IURTC is also entitled to receive reimbursement for all patent prosecution and maintenance related expenses. Our tiered royalties are in the low single-digits on annual net sales of the Licensed Products. In the event that we are required to pay a non-affiliate third party consideration for intellectual property owned or controlled by such non-affiliate third party that we or a sublicensee licensed for the development of Licensed Products, we can deduct such amounts from the royalty payments up to a certain amount of the running royalties owed that year. The royalty term will terminate on a country-by-country basis as to each Licensed Product, until the expiration or termination of the last valid claim within the patent rights covering such Licensed Product in that country.

On January 5, 2024, we and IURTC entered into a fourth amendment to the IURTC License Agreement (the "Fourth Amendment"). The Fourth Amendment specifies IURTC is entitled to the receipt of additional clinical and regulatory milestones, as defined in the Fourth Amendment, up to an aggregate of $9.0 million. Following the execution of the Fourth Amendment, future remaining clinical and regulatory milestone payments in the IURTC License Agreement and all amendments totaled up to $9.3 million. In 2025, we paid a $1.0 million milestone payment to IURTC related to the initiation of the Phase 1 clinical trial of MBX 4291. At December 31, 2025, future remaining clinical and regulatory milestone payments in the IURTC License Agreement and all amendments totaled up to $8.3 million.

The IURTC License Agreement will expire at the expiration of the last of the patent rights covered in the IURTC License Agreement, unless terminated earlier by mutual agreement or by one of the parties. We may terminate the IURTC License Agreement with or without cause upon ninety (90) days prior written notice to IURTC. IURTC may terminate the IURTC License Agreement if we commit a material breach of the IURTC License Agreement and fail to cure the breach within the respective cure period after receipt of the notice of material breach or upon our failure to undertake certain activities in furtherance of commercial development goals. Upon termination of the IURTC License Agreement, all rights granted by IURTC will terminate and automatically revert to IURTC.

Components of results of operations

Operating expenses

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

Research and development

The largest component of our total operating expenses since our inception has been research and development activities. Research and development expenses are expensed as incurred and consist primarily of:

- external research and development expenses incurred under agreements with contract research organizations ("CROs"), consultants and other third parties to conduct our clinical trials;
- costs related to manufacturing our product candidates for preclinical studies and clinical trials, including agreements with contract development and manufacturing organizations ("CDMOs");
- license fees, including any milestone-based payments;
- compensation and benefits, including stock-based compensation expense, for research and development personnel;
- the costs of acquiring research and development supplies and services;
- manufacturing process development costs;
- costs associated with regulatory activities;
- costs incurred in development of intellectual property;
- other outside services and consulting costs; and
- an allocated portion of facilities and other infrastructure costs associated with our research and development activities.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities to advance our programs and conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, expenses may vary significantly based on factors such as:

- the timing and progress of research and development, preclinical and clinical development activities;
- the number, scope and duration of clinical trials required for regulatory approval of our existing or future product candidates;
- the costs, timing, and outcome of regulatory review of any of our existing or future product candidates by the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more preclinical studies or clinical trials than those that we currently expect or for such authorities to change their requirements on studies that had previously been agreed to;
- the costs of manufacturing clinical and commercial supplies of our existing or future product candidates;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements, and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- our implementation of various computerized informational systems and efforts to enhance operational systems;
- expenses incurred to attract, hire and retain skilled research and development personnel;
- per subject clinical trial costs;
- the number of sites included in our clinical trials;
- the countries in which our clinical trials are conducted;
- length of time required to enroll subjects and initiate our clinical trials;
- the number of subjects that participate in our clinical trials;
- the drop-out and discontinuation rate of subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in our clinical trials and follow-up, including the duration of open label extensions;

- the timing of license agreement milestone payments related to development, regulatory and commercial events;
- manufacturing success with patient materials;
- mitigation/responses to potential health authority questions and/or inspections;
- the degree to which we obtain, maintain, defend and enforce our intellectual property rights; and
- the extent to which we establish collaboration, licensing or similar arrangements and the performance of any related third parties.

A change in the outcome of any of these variables with respect to the development of any of our existing or future product candidates could significantly change the costs and timing associated with the development of that product candidate.

General and administrative

General and administrative expenses consist primarily of compensation and benefits, including stock-based compensation expense for general and administrative personnel; other expenses for outside professional services, including legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, consulting and tax services; insurance costs; administrative travel expenses; website development costs; marketing and public relations costs; and facilities, information technology and other allocated overhead costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support continued growth of our research and development activities. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company. We also expect our intellectual property expenses to increase as we expand our intellectual property portfolio.

Other income

Interest and other income, net

Total other income, net, is comprised of interest income earned on our cash and cash equivalents and marketable securities and amortization expense and accretion income on our marketable securities.

Results of operations

Comparison of the years ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024 (in thousands):

	Years ended December 31,		Change
	2025	2024	$
Operating expenses:			
Research and development	$ 79,159	$ 57,415	$ 21,744
General and administrative	18,896	10,779	8,117
Total operating expenses	98,055	68,194	29,861
Loss from operations	(98,055)	(68,194)	(29,861)
Other income			
Interest and other income, net	11,084	6,272	4,812
Total other income, net	11,084	6,272	4,812
Net loss	$ (86,971)	$ (61,922)	$ (25,049)

Research and development expenses

The following table summarizes our research and development expenses for the periods indicated (in thousands):

	Year ended December 31,		Change
	2025	2024	$
Direct research and development program expenses:			
Canvuparatide (MBX 2109)	$ 37,225	$ 21,582	$ 15,643
MBX 4291 (1)	12,653	10,771	1,882
Imapextide (MBX 1416)	4,118	11,561	(7,443)
Preclinical and other (1)	6,032	1,341	4,691
Indirect research and development costs:			
Personnel related costs (including stock-based compensation)	16,524	10,245	6,279
Facility-related and other	2,607	1,915	692
Total research and development expense	$ 79,159	$ 57,415	$ 21,744

(1) Prior period amounts for MBX 4291 have been reclassified to conform to current period presentation.

Research and development expenses were $79.2 million for the year ended December 31, 2025, as compared to $57.4 million for the year ended December 31, 2024. The increase of $21.7 million consisted of the following:

Direct research and development program expenses related to canvuparatide increased by $15.6 million primarily due to increased activities related to conduct of the Phase 2 clinical trial and increased manufacturing in preparation for the Phase 3 clinical trial. Direct program expenses related to MBX 4291 increased by $1.9 million primarily due to a $1.0 million IURTC milestone that was triggered in the year ended December 31, 2025 and the start of the phase 1 clinical trial, partially offset by a decrease in costs related to IND-enabling preclinical studies. Direct program expenses related to imapextide decreased by $7.4 million, primarily due to the completion of the Phase 1 clinical trial in the first quarter of 2025, partially offset by costs related to the start of the Phase 2a clinical trial. Direct program expenses for preclinical and other programs increased by $4.7 million primarily due to pipeline candidate development activities. Personnel-related costs (including stock-based compensation), increased by $6.3 million, primarily due to increased headcount and stock-based compensation expense. Facility-related and other, which include allocated overhead, including rent, repairs and maintenance costs, common facilities and information technology-related expenses allocated to research and development increased by $0.7 million.

General and administrative expenses

General and administrative expenses were $18.9 million for the year ended December 31, 2025, as compared to $10.8 million for the year ended December 31, 2024. The increase of $8.1 million was primarily due to higher professional fees related to legal, accounting and consulting services and higher personnel-related costs, including compensation, benefits and stock-based compensation, as we expanded our infrastructure to support growth in our operations.

Interest and other income, net

Interest and other income, net, which includes interest income and amortization of premiums and discounts on our investments in marketable securities, were $11.1 million for the year ended December 31, 2025, as compared to $6.3 million for the year ended December 31, 2024. The increase of $4.8 million was due to increased interest on our cash, cash equivalents and marketable securities, which increased primarily due to the September 2025 Offering.

Liquidity and capital resources

Sources of liquidity

Since our inception, we have incurred significant operating losses. We have historically funded our operations primarily through our IPO, the September 2025 Offering, sales pursuant to our Open Market Sale Agreement, and sales of our convertible preferred stock and convertible notes, which have generated approximately $688.8 million in cumulative, aggregate gross proceeds to date. As of December 31, 2025 and December 31, 2024, we had $373.7 million and $262.1 million in cash, cash equivalents and marketable securities, respectively. We have not yet generated any revenue from product sales and do not expect to in the foreseeable future as our product candidates are in various phases of clinical and preclinical development.

Future funding requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the development of our product candidates. In addition, 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 timing and progress of research and development, preclinical and clinical development activities;
- the number, scope and duration of clinical trials required for regulatory approval of our existing or future product candidates;
- the costs, timing, and outcome of regulatory review of any of our existing or future product candidates by the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more preclinical studies or clinical trials than those that we currently expect or for such authorities to change their requirements on studies that had previously been agreed to;
- the costs of manufacturing clinical and commercial supplies of our existing or future product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our existing or future product candidates for which we receive regulatory approval;
- the cost of filing and prosecuting our patent applications, and maintaining and enforcing our patents and other intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements, and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our existing or future product candidates;
- our implementation of various computerized informational systems and efforts to enhance operational systems;
- expenses incurred to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payers;
- the extent to which we acquire or invest in businesses, products, and technologies;
- the effect of competing technological and market developments; and
- the impact of other factors, including inflation, economic uncertainty and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

We had $373.7 million and $262.1 million in cash, cash equivalents and marketable securities as of December 31, 2025 and December 31, 2024, respectively. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our current operating plan for at least the next 12 months from the date of issuance of the accompanying audited financial statements. Based on our current operating plan, we estimate that our existing cash, cash equivalents and marketable securities will be sufficient to fund our projected operating expenses and capital expenditure requirements into 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.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest for existing investors may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect existing investors' rights as a stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or 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 or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future

commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash flows

The following table summarizes our sources and uses of cash for the periods presented (in thousands):

	Years ended December 31,	
	2025	2024
Net cash used in operating activities	$ (79,949)	$ (54,681)
Net cash used in investing activities	(83,705)	(160,595)
Net cash provided by financing activities	189,592	234,104
Net increase in cash and cash equivalents	$ 25,938	$ 18,828

Cash flows from operating activities

Net cash used in operating activities for the year ended December 31, 2025 was $80.0 million. This was primarily due to our net loss of $87.0 million, partially offset by net cash provided by changes in our operating assets and liabilities of $1.6 million and non-cash charges of $5.4 million. The changes in our net operating assets and liabilities primarily consisted of a $4.3 million increase in net accounts payable and accrued expenses primarily related to balances with CDMOs, partially offset by a $2.7 million increase in prepaid expenses and other current assets related to prepaid balances with CROs. Non-cash charges primarily consisted of $8.7 million of stock-based compensation expense, $0.2 million of depreciation expense and $0.1 million of amortization of our ROU asset, partially offset by $3.6 million of net amortization and accretion of marketable securities.

Net cash used in operating activities for the year ended December 31, 2024 was $54.7 million. This was primarily due to our net loss of $61.9 million, partially offset by net cash provided by changes in our operating assets and liabilities of $4.6 million and non-cash charges of $2.6 million. The changes in our net operating assets and liabilities primarily consisted of a $7.1 million increase in accounts payable and accrued expenses primarily related to balances with CDMOs, partially offset by a $2.3 million increase in our prepaid expenses and other current assets related to prepaid balances with CROs. Non-cash charges primarily consisted of $5.2 million of stock-based compensation expense, partially offset by $2.9 million of net amortization and accretion of marketable securities.

Cash flows from investing activities

Net cash used in investing activities for the year ended December 31, 2025 was $83.7 million, which consisted of purchases of marketable securities of $358.1 million and purchases of property and equipment of $1.9 million, partially offset by maturities and redemptions of marketable securities of $276.4 million.

Net cash used in investing activities for the year ended December 31, 2024 was $160.6 million, which consisted of purchases of marketable securities of $239.5 million and purchases of property and equipment of $0.9 million, partially offset by maturities of marketable securities of $79.8 million.

Cash flows from financing activities

Net cash provided by financing activities for the year ended December 31, 2025 was $189.6 million, which consisted of proceeds of $187.9 million from the September 2025 Offering, net of underwriting discounts and commissions and $2.4 million of proceeds from the exercise of common stock options, partially offset by payments totaling $0.8 million related to offering costs for the September 2025 Offering.

Net cash provided by financing activities for the year ended December 31, 2024 was $234.1 million, which primarily consisted of proceeds from our IPO, net of underwriting discounts and commissions, of $174.5 million in September 2024, gross proceeds from our issuance of Series C Convertible Preferred Stock of $63.5 million in August 2024 and proceeds from the exercise of stock options of $0.4 million, partially offset by payments related to IPO costs of $4.1 million and preferred stock offering costs of $0.3 million.

Contractual obligations and commitments

Leases

We have entered into separate lease agreements for corporate office space and laboratory space, with terms extending through December 2028 and November 2026, respectively. The lease for our corporate office space was amended in May 2025 as further discussed in Note 9 to our audited condensed financial statements included elsewhere in this Annual Report. A new lease for laboratory space was signed in October 2025, effective December 1, 2025 through November 30, 2026. As of December 31, 2025, our future remaining operating lease payments were $1.0 million, with $0.5 million payable within the next twelve months, with respect to leases already commenced as of such date. As of December 31, 2024, our future remaining operating lease payments were $0.2 million, with $0.2 million payable within the next twelve months, with respect to leases already commenced as of such date.

Refer to Note 9 in our audited financial statements included elsewhere in this Annual Report for more information on our lease obligations.

License agreement and other agreements

Under the IURTC License Agreement, we have payment obligations that are contingent upon future events, such as the achievement of specified development, regulatory and commercial milestones, and in some cases, we are required to make royalty payments in connection with the sales of products developed under those agreements. Although we could be required to make milestone payments under the IURTC License Agreement, we are unable to estimate the timing or likelihood of achieving the milestones or making future product sales. For additional details regarding the IURTC License Agreement, see the section herein this Annual Report titled “Business-License Agreement.”

We enter into contracts in the normal course of business with clinical trial sites and clinical supply manufacturers and with vendors for preclinical studies and clinical trials, research supplies and other services and drugs for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts. In addition, certain of our supply agreements contain minimum purchase commitments in certain situations, the timing and likelihood of which we cannot estimate at this time.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our audited financial statements included elsewhere in this Annual Report.

Critical accounting policies and significant judgments and estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles, ("GAAP"). The preparation of these 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 financial statements, as well as the reported expenses incurred during the reporting periods.

On an ongoing basis, we evaluate our estimates and judgments, including but not limited to those related to accrued research and development costs, the fair value of common stock and stock-based compensation expense and other fair value measurements. These estimates and assumptions are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates and assumptions could occur in the future. 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. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

Accrued research and development expenses

Research and development expenses are recognized as services are performed and as costs occur. As part of our process of preparing our financial statements, we are required to estimate our research and development expenses as of each balance sheet date. Research and development expense accruals are estimated based on the level of services performed, progress of the work orders, including the phase or completion of events, and contracted costs. This process involves reviewing open contracts and purchase orders and communicating with our personnel to identify the level of services that have been performed. We then

make estimates of levels of service performed when we have not yet been invoiced or otherwise notified of actual costs incurred as of the balance sheet date. We make significant judgments and estimates in determining the accrual balance at each reporting period based on the facts and circumstances known to us at that time.

There may be instances in which vendors will require nonrefundable advance payments for goods or services to be received in the future. Such advance payments for use in research and development activities are capitalized and recorded in prepaid expenses and other current assets, and then expensed as the related goods are delivered or the services are performed.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the level of services and timing of services performed differ from actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular reporting period. To date, there have been no material differences between estimates of such expenses and the amounts actually incurred.

Stock-based compensation expense

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. We estimate the fair value of all stock option grants using the Black-Scholes option pricing model and recognize forfeitures as they occur. Estimating the fair value of equity awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of variables, including the risk-free interest rate, the expected stock price volatility, the expected term of stock options, the expected dividend yield and, prior to the IPO of our common stock, the fair value of the underlying common stock on the date of grant. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. See Note 12 to our audited financial statements included elsewhere in this Annual Report for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted for the years ended December 31, 2025 and 2024, respectively. A portion of our stock option program allowed for early exercise of granted options, before vesting requirements have been satisfied. Shares acquired through the early exercise of options which have not vested at the time of any employee's termination may be purchased by us at the lower of the original exercise price or the then current fair market value. As of December 31, 2025, the unrecognized stock-based compensation expense related to stock options was $25.2 million and is expected to be recognized as expense over a weighted-average period of approximately 2.7 years. The intrinsic value of all outstanding stock options as of December 31, 2025 was approximately $97.8 million, based on the closing NASDAQ stock price of $31.54 per share as of December 31, 2025.

Prior to our IPO in September 2024, there was no public market for our common stock. As a result, prior to our IPO, the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of grant. Following our IPO, the fair value of our common stock is determined based on the quoted market price of our common stock.

Off-balance sheet arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Emerging growth company and smaller reporting company status

We qualify as an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012 (the "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: (i) 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 Annual Report; (ii) reduced disclosure about our executive compensation arrangements; (iii) not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved; (iv) an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002; and (v) 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 our IPO; (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 Annual Report. 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 will 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 audited financial statements and unaudited condensed 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 may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We are also a “smaller reporting company,” meaning that the market value of our shares held by nonaffiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by nonaffiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by nonaffiliates is less than $700 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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report beginning on page F-1. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, mean controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as

of December 31, 2025, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025 based on the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework (2013). Based on this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

This Annual Report on Form 10-K does not include an attestation report of our independent registered accounting firm due to a transition period established by rules of the SEC for newly public and emerging growth companies.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a) None.

(b) Trading Plans

During the three months ended December 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted or terminated any Rule 10b5-1 trading arrangements (as defined in Item 408(a) of Regulation S-K), except as follows:

Name	Title	Reporting Action	Plan Start Date	Plan End Date	Maximum number of Shares of Common Stock to be Sold	Intended to Satisfy Rule 10b5-1(c)?
Richard Bartram	Chief Financial Officer	Plan Adoption	December 19, 2025	March 15, 2027	121,485	Yes

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

We have adopted a code of business conduct and ethics for directors, officers, and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at https://investors.mbxbio.com/corporate-governance/governance-overview. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver. Shareholders may request a free copy of the Code of Business Conduct and Ethics from our Compliance Officer, c/o MBX Biosciences, 11711 N. Meridian Street, Suite 300 Carmel, Indiana.

We maintain an insider trading policy governing the purchase, sale and other dispositions of our securities that applies to all of our directors, officers, employees and other covered persons. We believe that the insider trading policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to us. It is also our policy to comply with all insider trading laws and regulations. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

Item 14. Principal Accounting Fees and Services.

Our independent public accounting firm is Ernst & Young LLP, Indianapolis, Indiana (PCAOB ID: 0042).

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Financial Statements.

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report, incorporated into this Item by reference.

(2) Financial Statement Schedules.

All financial schedules have been omitted because the required information is either presented in the consolidated financial statements or the notes thereto or is not applicable or required.

(3) Exhibits.

Exhibit Number	Description
3.1	Fourth Amended and Restated Certificate of Incorporation of MBX Biosciences, Inc. (as currently in effect) (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-42272) filed with the SEC on September 16, 2024).
3.2	Amended and Restated Bylaws of MBX Biosciences, Inc. (as currently in effect) (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-42272) filed with the SEC on September 16, 2024).
4.1+	Second Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated August 2, 2024) (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
4.2	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
4.3	Description of Registrant's Securities (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K (File No. 001-42272) filed with the SEC on March 17, 2025).
10.1#	2019 Stock Option and Grant Plan, as amended, and forms of award agreements thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
10.2#	2024 Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
10.3#	2024 Employee Stock Purchase Plan(incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
10.4#*	2026 Inducement Plan and form of award agreement thereunder.
10.5#	Form of Officer Indemnification Agreement (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
10.6#	Form of Director Indemnification Agreement (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
10.7#	Senior Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
10.8#	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
10.9†	Exclusive License Agreement, dated as of June 10, 2020, between Indiana University Research and Technology Corporation and MBX Biosciences, Inc., as amended (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
10.10	Office Lease between Zeller-Carmel Property, L.L.C. and MBX Biosciences, Inc., dated April 28, 2022 (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 (File No. 333-281764).
10.11#	Employment Agreement between the Registrant and P. Kent Hawryluk, President and Chief Executive Officer, to be in effect upon the closing of this offering (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).

10.12#	Employment Agreement between the Registrant and Richard Bartram, Chief Financial Officer, to be in effect upon the closing of this offering (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
10.13#	Separation Agreement between the Registrant and Rick Bartram, Chief Financial Officer, to be in effect on March 15, 2026 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on February 27, 2026).
10.14#	Consulting Agreement between MBX Biosciences, Inc. and Richard Bartram dated February 25, 2026 (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on February 27, 2026).
10.15#	Employment Agreement between the Registrant and John Smither, Interim Chief Financial Officer, to be in effect March 16, 2026 (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed with the SEC on February 27, 2026).
10.16#	Employment Agreement between the Registrant and Salomon Azoulay, Chief Medical Officer, to be in effect upon the closing of this offering (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
10.17	First Amendment to Office Lease between Zeller-Carmel Property, L.L.C. and MBX Biosciences, Inc. dated May 9, 2025 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-42272) filed with the SEC on May 12, 2025).
10.18†	Lease Agreement between MBX Biosciences, Inc. and 5 Burlington Woods, LLC dated February 24, 2026 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 27, 2026).
19.1	MBX Biosciences, Inc. Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K (File No. 001-42272) filed with the SEC on March 17, 2025).
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included on signature page to this Annual Report).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	MBX Biosciences, Inc. Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K (File No. 001-42272) filed with the SEC on March 17, 2025).
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

**This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

# Indicates a management contract or any compensatory plan, contract or arrangement

† Portions of this exhibit (indicated by asterisks) will be omitted in accordance with the rules of the SEC because the Registrant has determined that information is both not material and is the type that the registrant treats as private or confidential.

+ Certain exhibits and schedules to these agreements have been omitted pursuant to Item 601(a)(5) and (6) of Regulation S-K. The registrant will furnish copies of any of the exhibits and schedules to the SEC upon request.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

MBX Biosciences, Inc.

Date: March 12, 2026

By: /s/ P. Kent Hawryluk
P. Kent Hawryluk
President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY AND SIGNATURES

KNOW ALL BY THESE PRESENT, that each individual whose signature appears below hereby constitutes and appoints each of P. Kent Hawryluk and Steven L. Hoerter, as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed by the following person in the capacities and on the date indicated.

NAME	TITLE	DATE
/s/ P. Kent Hawryluk P. Kent Hawryluk	President, Chief Executive Officer and Director (Principal Executive Officer)	March 12, 2026
/s/ Richard Bartram Richard Bartram	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 12, 2026
/s/ Tiba Aynechi Tiba Aynechi	Director	March 12, 2026
/s/ Steven L. Hoerter Steven L. Hoerter	Director	March 12, 2026
/s/ Patrick Heron Patrick Heron	Director	March 12, 2026
/s/ Edward T. Mathers Edward T. Mathers	Director	March 12, 2026
/s/ Ora Pescovitz Ora Pescovitz	Director	March 12, 2026
/s/ Steven Ryder Steven Ryder	Director	March 12, 2026
/s/ Laurie Stelzer Laurie Stelzer	Director	March 12, 2026

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of MBX Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of MBX Biosciences, Inc. (the Company) as of December 31, 2025 and 2024, the related statements of operations and comprehensive loss, stockholders' equity (deficit) and convertible preferred stock and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2023.

Indianapolis, Indiana

March 12, 2026

MBX BIOSCIENCES, INC.

BALANCE SHEETS
(in thousands, except share and per share amounts)

	Years ended December 31,	
	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 75,289	$ 49,351
Marketable securities	298,416	212,798
Prepaid expenses and other current assets	7,834	5,137
Total current assets	381,539	267,286
Property and equipment, net	2,735	1,080
Right-of-use assets	487	119
Other assets	383	50
Total assets	$ 385,144	$ 268,535
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,977	$ 5,335
Accrued expenses	12,346	5,545
Operating lease liability, current	172	171
Total current liabilities	15,495	11,051
Share repurchase liability	2	42
Operating lease liability, net of current	424	—
Total liabilities	15,921	11,093
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit)		
Undesignated preferred stock, $0.0001 par value, 10,000,000 shares authorized and zero issued and outstanding as of December 31, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value, 500,000,000 shares authorized and 44,927,953 issued and outstanding as of December 31, 2025 and 500,000,000 shares authorized and 33,421,525 issued and outstanding as of December 31, 2024	6	5
Additional paid-in-capital	593,407	394,887
Accumulated deficit	(224,476)	(137,505)
Accumulated other comprehensive income	286	55
Total stockholders' equity	369,223	257,442
Total liabilities and stockholders' equity	$ 385,144	$ 268,535

The accompanying notes are an integral part of these financial statements.

MBX BIOSCIENCES, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

	Years ended December 31,	
	2025	**2024**
Operating expenses		
Research and development	$ 79,159	$ 57,415
General and administrative	18,896	10,779
Total operating expenses	98,055	68,194
Loss from operations	(98,055)	(68,194)
Interest and other income, net	11,084	6,272
Net loss	$ (86,971)	$ (61,922)
Unrealized gain on marketable securities	285	54
Reclassification of net gains included in net loss	(54)	(59)
Total other comprehensive gain (loss)	231	(5)
Total comprehensive loss	$ (86,740)	$ (61,927)
Net loss attributable to common stockholders	$ (86,971)	$ (61,922)
Net loss per common share, basic and diluted	$ (2.38)	$ (5.82)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	36,506,092	10,642,954

The accompanying notes are an integral part of these financial statements.

MBX BIOSCIENCES, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) AND CONVERTIBLE PREFERRED STOCK
(in thousands, except share amounts)

	Common Stock		Additional		Accumulated Other	Total
	Outstanding Shares	Amount	Paid-in Capital	Accumulated Deficit	Comprehensive Income	Stockholders' Equity
Balance at January 1, 2025	33,421,525	$ 5	$ 394,887	$ (137,505)	$ 55	$ 257,442
Issuance of common stock from public offering, net of issuance costs	11,108,055	1	187,389	—	—	187,390
Issuance of common stock upon exercise of stock options	398,546	—	2,435	—	—	2,435
Repurchase of restricted stock due to early exercised unvested stock options	(173)	—	19	—	—	19
Stock-based compensation expense	—	—	8,677	—	—	8,677
Net loss	—	—	—	(86,971)	—	(86,971)
Other comprehensive income	—	—	—	—	231	231
Balance at December 31, 2025	44,927,953	$ 6	$ 593,407	$ (224,476)	$ 286	$ 369,223

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional		Accumulated Other	Total
	Outstanding Shares	Amount	Outstanding Shares	Amount	Outstanding Shares	Amount	Outstanding Shares	Amount	Paid-in Capital	Accumulated Deficit	Comprehensive Income (Loss)	Stockholders' Equity
Balance at January 1, 2024	53,598,587	$ 36,501	129,240,032	$ 115,856	—	$ —	1,257,080	$ 1	$ 3,054	$ (75,583)	$ 60	$ (72,468)
Issuance of Series C Convertible Preferred Stock, net of $279 issuance costs	—	—	—	—	61,650,480	63,221	—	—	—	—	—	—
Conversion of Series A Convertible Preferred Stock to common stock upon closing of the initial public offering	(53,598,587)	(36,501)	—	—	—	—	4,458,324	—	36,501	—	—	36,501
Conversion of Series B Convertible Preferred Stock to common stock upon closing of the initial public offering	—	—	(129,240,032)	(115,856)	—	—	10,750,183	1	115,855	—	—	115,856
Conversion of Series C Convertible Preferred Stock to common stock upon closing of the initial public offering	—	—	—	—	(61,650,480)	(63,221)	5,128,092	1	63,220	—	—	63,221
Issuance of common stock from initial public offering, net of $17,210 issuance costs	—	—	—	—	—	—	11,730,000	1	170,468	—	—	170,469
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	106,088	1	567	—	—	568
Repurchase of restricted stock due to early exercised unvested stock options	—	—	—	—	—	—	(8,242)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	5,222	—	—	5,222
Net loss	—	—	—	—	—	—	—	—	—	(61,922)	—	(61,922)
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	(5)	(5)
Balance at December 31, 2024	—	$ —	—	$ —	—	$ —	33,421,525	$ 5	$ 394,887	$ (137,505)	$ 55	$ 257,442

The accompanying notes are an integral part of these financial statements.

MBX BIOSCIENCES, INC.

STATEMENTS OF CASH FLOWS
(in thousands)

	Years ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (86,971)	$ (61,922)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,677	5,222
Non cash operating lease expense	133	106
Accretion and amortization of marketable securities, net	(3,611)	(2,928)
Depreciation expense	248	244
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,697)	(2,348)
Accounts payable	(2,456)	3,927
Accrued expenses	6,796	3,171
Other assets	8	—
Operating lease right-of-use asset	(501)	—
Operating lease liability	425	(153)
Net cash used in operating activities	(79,949)	(54,681)
Cash flows from investing activities:		
Purchases of property and equipment	(1,929)	(874)
Purchases of marketable securities	(358,148)	(239,471)
Maturities of marketable securities	267,872	79,750
Call redemptions of marketable securities	8,500	—
Net cash used in investing activities	(83,705)	(160,595)
Cash flows from financing activities:		
Proceeds from public offering, net of underwriting discounts and commissions	187,948	—
Proceeds from initial public offering, net of underwriting discounts and commissions	—	174,542
Proceeds from exercise of common stock options	2,415	403
Payments related to offering costs	(771)	(4,062)
Proceeds from the issuance of Series C Convertible Preferred Stock	—	63,500
Preferred stock issuance costs	—	(279)
Net cash provided by financing activities	189,592	234,104
Net increase in cash and cash equivalents	25,938	18,828
Cash and cash equivalents, beginning of period	49,351	30,523
Cash and cash equivalents, end of period	$ 75,289	$ 49,351
Supplemental disclosure of non-cash investing and financing activities:		
Vesting of early exercised stock options and founder shares	$ 40	$ 232
Property and equipment in accounts payable and accrued liabilities	26	29
Deferred public offering costs included in accounts payable and accrued expenses	127	—
Conversion of convertible preferred stock to common stock upon initial public offering	—	215,578

The accompanying notes are an integral part of these financial statements.

MBX BIOSCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS

1. NATURE OF BUSINESS AND LIQUIDITY

MBX Biosciences, Inc. (“MBX” or the “Company”) is a clinical-stage biopharmaceutical company focused on the discovery and development of novel precision peptide therapies for the treatment of endocrine and metabolic disorders. The Company is advancing a pipeline of novel candidates for endocrine and metabolic disorders. The Company was organized in August 2018 in Indiana as a Limited Liability Company and converted to a C corporation in the state of Delaware in April 2019. The Company maintains its corporate offices in Carmel, Indiana.

Since inception, the Company has devoted substantially all of its resources to drug discovery and development of its product candidates canvuparatide (MBX 2109), imapextide (MBX 1416) and MBX 4291, and other preclinical programs, building an intellectual property portfolio, organizing and staffing the Company, business planning, raising capital and providing general and administrative support for these operations. The Company does not have any products approved for sale and has not generated any revenue from product sales. The Company has historically funded its operations primarily through the issuance and sale of our common stock, including through our initial public offering (the "IPO"), convertible preferred stock and convertible notes, which generated approximately $401.8 million in aggregate gross proceeds, and an underwritten public offering in September 2025 (the "September 2025 Offering"), which generated approximately $199.9 million in aggregate gross proceeds, resulting in $601.7 million in cumulative, aggregate gross proceeds as of December 31, 2025.

September 2025 Public Offering

On September 24, 2025, the Company completed its September 2025 Offering, pursuant to which it sold 11,108,055 shares of its common stock at a purchase price per share of $18.00, resulting in net proceeds of approximately $187.4 million, after deducting the underwriting discounts, commissions and other offering costs.

Initial Public Offering

On September 16, 2024, the Company completed its initial public offering ("IPO"), pursuant to which it sold 11,730,000 shares of its common stock at a public offering price of $16.00 per share, resulting in net proceeds of approximately $170.5 million, after deducting underwriting discounts, commissions and other offering costs. Immediately prior to the closing of the IPO, the Company's outstanding convertible preferred stock automatically converted into 20,336,599 shares of common stock. Following the closing of the IPO, zero shares of convertible preferred stock were authorized, issued or outstanding.

Reverse Stock Split

On September 6, 2024, the Company effected a one-for-12.0221 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion prices for the Company's convertible preferred stock (see Note 10). Accordingly, all issued and outstanding share and per share amounts of common stock and stock option awards for all periods presented in the accompanying financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split. The par value and the number of authorized shares of the common stock and convertible preferred stock were not adjusted in connection with the reverse stock split.

Liquidity

From inception and through December 31, 2025, the Company has devoted substantially all of its efforts to drug discovery and development. The Company has a limited operating history, has incurred operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. The Company incurred net losses of $87.0 million and $61.9 million for the years ended December 31, 2025 and December 31, 2024, respectively. As of December 31, 2025, the Company has an accumulated deficit of $224.5 million and cash, cash equivalents and marketable securities of $373.7 million. Based on the Company’s current operating plan, management believes that existing cash, cash equivalents and marketable securities will be sufficient to fund the Company’s obligations for at least 12 months from the date of issuance of these financial statements.

Basis of presentation

The accompanying audited financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (US GAAP).

We operate as a single operating segment engaged in the discovery and development of novel precision peptide therapies for the treatment of endocrine and metabolic disorders. See Note 16 for additional information.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management to make judgments, assumptions, and estimates that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of financial statements, and the reported amounts of income and expense during the reporting period. The most significant estimates relate to the determination of the fair value of stock option grants and estimates related to the amount of prepaid and accrued research and development expenses as of the balance sheet date. Management evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors, including the current economic environment, and makes adjustments when the facts and circumstances dictate. These estimates are based on information available as of the date of the financial statements; therefore, actual results could differ from those estimates.

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. As of December 31, 2025 and 2024, cash and cash equivalents consisted primarily of checking and savings deposits, money market fund holdings, and commercial paper.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company's investment policy includes guidelines regarding the quality of the financial institutions and financial instruments and defines allowable marketable securities that it believes minimizes the exposure to concentration of credit risk. The Company may invest in money market funds (minimum of $10 billion in assets), U.S. Treasury securities, corporate debt, bank debt, U.S. government-related agency securities, other sovereign debt, municipal debt and commercial paper. These deposits may exceed federally insured limits. The Company has not experienced any losses historically in these accounts.

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 asset, generally three to seven years. Leasehold improvements are depreciated over the shorter of the lease term or the estimated useful life of the asset. Upon retirement or sale, the cost of assets disposed of, and the related accumulated depreciation, are removed from the accounts and any resulting gain or loss is included in loss from operations in the period realized. Repairs and maintenance charges that do not increase the useful life of the assets are charged to operating expenses as incurred.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, which consist primarily of property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. No impairment losses have been recognized during the years ended December 31, 2025 and 2024.

Fair Value of Financial Instruments

Fair value is defined as the price that the Company would receive to sell an investment in a timely transaction or pay to transfer a liability in a timely transaction with an independent buyer in the principal market, or in the absence of a principal market, the most advantageous market for the investment or liability. A framework is used for measuring fair value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 investments) and the lowest priority to unobservable inputs (Level 3 investments).

The three levels of the fair value hierarchy are as follows:

- Level 1 inputs: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2 inputs: Quoted prices in markets that are not considered to be active or financial instrument valuations for which all significant inputs are observable, either directly or indirectly; and
- Level 3 inputs: Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

Financial instruments are categorized in their entirety based on the lowest level of input that is significant to the fair value measurement. The assessment of the significance of a particular input to the fair value measurement requires judgment and considers factors specific to the investment.

The Company's money market funds and marketable securities are carried at fair value determined according to the fair value hierarchy described above (Level 1 and Level 2, respectively).

Research and Development Expenses

Research and development expenses include employee-related expenses, including salaries, benefits, travel and stock-based compensation expense; external research and development expenses incurred under arrangements with third parties, such as contract research organization agreements, contract manufacturing organization agreements, clinical sites and consultants; costs associated with preclinical and clinical activities; costs associated with required regulatory filings, licenses and fees; costs incurred in development of intellectual property; and an allocated portion of facilities and other infrastructure costs associated with our research and development activities. Costs incurred in connection with research and development activities, both internal and external, are expensed as incurred.

Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided to the Company by its clinical sites and vendors. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company. Depending upon the timing of payments to the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved, and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly.

Patent Costs

Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. These costs are included in general and administrative expenses.

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees, nonemployees, and directors based on the fair value on the date of the grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues stock option awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company's policy is to account for forfeitures when they occur.

The Company classifies stock-based compensation expense in its statement of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the US 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. Expected dividend yield is zero because the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

In determining the exercise prices for options granted prior to the IPO of common stock, the Company considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock prior to the IPO was determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including convertible preferred stock), the effect of the rights and preferences of the preferred shareholders, and the prospects of a liquidity event. Among other factors were the Company's financial position and historical financial performance, forecasted future operations of the Company, an evaluation or benchmark of the Company's competition, and the business climate in the marketplace at that time. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Income Taxes

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. Any accrued interest and penalties are included within the related tax liability.

Leases

The Company records a right-of-use ("ROU") asset and lease liability for substantially all leases for which it is a lessee, in accordance with ASC 842. Leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company recognizes lease expense for leases on a straight-line basis over the lease term. At inception of a contract, the Company considers all relevant facts and circumstances to assess whether or not the contract represents a lease by determining whether or not the contract conveys the right to control the use of an identified asset, either explicit or implicit, for a period of time in exchange for consideration.

Basic and Diluted Net Loss Per Share

The Company calculates basic and diluted net loss per share using the two-class method. The two-class method requires income available to common stockholders for the period to be allocated between common stock and participating securities, when outstanding, based upon their respective rights to receive dividends as if all income for the period had been distributed. The Company's Convertible Preferred Stock are participating securities until their conversion to common stock. These participating securities do not contractually require the holders of such shares to participate in the Company's losses. As such, net losses for the years presented were not allocated to the Company's participating securities. Accordingly, basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per share is computed by dividing the net loss by the sum of the weighted average number of common shares outstanding during the period plus the dilutive effects of potentially dilutive securities outstanding during the period. Potentially dilutive securities include vested and unexercised stock options, restricted stock issued upon early exercise of stock options, restricted stock related to unvested founder shares and convertible preferred shares. The dilutive effect of stock options are computed using the treasury stock method and the dilutive effect of convertible

preferred shares is calculated using the if-converted method. The Company has generated a net loss for all periods presented, therefore diluted net loss per share is the same as basic net loss per share since the inclusion of potentially dilutive securities would be anti-dilutive.

Deferred offering costs

The Company capitalizes as deferred offering costs all direct and incremental legal, professional, accounting and other third-party fees incurred in connection with the Company's public offerings. The deferred offering costs are offset against the related proceeds upon the consummation of the applicable offering. As of December 31, 2025, the Company had $0.3 million of deferred offering costs included in other assets, of which $0.1 million were included in accounts payable and accrued expenses, in the accompanying balance sheets.

Comprehensive Income (Loss)

Comprehensive income (loss) represents net income (loss) for the period plus the results of certain other changes in stockholders' equity. The Company's comprehensive loss included unrealized gains (losses) related to marketable securities for the years ended December 31, 2025, and 2024.

Recently issued accounting pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard-setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the accompanying financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes: Improvements to Income Tax Disclosures (Topic 740), which establishes incremental disaggregation of income tax disclosures pertaining to the effective tax rate reconciliation and income taxes paid. This new standard is effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The standard should be applied prospectively to financial statements issued for periods after the effective date of this ASU with the option to apply it retrospectively. The Company adopted this standard retrospectively for the years ended December 31, 2025 and 2024, and the impact of the adoption of the amendments in this update was not material to the Company's financial position and results of operation for the years then ended, since the amendments are disclosure related only. See Note 13 for the income tax disclosures as required by Topic 740, as amended by ASU 2023-09.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which is intended to provide more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation and amortization) included in certain expense captions presented on the face of our consolidated income statements. This new standard is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the consolidated financial statements. We are currently assessing the impact ASU 2024-03 will have on our financial statements, including our footnote disclosures.

3. FAIR VALUE MEASUREMENTS

The following table presents information about the Company's financial instruments as of December 31, 2025 and December 31, 2024, that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the inputs the Company utilized to determine such fair value (*in thousands*):

	December 31, 2025			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Money market funds (cash equivalents)	$ 61,646	$ 61,646	$ —	$ —
Marketable securities (cash equivalents)	12,466	12,466	—	—
Marketable securities	298,416	287,443	10,973	—
Total financial assets measured at fair value	$ 372,528	$ 361,555	$ 10,973	$ —

	December 31, 2024			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Money market funds (cash equivalents)	$ 37,989	$ 37,989	$ —	$ —
Marketable securities (cash equivalents)	9,990	4,997	4,993	—
Marketable securities	212,798	204,385	8,413	—
Total financial assets measured at fair value	$ 260,777	$ 247,371	$ 13,406	$ —

4. MARKETABLE SECURITIES

The fair value of the Company's marketable securities as of December 31, 2025 and December 31, 2024 is based on Level 1 and Level 2 inputs. The Company's investments consist mainly of U.S. government and agency securities. Fair value is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs. There were no transfers between levels within the fair value hierarchy during the years ended December 31, 2025 and December 31, 2024. The Company has assessed U.S. government treasuries as Level 1 and all other marketable securities as Level 2 within the fair value hierarchy of ASC 820. The Company classifies its entire investment portfolio as available-for-sale as defined in ASC 320, Debt Securities, and views all investments as available for use in its current operations. We have therefore classified all securities as current, even if we do not necessarily intend to dispose of the securities in the following year. Securities are carried at fair value with the unrealized gains (losses) reported in other comprehensive income (loss).

As of December 31, 2025 and December 31, 2024, none of the Company's investments were determined to be other than temporarily impaired.

The following table summarizes the Company's investments (*in thousands*):

		December 31, 2025			
	Balance Sheet Classification	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Government and agency securities	Marketable securities	298,131	286	(1)	298,416
Total		$ 298,131	$ 286	$ (1)	$ 298,416

		December 31, 2024			
	Balance Sheet Classification	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Government and agency securities	Cash equivalents	$ 9,989	$ 1	$ —	$ 9,990
Government and agency securities	Marketable securities	212,744	107	(53)	212,798
Total		$ 222,733	$ 108	$ (53)	$ 222,788

The fair values of available-for-sale debt securities as of December 31, 2025, by contractual maturity, are summarized as follows (*in thousands*):

	December 31, 2025
Due in one year or less	$ 219,952
Due after one year	78,464
Total	$ 298,416

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid and other current assets consisted of the following (*in thousands*):

	December 31,	
	2025	2024
Prepaid research and development expenses	$ 4,853	$ 3,652
Interest receivable	2,120	682
Other current assets	861	803
Total prepaid and other current assets	$ 7,834	$ 5,137

6. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following *(in thousands)*:

	December 31,	
	2025	2024
Furniture and fixtures	$ 303	$ 214
Computer equipment and software	81	81
Equipment	885	816
Leasehold improvements	520	391
Construction in progress	1,616	—
Total property and equipment	3,405	1,502
Less accumulated depreciation	(670)	(422)
Property and equipment, net	$ 2,735	$ 1,080

Depreciation expense was $0.2 million and $0.2 million for the years ended December 31, 2025 and 2024, respectively.

7. ACCRUED EXPENSES

Accrued expenses consisted of the following (*in thousands*):

	December 31,	
	2025	2024
Compensation and benefits	$ 4,321	$ 2,324
Research and development expenses	7,404	3,063
Other	621	158
Total accrued expenses	$ 12,346	$ 5,545

8. OTHER ASSETS

Other assets consisted of the following (*in thousands*):

	December 31,	
	2025	2024
Security deposits	$ 42	$ 50
Deferred offering costs	341	—
Total other assets	$ 383	$ 50

9. COMMITMENTS AND CONTINGENCIES

Leases

In April 2022, the Company entered into an operating lease agreement for a principal executive office in Carmel, Indiana (the "Carmel Lease"). The Carmel Lease commenced in October 2022 and had an initial term of 39 months, a termination date of December 31, 2025, and an option to extend for 36 additional months at the Company's discretion. The option to extend was not considered reasonably certain as of the lease inception. On May 9, 2025, the Company entered into the first amendment of

the Carmel Lease (the "First Amendment"). Pursuant to the terms of the First Amendment, the leased premises were expanded, and the lease term was extended through December 31, 2028, with an option to extend for 36 additional months at the Company's discretion. The option to extend is not considered reasonably certain as of date of the First Amendment.

In December 2023, the Company entered into an operating lease agreement for laboratory space in Indianapolis, Indiana (the "Laboratory Lease"). The Laboratory Lease commenced in December 2023 and had a term of 12 months, terminating in December 2024. The Company entered into a new lease for laboratory space in August 2024, commencing in December 2024, and terminating in December 2025. In October 2025, the Company entered into a new operating lease agreement for laboratory space in Indianapolis, Indiana, commencing in December 2025 and terminating in November 2026. All laboratory leases are short-term leases with no corresponding lease liability or right-of-use asset recorded, and lease payments are recognized as expense on a straight-line basis over the lease terms.

The Company has no other operating or finance leases as of December 31, 2025, or December 31, 2024.

Pursuant to ASC 842, the Company evaluated the new terms of the First Amendment of the Carmel Lease and determined the First Amendment should be treated as a lease modification of the existing Carmel Lease. In accordance with the accounting guidance, the Company remeasured the lease liability as of May 9, 2025, the First Amendment commencement date, to reflect the changes in the lease payments and the change in the lease term. This resulted in an increase of $0.6 million to the Company's lease liability and a corresponding increase to its right-of-use asset as shown on the balance sheet as of December 31, 2025.

The future minimum rent payments relating to the Carmel Lease under the terms and conditions existing as of December 31, 2025, are summarized as follows (*in thousands*):

(in thousands)	Amount
2026	229
2027	234
2028	240
Total lease payments	703
Less: imputed interest	(107)
Present value of lease liabilities	$ 596

The Company incurred $0.3 million and $0.2 million of rent expense for the years ended December 31, 2025, and 2024, respectively.

The following table summarizes the operating lease term and discount rate for the Carmel Lease as of December 31, 2025, and December 31, 2024:

	December 31,	
	2025	2024
Weighted-average remaining lease term (years)	3.0	1.0
Weighted-average discount rate	11.0%	8.0%

Cash paid for amounts included in the measurement of the Company's operating lease liability was $0.2 million and $0.2 million for the years ended December 31, 2025, and December 31, 2024, respectively.

The following table sets forth the amount of right-of-use assets and lease liabilities included on the Company's balance sheet as of December 31, 2025, and December 31, 2024 (*in thousands*):

	December 31,	
	2025	2024
Right-of use assets	$ 487	$ 119
Operating lease liability, current	172	171
Operating lease liability, net of current	424	—

License agreement

In January 2024, the Company entered into an amendment (the "Amendment") for the Exclusive License Agreement with Indiana University Research and Technology Corporation (“IURTC”) (the “License Agreement”), to license certain intellectual property arising under the Master Research Agreement with The Trustees of Indiana University (the "Research Agreement"). The Amendment specifies IURTC is entitled to the receipt of additional clinical and regulatory milestones, as defined in the Amendment, up to an aggregate of $9.0 million. Following the execution of the Amendment, future remaining clinical and regulatory milestone payments in the License Agreement and all amendments totaled up to $9.3 million. In the year ended December 31, 2025, the Company paid a $1.0 million milestone payment to IURTC related to the initiation of the Phase 1 clinical trial of MBX 4291. At December 31, 2025, future remaining clinical and regulatory milestone payments in the IURTC License Agreement and all amendments totaled up to $8.3 million. In consideration for the license, the Company paid immaterial licensing fees to IURTC during the and years ended December 31, 2025, and December 31, 2024.

Legal proceedings

The Company is not currently a party to any material legal proceedings. At each reporting date, the Company evaluates whether a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to its legal proceedings.

10. CONVERTIBLE PREFERRED STOCK

Prior to its IPO, the Company issued Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series C Convertible Preferred Stock.

On August 30, 2024, the Company's board of directors (the "Board") and stockholders approved the fourth amended and restated certificate of incorporation, which was effective immediately prior to the closing of the IPO on September 16, 2024, and which, among other things, authorized 10,000,000 undesignated shares of preferred stock, $0.0001 par value per share.

Immediately prior to the closing of the Company's IPO on September 16, 2024, pursuant to the reverse stock split and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock as discussed further below, all of the Company's outstanding shares of convertible preferred stock were converted into an aggregate of 20,336,599 shares of common stock, as follows: 4,458,324 shares of common stock were issued as a result of the conversion of Series A convertible preferred stock; 10,750,183 shares of common stock were issued as a result of the conversion of Series B convertible preferred stock; and 5,128,092 shares of common stock were issued as a result of the conversion of Series C convertible preferred stock. Prior to the conversion of the Company's convertible preferred stock, holders of the Series A, Series B and Series C Convertible Preferred Stock had certain rights and preferences, including voting and conversion rights and dividend and liquidation preferences. The Company had no shares of convertible preferred stock outstanding at December 31, 2025.

Issuances of convertible preferred stock

In July 2020, the Company entered into a Series A convertible preferred stock purchase agreement (“Series A SPA”) under which it issued 29,112,081 shares of Series A Convertible Preferred Stock, for cash, at a price of $0.687 per share, for gross proceeds of $20.0 million (the “Initial Series A Closing”). The Company incurred issuance costs of $0.3 million in relation to the issuance of Series A Convertible Preferred Stock, which have been recorded as a reduction to the value of the Series A Convertible Preferred Stock in mezzanine equity in the accompanying balance sheets. The Series A SPA contained provisions that potentially obligated the Company to sell an additional 14,556,039 shares of Series A Convertible Preferred Stock at $0.687 per share in an additional closing contingent upon either the achievement of a regulatory milestone defined in the Series A SPA or upon the agreement of the Company’s Board and lead investor to waive the requirement to achieve the milestone. In the event that an Initial Series A Closing purchaser failed to purchase all of their required shares in the subsequent Series A closing, each of the Series A Convertible Preferred Stock held by such purchaser automatically converted into one-half of a share of common stock.

Concurrently with the Initial Series A Closing, convertible notes issued by the Company in 2019 and 2020, including accrued interest and accrued deferred compensation, plus interest, were converted into 8,474,865 shares of Series A convertible preferred stock at a conversion price equal to 90% of the Series A financing, or $0.6183, representing a total of $5.4 million.

On November 12, 2021, the Company sold 16,011,641 additional shares of Series A convertible preferred stock at the same terms and conditions as those contained in the initial Agreement. The gross proceeds from the sale of Series A Convertible Preferred Stock upon achieving the milestone event was $11.0 million at $0.687 per share. The Company incurred immaterial issuance costs in relation to the issuance of Series A Convertible Preferred Stock, which have been recorded as a reduction to the value of the Series A Convertible Preferred Stock in mezzanine equity in the accompanying balance sheets.

On November 7, 2022 (the "Initial Series B Closing"), the Company entered into a Series B preferred stock purchase agreement to issue certain investors Series B Convertible Preferred Stock at a purchase price of $0.90 per share ($0.0001 par value). The Company amended the Certificate of Incorporation ("Charter") on November 7, 2022, which authorized the issuance of 129,240,032 shares of Series B Convertible Preferred Stock, in addition to 53,598,587 shares of Series A Convertible Preferred Stock issued and outstanding. The Company also executed the Amended and Restated Right of First Refusal and Co-Sale Agreement and the Amended and Restated Investors' Rights Agreement.

The Initial Series B Closing resulted in the issuance of 40,545,552 shares of Series B Convertible Preferred Stock, at a price of $0.90 per share, for gross cash proceeds of $36.5 million. The Company incurred issuance costs of $0.4 million in relation to the issuance of Series B Convertible Preferred Stock, which have been recorded as a reduction to the value of the Series B Convertible Preferred Stock in mezzanine equity in the accompanying balance sheets. Concurrently with the Initial Series B Closing, the 2022 Notes, including accrued interest, were converted into 12,573,381 shares of Series B Convertible Preferred Stock at a conversion price equal to 90% of the Series B financing. After the Initial Closing, the Company agreed to sell on the same terms and conditions as the first sale, an additional 76,121,099 shares of Series B Preferred Stock (the "Series B Milestone Issuance") upon achieving certain development milestones.

On August 15, 2023, the Company issued 76,121,099 shares of Series B Convertible Preferred Stock, at a price of $0.90 per share, for gross cash proceeds of $68.5 million in the Series B Milestone Issuance. The Company incurred immaterial issuance costs in relation to this issuance of Series B Convertible Preferred Stock, which have been recorded as a reduction to the value of the Series B Convertible Preferred Stock in mezzanine equity in the accompanying balance sheets.

On August 2, 2024, the Company entered into a Series C convertible preferred stock purchase agreement under which it issued 61,650,480 shares of Series C Convertible Preferred Stock, for cash, at a price of $1.03 per share, for gross proceeds of $63.5 million. The Company incurred issuance costs of $0.3 million in relation to the issuance of Series C Convertible Preferred Stock, which were initially recorded as a reduction to the value of Series C Convertible Preferred Stock.

The holders of the Series A, Series B and Series C Convertible Preferred Stock were entitled to the following rights and preferences:

Voting rights

Series A, Series B and Series C Convertible Preferred Stock were entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of Series A, Series B and Series C Convertible Preferred Stock held by such holder were then convertible as of the record date for determining stockholders entitled to vote on such matter.

Election of directors

The holders of record of shares of Series A Convertible Preferred Stock, exclusively and as a separate class, were entitled to elect three directors of the Company. The holders of record of shares of Series B Convertible Preferred Stock, exclusively and as a separate class, were entitled to elect one director of the Company. The holders of record of shares of Series C Convertible Preferred Stock, exclusively and as a separate class, were not entitled to elect any directors of the Company.

Non-cumulative dividend

Holders of Series A, Series B and Series C Convertible Preferred Stock, in preference to the holders of common stock, were entitled to receive, when, as and if declared by the Board of the Company, but only out of funds that are legally available therefor, cash dividends at the rate of eight percent (8%) of the Series A, Series B and Series C original issue price per annum on each outstanding share of Series A, Series B and Series C Convertible Preferred Stock (the "Preferred Dividends"). All such Preferred Dividends would have been payable only when, as and if declared by the Board of the Company and would have been non-cumulative. No dividends have been declared to-date as of December 31, 2025.

Conversion right

Each share of Series A, Series B and Series C Convertible Preferred Stock was to be automatically converted into common stock upon either (a) the closing of the sale of shares of common stock to the public at a price of at least $2.061, $2.25 or $2.25, respectively, per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $50,000,000 of gross proceeds to the Corporation and in connection with such offering the common stock is listed for trading on the Nasdaq Stock Market's National Market, the New York Stock Exchange or another exchange or marketplace approved the Board or (b) the affirmative vote or written consent of the majority preferred stockholders. All outstanding convertible preferred stock was converted into common stock immediately prior to the closing of the Company's IPO.

Liquidation preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Series A, Series B and Series C Convertible Preferred Stock then outstanding would have been entitled to be paid out of the assets of the Company available for distribution to its stockholders, and in the event of a Deemed Liquidation Event (as defined in the Company's Charter), the holders of shares of Series A, Series B and Series C Convertible Preferred Stock then outstanding would have been entitled to be paid out of the consideration payable to stockholders in such Deemed Liquidation Event or out of the available proceeds, as applicable, before any payment shall be made to the holders of common stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the Series A, Series B and Series C Convertible Preferred Stock original issue prices, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series A, Series B and Series C Convertible Preferred Stock been converted into common stock immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event.

11. COMMON STOCK

On August 30, 2024, the Company's stockholders approved the fourth amended and restated certificate of incorporation, which was filed upon the closing of the IPO on September 16, 2024, and which, among other things, increased the number of shares of common stock authorized for issuance to 500,000,000 shares of common stock, $0.0001 par value.

On September 16, 2024, the Company completed the IPO of its common stock and issued and sold 11,730,000 shares of its common stock at a price of $16.00 per share. As a result, the Company received $170.5 million in net proceeds, after deducting underwriting discounts and commissions and offering costs of $17.2 million.

On September 26, 2025, the Company completed the September 2025 Offering and issued and sold 11,108,055 shares of its common stock at a price of $18.00 per share. As a result, the Company received $187.4 million in net proceeds, after deducting underwriting discounts and commissions and offering costs of $12.5 million.

As of December 31, 2025, and December 31, 2024, there were 44,927,953 and 33,421,525 shares of common stock issued and outstanding, respectively. Shares of common stock issued and outstanding as of December 31, 2025, include 694 shares of restricted stock related to the unvested portion of early exercised common stock options. Shares of common stock issued and outstanding as of December 31, 2024 include 12,608 shares of restricted stock related to the unvested portion of early exercised common stock options. These are included in shares of common stock as they are considered to be legally outstanding as of December 31, 2025, and December 31, 2024, respectively. These shares are subject to the Company's option to repurchase and are not transferrable until such time as they are fully vested.

Common stock reserved

The number of shares of common stock that have been reserved for future issuance in connection with outstanding stock options granted under the Company's 2019 Stock Option and Grant Plan (the "2019 Plan") and the 2024 Stock Option and Incentive Plan (the "2024 Plan"), stock options available for grant under the 2019 Plan and 2024 Plan and shares available for future issuance under the Company's 2024 Employee Stock Purchase Plan (the "2024 ESPP") as of December 31, 2025 and December 31, 2024, are as follows:

	December 31,	
	2025	2024
Outstanding common stock options	4,632,648	3,502,440
Common stock options available for grant	2,745,748	2,603,253
Shares available for issuance under 2024 ESPP	623,651	289,436
Total	8,002,047	6,395,129

12. STOCK-BASED COMPENSATION

2019 Stock Option and Grant Plan ("2019 Plan")

The Company's 2019 Plan, as amended, provides for the Company to sell or issue common stock or restricted common stock or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the Board, and consultants of the Company. The 2019 Plan is administered by the Board or at the discretion of the Board by a committee of the Board. The exercise prices, vesting periods, and other restrictions are determined at the discretion of the Board or a committee of the Board, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the contractual term of stock option may not be greater than 10 years. Stock options granted to date typically vest and become exercisable over four years from the date of grant.

As of the date the 2024 Plan became effective, there will be no further awards granted under the 2019 Plan, but all outstanding awards under the 2019 Plan will continue to be governed by their existing terms. 2,458,082 stock options to purchase common stock were outstanding under the 2019 Plan as of December 31, 2025.

2024 Stock Option and Incentive Plan ("2024 Plan")

In August 2024, the Company's board of directors adopted, and its stockholders approved, the 2024 Plan, which became effective in September 2024. The 2024 Plan allows the Company to make equity-based and cash-based incentive awards to its officers, employees, directors and consultants. The 2024 Plan provides for the grant of incentive stock options, stock options, stock appreciation rights, restricted shares of common stock, restricted stock units, dividend equivalent rights and cash bonuses. The number of shares initially reserved for issuance under the 2024 Plan is 3,065,000 shares. In addition, the number of shares reserved and available for issuance under the 2024 Plan will automatically increase on January 1, 2025 and each January 1 thereafter, by five percent (5%) of the sum of the outstanding number of shares of common stock and the numbers of shares of common stock issuable pursuant to the exercise of any outstanding warrants to acquire common stock for a nominal exercise price on the immediately preceding December 31 or such lesser number of shares as determined by the compensation committee. The number of shares reserved under the 2024 Plan is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. As of December 31, 2025, 2,174,566 stock options to purchase common stock were outstanding under the 2024 Plan and 2,745,748 shares remained available for future grant under the 2024 Plan. The shares available for issuance under the 2024 Plan may be authorized but unissued shares or shares reacquired by the Company.

The shares of common stock underlying any awards under the 2024 Plan and the 2019 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 2024 Plan.

2024 Employee Stock Purchase Plan ("2024 ESPP")

In August 2024, the Company's board of directors adopted, and its stockholders approved, the 2024 ESPP, which became effective in September 2024. A total of 289,436 shares of common stock were initially reserved for issuance under the 2024 ESPP. The 2024 ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2025 and each January 1 thereafter, by the least of (i) 578,872 shares of common stock, (ii) one percent (1%) of the

number of shares of common stock issued and outstanding on the immediately preceding December 31, or (iii) such lesser number of shares of common stock as determined by the administrator of the 2024 ESPP. The number of shares reserved under the 2024 ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. As of December 31, 2025, 623,651 shares remained available for issuance under the 2024 ESPP. No shares were issued under the 2024 ESPP during the years ended December 31, 2025 and 2024.

Stock option valuation

The determination of the grant date fair value of stock-based awards granted to employees, directors and nonemployees during the years ended December 31, 2025, and 2024, is estimated using the Black-Scholes option-pricing model and was calculated based on the following assumptions.

	Years ended December 31,	
	2025	2024
Fair value of common stock	$6.00 - $33.00	$9.14 - $22.46
Dividend yield	0%	0%
Volatility	93.6% - 106.3%	88% - 110%
Risk-free interest rate	3.64% - 4.42%	3.52% - 5.18%
Expected term (years)	5.27 - 6.08	0.50 - 6.08

Summary of option activity

The Company's stock option activity regarding employees, directors, and nonemployees for the years ended December 31, 2025, and 2024, is summarized as follows (*in thousands except share and per share amounts*):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)	Aggregate intrinsic value
Options outstanding - December 31, 2023	2,493,777	$ 6.00	9.26	$ 4,543
Granted	1,394,761	12.63		
Exercised	(108,661)	3.94		
Forfeited	(188,787)	6.68		
Cancelled	(88,650)	4.30		
Options outstanding - December 31, 2024	3,502,440	$ 8.70	8.89	$ 34,307
Granted	1,762,649	13.03		
Exercised	(398,546)	6.06		
Forfeited	(225,228)	10.77		
Cancelled	(8,667)	16.00		
Options outstanding - December 31, 2025	4,632,648	$ 10.46	8.33	$ 97,751
Options vested and expected to vest - December 31, 2025	4,632,648	$ 10.46	8.33	$ 97,751
Options exercisable - December 31, 2025	2,310,401	$ 7.70	7.52	$ 55,079

Additional information with regard to stock option activity involving employees and directors for the year ended December 31, 2025, and 2024, is as follows (*in thousands except per share amounts*):

	December 31,	
	2025	2024
Weighted-average grant date fair value per option of total options granted	$ 10.21	$ 9.60
Aggregate intrinsic value of stock options exercised	3,485	1,222

The total fair value of shares vested during the years ended December 31, 2025 and 2024 was $6.9 million and $3.8 million, respectively.

As of December 31, 2025, total unrecognized compensation cost related to the unvested awards to employees, directors, and nonemployees is $25.2 million, which is expected to be recognized over a weighted-average period of 2.7 years.

Stock-based compensation

During the years ended December 31, 2025, and 2024, the Company recorded stock-based compensation expense regarding its employees, directors, and nonemployees as follows (*in thousands*):

	Years ended December 31,	
	2025	2024
Research and development expense	$ 3,563	$ 2,539
General and administrative expense	5,114	2,683
Total	$ 8,677	$ 5,222

13. INCOME TAXES

The Company reported pre-tax losses in the United States of $87.0 million and $61.9 million for the years ended December 31, 2025 and 2024, respectively. The Company recorded no income tax benefit for the net loss incurred for the years ended December 31, 2025 and 2024, due to the uncertainty of realizing a benefit from such losses. All of the Company's operating losses since inception have been generated in the United States.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective tax rate, applying ASU 2023-09 retrospectively, is as follows:

	As of December 31,			
	2025		2024	
Income tax benefit at statutory federal rate	$ (18,264)	21.0%	$ (13,004)	21.0%
State and local income taxes, net of federal benefit (1)	(246)	0.3%	(129)	0.2%
Tax credits - research and development	(7,451)	8.6%	(6,347)	10.3%
Nontaxable or nondeductible items				
Executive compensation expense	947	(1.1)%	382	(0.6)%
Other	24	—	21	—
Other provision adjustments	151	(0.2)%	10	(0.1)%
Change in unrecognized tax benefits	2,331	(2.7)%	2,183	(3.5)%
Change in valuation allowance	22,508	(25.9)%	16,884	(27.3)%
Benefit for income taxes	$ —	0.0%	$ —	0.0%

(1) State tax benefit in Indiana made up the majority (greater than 50%) of the tax effect in this category.

Due to income tax losses, the Company did not pay any federal or state income taxes for the years ended December 31, 2025 and 2024.

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes. The principal components of the Company's deferred tax assets and liabilities as of December 31, 2025 and 2024, are included in the table below (in thousands):

	As of December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 35,463	$ 14,903
Capitalized research and development expenses	15,650	17,076
Research and development credit carryforwards	14,116	8,177
Stock-based compensation expense	1,382	824
Accrued expenses	1,090	583
Lease liability	148	43
Other, net	221	36
Total deferred tax assets:	68,070	41,642
Deferred tax liabilities:		
Operating lease right-of-use assets	(121)	(30)
Depreciation	(155)	(156)
Total deferred tax liabilities:	(276)	(186)
Less valuation allowance	(67,794)	(41,456)
Net deferred tax assets	$ —	$ —

The Company's management has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are composed primarily of net operating loss ("NOL") carryforwards, capitalized research and development costs and research and development credit carryforwards. Management has considered the Company's history of net losses incurred since inception and probability of future losses to conclude it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. As a result, the Company has established a valuation allowance for the full amount of the net deferred tax assets as of December 31, 2025, and 2024. At such time as it is determined that it is more likely than not that the deferred tax assets will be realizable, the valuation allowance will be reduced. The valuation allowance increased by $26.3 million during the year ended December 31, 2025, due to the increase in the deferred tax assets by the same amounts.

As of December 31, 2025, the Company had $128.3 million and $219.7 million of US federal NOLs and state NOL carryforwards, respectively. The federal NOLs have no expiration and the state NOLs begin to expire in 2039. In addition, the Company had US federal research and development tax credit carryforwards of $18.5 million, which may be available to reduce future tax liabilities which start to expire in 2039. The Company had Indiana state research and development tax credits of $2.7 million as of December 31, 2025, which begin to expire in 2029.

Realization of the future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the NOL carryforward period. Under the provisions of Sections 382 and 383 of the Internal Revenue Code, and corresponding provisions of state law, certain substantial changes in the Company's ownership, including a sale of the Company or significant changes in ownership due to sales of equity, may have limited, or may limit in the future, the amount of NOL carryforwards, which could be used annually to offset future taxable income.

Due to the existence of the valuation allowance, future recognition of previously unrecognized tax benefits will not impact the Company's effective tax rate. The Company is subject to taxation in the U.S and various state jurisdictions. All tax years since incorporation remain open to examination by the major taxing jurisdictions (state and federal) to which the Company is subject, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service (IRS) or other authorities if they have or will be used in a future period. The Company is not currently under examination by the IRS or any other jurisdictions for any tax year. The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense.

The Company had no material accrued interest or penalties related to income tax matters in the Company's balance sheets as of December 31, 2025, and 2024. Further, the Company is not currently under examination by any federal, state or local tax authority.

The following table summarizes the changes to the Company's gross unrecognized tax benefits for the years ended December 31, 2025, and 2024, respectively (in thousands):

	2025	2024
Balance at January 1,	$ 4,331	$ 2,114
Increase related to current year tax positions	2,255	2,091
Increase related to prior year tax positions	141	126
Balance at December 31,	$ 6,727	$ 4,331

The unrecognized tax benefit amounts are reflected in the determination of the Company's deferred tax assets. If recognized, none of these amounts would affect the Company's effective tax rate, since it would be offset by an equal corresponding adjustment in the valuation allowance. The Company does not foresee material changes to its liability for uncertain tax benefits within the next twelve months.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted into law. The OBBBA makes changes to US corporate income taxes including reinstating the option to claim 100% accelerated depreciation on qualified property, with retroactive application beginning January 20, 2025 and immediate expensing of domestic research and development costs, with retroactive application beginning January 1, 2025. The impact of this legislation was not material to the Company's consolidated financial position and results of operations for the year ended December 31, 2025.

14. DEFINED CONTRIBUTION PLAN

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. In the year ended December 31, 2025, the Company began contributing to the plan on behalf of its employees made contributions to the plan totaling $0.3 million. As of December 31, 2024, the Company had not made any contributions to the plan on behalf of its employees.

15. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

Net loss per share

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands except share and per share amounts).

	Years ended December 31,	
	2025	2024
Net loss and net loss attributable to common stockholders	$ (86,971)	$ (61,922)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.38)	$ (5.82)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	36,506,092	10,642,954

The Company's potential dilutive securities, which include convertible preferred stock, restricted stock related to early exercise of common stock options, restricted stock related to unvested founder shares and outstanding common stock options, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The potential dilutive securities included in the table below, presented on an as converted basis, were excluded from the calculation of net loss per share due to their anti-dilutive effect:

	December 31,	
	2025	2024
Outstanding common stock options	4,632,648	3,502,440
Restricted stock related to early exercise of options to purchase common stock	694	12,608
Total	4,633,342	3,515,048

16. RELATED PARTY TRANSACTIONS

In April 2019, the Company executed the Research Agreement pursuant to which the Company agreed to fund certain research of a director and former officer of the Company. The period of performance for this agreement is June 1, 2019 through April 30, 2022 and the contract totals approximately $2.8 million. On February 14, 2022, the Research Agreement was amended to extend the period of performance from April 30, 2022 to April 30, 2025 and increase the total contract costs by $3.0 million. On January 16, 2025, the Research Agreement was amended to extend the period of performance from April 30, 2025 through April 1, 2026 and increase the total contract costs by $1.0 million. The Company paid $1.0 million and $1.1 million pursuant to this agreement during the years ended December 31, 2025 and 2024, respectively. The Research Agreement also provides the Company an option to license the technology arising under the agreement (see Note 9).

One of the officers of the Company, who is also a director, participated in the Series C Issuance financing totaling $1.0 million in August 2024.

17. SEGMENT INFORMATION

The Company operates as a single reportable segment engaged in the discovery and development of novel precision peptide therapies for the treatment of endocrine and metabolic disorders. The Company's determination that it operates as a single segment is consistent with the nature of its operations and the financial information regularly reviewed by the chief executive officer, in his capacity as the chief operating decision maker (CODM), for the purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting for future periods. The Company's purpose is to help people with endocrine and metabolic disorders live fuller and healthier lives. The Company's long-term success is significantly dependent on its ability to research and develop innovative medicines. The CODM uses net loss to assess performance of the Company, ensuring that it is investing in the research and development of product candidates. The CODM allocates research and development resources based upon several factors, including the likelihood of technical success, unmet medical needs, and the viability of commercial success. A significant component of the CODM’s decision-making process is to ensure a balanced investment in the research and development portfolio to drive near-term success and long-term sustainability.

The following table summarizes our significant segment expenses and segment net loss:

	Years ended December 31,	
	2025	2024
Expenses:		
Canvuparatide direct program expense	$ 37,225	$ 21,582
MBX 4291 direct program expense (1)	12,653	$ 10,771
Imapextide direct program expense	4,118	11,561
Preclinical and other research and development direct expense (1)	6,032	1,341
Research and development overhead expense	19,131	12,160
Other segment items (2)	7,812	4,507
Net loss	$ 86,971	$ 61,922

(1) Prior period amounts for MBX 4291 have been reclassified to conform to current period presentation.

(2) Other segment items are primarily comprised of general and administrative expenses and interest and other income.

18. SUBSEQUENT EVENTS

In February 2026, the Company closed on the sale and issuance of an aggregate of 2,250,986 shares of its common stock (the "Shares") at a volume weighted average price per share of $38.76 for gross proceeds of approximately $87.1 million. The Shares were sold pursuant to the Company's Open Market Sale Agreement℠ with Jefferies, LLC dated November 6, 2025 and a shelf registration statement on Form S-3 (File No. 333-291308) previously filed by the Company and declared effective by the Securities and Exchange Commission on December 8, 2025, which included a prospectus supplement relating to the Company's at the market offering program.

In February 2026, the Company entered into a lease agreement with 5 Burlington Woods, LLC to lease approximately 13,642 of new office and laboratory space in Burlington, Massachusetts. The Lease Agreement provides an estimated lease commencement date for the Premises of May 1, 2026 ("Lease Commencement Date"), with the rent commencing five months from the Lease Commencement Date ("Rent Commencement Date"). Additionally, the Lease Agreement provides that the

lease term will be four years beginning on the Rent Commencement Date and expiring on the last day of the month in which the fourth anniversary of the Rent Commencement Date occurs (the "Lease Term'). The Company has a one-time option to extend the Lease Term for a period of three years ("Extension Option"). In exchange for leasing the Premises, the Company will pay 5 Burlington Woods base rent of approximately $68,200 for the first twelve months, or a total of $818,000 ("base rent"), with annual increases of approximately 3.0%. The Lease Agreement provides that the Company will pay additional expenses to 5 Burlington Woods related to the Company's share of operating expenses, taxes and utilities related to the Premises using a ratable percentage set forth in the Lease Agreement ("Additional Rent"). Neither party may terminate the lease for the Premises other than in accordance with certain provisions of the Lease related to breach or bankruptcy. The aggregate base rent over the four-year lease term is approximately $3.4 million. The Company is evaluating the new lease terms pursuant to ASC 842 and is still assessing the financial statement impact.

In March 2026, the Company's board of directors approved the MBX Biosciences, Inc. 2026 Inducement Plan.

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MBX BIOSCIENCES, INC. CORPORATE AND OTHER INFORMATION

BOARD OF DIRECTORS

P. Kent Hawryluk
Chief Executive Officer and President

Steven L. Hoerter
Executive Chair of the Board of Directors, MBX Biosciences, Inc.; Former Chief Executive Officer and Director, Deciphera Pharmaceuticals, Inc

Tiba Aynechi
General Partner, Norwest Venture Partners

Patrick J. Heron
Managing Partner, Frazier Life Sciences

Edward T. Mathers
Partner, New Enterprise Associates

Ora Pescovitz, M.D.
President, Oakland University and former Senior Vice President, Lilly Biomedicines

Steven Ryder, M.D.
Chief Medical Officer, Rallybio Corporation

Laurie Stelzer
Former Chief Financial Officer, Kailera Therapeutics, Inc.

EXECUTIVE OFFICERS

P. Kent Hawryluk
Chief Executive Officer and President

John Smither
Interim Chief Financial Officer

Salomon Azoulay, M.D.
Chief Medical Officer

BOARD COMMITTEES

Audit Committee
Compensation Committee
Nominating and Corporate Governance Committee
Science and Medicine Committee

CORPORATE HEADQUARTERS

MBX Biosciences, Inc.
11711 N. Meridian Street, Suite 300
Carmel, Indiana 46032

ANNUAL MEETING

The 2026 Annual Meeting of Stockholders will be held online, on the day and time as set forth in the notice of the meeting, proxy statement and form of proxy that will be provided to stockholders in advance of the meeting.

VISIT US ON THE WEB

https://mbxbio.com/

STOCK EXCHANGE

MBX Biosciences, Inc.'s common shares are listed on Nasdaq Global Select Market under the trading symbol "MBX."

INVESTOR RELATIONS

investors@mbxbio.com

TRANSFER AGENT

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