PMV PHARMACEUTICALS, INC.

FORM 10-K
(Annual Report)

Filed 03/06/26 for the Period Ending 12/31/25

Address	400 ALEXANDER PARK DRIVE SUITE 301 PRINCETON, NJ, 08540
Telephone	(609) 642-6670
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Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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 001-39539

PMV PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**46-3218129**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
400 Alexander Park Drive, Suite 301 Princeton, NJ	**08540**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (609) 642-6670

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 $0.00001	PMVP	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 Stock Market on June 30, 2025 (the last business day of the Registrant's most recently completed second fiscal quarter), was $53,435,814. Shares of the Registrant's common stock held by each executive officer, director and holder of 10% or more of the outstanding common stock have been excluded because such persons may be deemed affiliates. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose.

The number of shares of Registrant's common stock outstanding as of March 6, 2026 was 53,329,392.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement relating to the 2026 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2025.

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, development plans, planned preclinical studies and clinical trials, future results of clinical trials, expected research and development costs, regulatory strategy and approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements.

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

- our financial performance;
- the sufficiency of our existing cash, cash equivalents, and marketable securities to fund our future operating expenses and capital expenditure requirements;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- our ability to obtain additional funding for our operations, when needed, including funding necessary to complete further development and commercialization of our product candidates, if approved;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our anticipated use of our existing cash, cash equivalents, and marketable securities and any proceeds from the ATM Program (as defined below);
- the implementation of our strategic plans for our business and product candidates;
- the size of the market opportunity for our product candidates and our ability to maximize those opportunities;
- the initiation, timing, progress and results of our research and development programs, preclinical studies, clinical trials and investigational new drug applications, or IND, and other regulatory submissions;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our estimates of the number of patients for each of our programs including patients expected to have certain p53 mutations and the number of patients that will enroll in our clinical trials;
- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other favorable results;
- our plans relating to the clinical development of our product candidates, including the disease areas to be evaluated;
- the timing, progress and focus of our clinical trials, and the reporting of data from those trials;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to commercializing our product candidates, if approved;
- the expected benefits of our existing and any potential future strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise;
- the success of competing therapies that are or may become available;
- the timing or likelihood of regulatory filings and approvals, including our expectation to seek accelerated reviews or special designations, such as breakthrough therapy and orphan drug designation, for our

product candidates, including our intention to seek accelerated approval for rezatapopt, our lead product candidate, for a tumor-agnostic indication;

- our plans relating to the further development and manufacturing of our product candidates, including for additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- our plans to rely on third parties to conduct and support preclinical and clinical development;
- our ability to retain the continued service of our key personnel and to identify, hire and then retain additional qualified personnel; and
- the impact of geopolitical tensions, such as the Ukraine-Russia war and the conflict in the Middle East, the impact of other disruptions resulting from public health epidemics, macroeconomic events such as future changes in trade regulations, tariff structures, global supply chain challenges, elevated inflation and interest rates and monetary policy changes (including the impact of changes to U.S. federal income tax law), instability in the global banking system, or other related disruptions on our business and the execution of our clinical trials.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions described in the section titled "Item 1A. Risk Factors" and elsewhere in this Annual Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

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

PART I

Item 1. Business.

We are a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53. p53 is a well-defined tumor suppressor protein known as the "guardian of the genome," and normal, or wild-type, p53 has the ability to eliminate cancer cells. However, mutant p53 proteins can be misfolded and lose their wild-type tumor suppressing function. These p53 mutations are found in approximately half of all cancers. The field of p53 biology was established by our co-founder Dr. Arnold Levine when he discovered the p53 protein in 1979. We have leveraged more than four decades of research experience and developed unique insights into p53 to create a precision oncology platform designed to generate selective, small molecule, tumor-agnostic therapies that structurally correct specific mutant p53 proteins to restore their wild-type function. We are deploying our precision oncology platform to target p53 mutations and other p53-related cancers.

Our lead product candidate, rezatapopt, is an orally available small molecule designed to potently and selectively correct p53 misfolding caused by a specific p53 mutation, Y220C, while sparing wild-type p53. The p53 Y220C mutation is associated with approximately 1% of all cancers, including endometrial, breast, non-small cell lung cancer, or NSCLC, colorectal, pancreatic and notably, approximately 3% of ovarian cancers.

Rezatapopt is designed to restore the wild-type conformation by occupying the pocket created by the tyrosine to cysteine mutation in amino acid position 220. We are pursuing a tumor-agnostic development strategy and initiated a Phase 1/2 clinical trial, PYNNACLE, in October 2020. Our strategy is to seek approval under an accelerated pathway, and we believe the Phase 2 portion of the PYNNACLE clinical trial has the potential to serve as a pivotal study. In October 2020, we were granted U.S. Food and Drug Administration, or FDA, Fast Track designation of rezatapopt for the treatment of patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation. In July 2023, we met with the FDA at an End of Phase 1 meeting where alignment was obtained on the recommended Phase 2 dose and key elements of the single arm, Phase 2 registrational portion of the PYNNACLE study. In October 2023, we presented our updated Phase 1 clinical data for rezatapopt at the 2023 American Association for Cancer Research, or AACR, the National Cancer Institute, or NCI, and the European Organisation for Research and Treatment of Cancer, or EORTC, International Conference on Molecular Targets and Cancer Therapeutics Annual Meeting. We dosed our first patient in the pivotal Phase 2 monotherapy portion of the PYNNACLE study in the first quarter of 2024. In September 2025, we announced interim data from the Phase 2 pivotal portion of the PYNNACLE clinical trial, which was updated in October 2025 in a late-breaking oral presentation and poster presentation at the 2025 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics Meeting. In March 2026, rezatapopt was granted orphan drug designation (ODD) from the FDA for the treatment of TP53 Y220C positive ovarian cancer, fallopian tube cancer, and primary peritoneal cancer. We plan to submit a New Drug Application, or NDA, for the treatment of patients with platinum-resistant/refractory ovarian cancer harboring a TP53 Y220C mutation to the FDA for rezatapopt in the first quarter of 2027.

A better understanding of mutations that drive cancers has facilitated the development of precise, gene- and protein-specific drugs known as targeted therapies. Targeted therapies have the potential to transform the treatment of some cancers by providing robust clinical benefit to patients. In many cases, clinical responses can be dramatic enough to support expedited regulatory approval of these therapies. Further, recent advancements in next-generation-sequencing, or NGS, have accelerated the development of targeted therapies. A recent study found that 75% of oncologists in the United States employ genomic sequencing. We believe p53 mutations are particularly well-suited for the evolving precision oncology paradigm, as a single mutation can cause p53 malfunction, and p53 is one of the genes commonly sequenced in NGS panels. We believe that our precision oncology platform offers a substantial opportunity to expand the number of patients who will benefit from targeted therapies.

Rezatapopt and Pipeline

We are leveraging our precision oncology platform to develop a pipeline of orally available, potent and highly selective small molecule product candidates that target p53 mutations or other p53-related cancers.

An overview of our development pipeline is shown in the table below.

(1) In Discovery, we screen compounds against biological assays to identify lead compounds.

(2) In Lead Optimization, we modify the lead compound to improve potency, selectivity, pharmacokinetic and toxicity parameters and physical chemical properties important for clinical development.

(3) In IND-Enabling Studies, we conduct preclinical studies, in accordance with Good Laboratory Practice, or GLP, required for an IND submission to the FDA.

Our lead product candidate, rezatapopt, is designed to be an orally available small molecule that structurally corrects the mutant p53 protein with the Y220C mutation. The p53 Y220C mutation results from tyrosine being substituted by a cysteine at amino acid position 220 and is associated with approximately 1% of all cancers, including endometrial, breast, NSCLC, colorectal, and pancreatic cancers. In addition, the p53 Y220C mutation is found in approximately 3% of ovarian cancer cases. There are currently no products approved by the FDA that selectively target the p53 Y220C mutation.

Rezatapopt is designed to bind to the mutation site and structurally correct the misfolded p53 protein, while sparing wild-type p53. Our approach has yielded a highly selective product candidate, which we believe can maximize the potential therapeutic potency and minimize risk to normal functioning cells. In preclinical studies, rezatapopt has shown selective on-target activity (*i.e.*, primarily functions in cells with the p53 Y220C mutation) and exhibited robust anti-tumor activity evidenced by potent tumor growth inhibition, or TGI, and strong tumor regression as a single agent.

We initiated a Phase 1/2 clinical trial, PYNNACLE, in October 2020 for our lead product candidate, rezatapopt. Our strategy is to seek approval under an accelerated pathway, and we believe the Phase 2 portion of the PYNNACLE clinical trial has the potential to serve as a pivotal study. In October 2020, we were granted FDA Fast Track designation of rezatapopt for the treatment of patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation. In July 2023, we met with the FDA at an End of Phase 1 meeting where alignment was obtained on the recommended Phase 2 dose and key elements of the single arm, Phase 2 registrational portion of the PYNNACLE study. In October 2023, we presented our updated Phase 1 clinical data for rezatapopt at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics Annual Meeting. We dosed our first patient in the pivotal Phase 2 monotherapy portion of the PYNNACLE study in the first quarter of 2024. In September 2025, we announced interim data from the Phase 2 pivotal portion of the PYNNACLE clinical trial, which was updated in October 2025 in a late-breaking oral presentation and poster presentation at the 2025 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics Meeting. In March 2026, rezatapopt was granted ODD from the FDA for the

treatment of TP53 Y220C positive ovarian cancer, fallopian tube cancer, and primary peritoneal cancer. We plan to submit an NDA for the treatment of patients with platinum-resistant/refractory ovarian cancer harboring a TP53 Y220C mutation to the FDA for rezatapopt in the first quarter of 2027.

Our Strategy

Our vision is to become a leading precision oncology company by designing, developing and commercializing novel precision medicines for every patient with a p53-driven tumor. We believe we are well positioned to leverage our deep experience in p53 biology, precision oncology platform and foundational knowledge acquired through our lead program to bring these therapies to patients. The critical components of our strategy include:

- **Advancing our lead product candidate, rezatapopt, as a tumor-agnostic, oral small molecule therapy for cancer patients**. We have designed rezatapopt to be an orally available, tumor-agnostic therapeutic and, if approved, we believe it could become the first agent to address the p53 Y220C mutation-defined patient population. In October 2020, we initiated a Phase 1/2 clinical trial for rezatapopt in multiple solid tumors with the p53 Y220C mutation. We are conducting our clinical trials in this genomically-defined patient population and leveraging learnings from recently approved tumor-agnostic drugs to inform the clinical and regulatory pathways for rezatapopt. In October 2023, we presented our Phase 1 clinical data for rezatapopt and observed partial responses across multiple tumor types. The pivotal Phase 2 monotherapy portion of our PYNNACLE trial was initiated in the first quarter of 2024. In September 2025, we announced interim data from the Phase 2 pivotal portion of the PYNNACLE clinical trial, which was updated in October 2025 in a late-breaking oral presentation and poster presentation at the 2025 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics Meeting. We plan to submit an NDA for the treatment of patients with platinum-resistant/refractory ovarian cancer harboring a TP53 Y220C mutation to the FDA for rezatapopt in the first quarter of 2027.
- **Leveraging the advantages of precision medicine and our expertise in p53 biology to pursue accelerated approval of our product candidates**. For our lead product candidate, rezatapopt, we are actively working with physicians and leading clinical trial institutions to enroll patients with the p53 Y220C mutation identified via NGS in our Phase 2 clinical trial. In order to rapidly confirm mechanistic and clinical proof of concept, we utilize assays to measure target engagement and biomarkers, as well as assess clinical responses in patients. We expect this strategy, which we also plan to replicate for our other future product candidates, will enable a rapid determination of target engagement and has the potential to serve as a predictive marker of efficacy, thereby providing clear decision points for clinical development and efficient advancement of our product candidates towards approval. Based on our encouraging PYNNACLE clinical trial results, we plan to seek breakthrough therapy designation from the FDA for rezatapopt, which, if granted, is intended to expedite clinical development and regulatory review. We intend to maximize the benefit of our product candidates by pursuing a tumor-agnostic approach.
- **Identifying and exploring combination therapy approaches for our product candidates**. Though rezatapopt has demonstrated clear and robust tumor regression as a single agent in preclinical animal models and clinical proof of concept, we believe that the mechanism of correcting the structure of mutant p53 can be complementary to other oncology therapies. Leveraging our expertise in p53 biology, chemistry and cancer pharmacology, we plan to identify and explore combination strategies with multiple cancer therapies. For example, chemotherapy and radiation therapy, approaches that result in deoxyribonucleic acid, or DNA, damage and upregulate p53 are natural candidates for combining with our product candidates. In addition, we believe that p53 plays a role in influencing the tumor microenvironment. Therefore, bevacizumab, pan-KRAS inhibitors, PI3K inhibitors and immune checkpoint inhibitors could also be considered as potential combination agents for use with our product candidates. We believe that our unique expertise will enable us to prioritize therapeutic strategies and optimize outcomes for clinical studies.
- **Harnessing the power of our precision oncology platform to discover and develop additional differentiated product candidates.** Using our extensive in-house expertise, deep understanding of chemistry and decades of experience researching the p53 protein, we believe that we will be able to

leverage and apply foundational knowledge from the advancement of rezatapopt to the discovery and development of additional product candidates.

Background on Targeted Therapies

Cancer is a genomic disease that results from changes in a person's DNA that causes cells to grow and divide uncontrollably. Genes are the distinct segments in a cell's DNA that can encode proteins with structural or functional roles in the body. Alterations in some genes can lead to the expression of mutant proteins with impaired or abnormal functions that can cause cancer. Cancer has historically been both diagnosed and treated based on a tumor's organ site, such as the breast, lung, ovary, brain, pancreas, skin, bone or blood.

Recent advances in genomic sequencing and a better understanding of the genomic alterations that drive tumor development and growth have facilitated precise, gene and protein-specific drug development, known as targeted therapies. Targeted therapies have the potential to transform the treatment of some cancers by providing robust clinical benefit to patients. In notable cases, the clinical outcomes have been dramatic enough to support expedited regulatory approval of these therapies. For example, Retevmo in RET-altered NSCLC and thyroid cancers (Lilly/Loxo); Ayvakit, in platelet-derived growth factor receptor alpha exon 18 mutated advanced gastrointestinal stromal tumor, or GIST (Blueprint); Rozlytrek, in solid tumors with a neurotrophic tropomyosin receptor kinase, or NTRK, gene fusion (Roche); Vitrakvi, in solid tumors with an NTRK gene fusion (Bayer/Loxo); Zykadia, in anaplastic lymphoma kinase-positive, or ALK+, advanced NSCLC (Novartis); Zelboraf, in advanced melanoma with a BRAF V600E mutation (Roche Genentech); Xalkori, in ALK+ advanced NSCLC (Pfizer); Tagrisso, in epidermal growth factor receptor mutation-positive, or EGFR+, advanced NSCLC (AstraZeneca); Qinlock, in GIST (Ono/Deciphera); Krazati and Lumakras in KRAS G12C mutated NSCLC (BMS/Mirati and Amgen); Augtyro in ROS1 positive NSCLC tumors (BMS/Turning Point); and Bizengri in NSCLC and pancreatic tumors with a NRG1-positive gene fusion (Merus) all received approvals within five years of first dosing in humans. This time period is significantly reduced compared to conventional drug development timelines. Despite this progress, a recent analysis found that only 16% of patients with metastatic cancer have tumors with genomic profiles eligible for treatment with an approved targeted agent, which leaves a large opportunity for precision oncology.

There is an emerging change in the development of targeted therapies, in that cancer is increasingly being targeted through a tumor-agnostic approach with a focus on selectively targeting a genetic or protein mutation, irrespective of tumor type. For example, there are now multiple tumor-agnostic product approvals that are based on a genomic mutation that defines the disease, as opposed to the tumor type. These include the aforementioned Vitrakvi, Rozlytrek and Augtyro approvals in NTRK gene fusion-positive solid tumors, as well as KEYTRUDA and Jemperli, respectively, approval in metastatic microsatellite instability-high or deficient mismatch repair solid tumors. KEYTRUDA is also approved in tumor mutational burden-high-(TMB-H) solid tumors. In addition, the combination of Taflinar and Mekinist was approved for BRAF V600E mutation positive unresectable or metastatic solid tumors (with the exception of colorectal cancer). In addition, Retevmo was approved for RET gene fusion-positive solid tumors and Enhertu was approved for HER2-Positive (IHC 3+) unresectable or metastatic solid tumors. We believe that these approvals represent a fundamental shift in the development of targeted therapies and will increasingly lead to cancer being characterized for treatment in a genomic, rather than in a tumor-specific, manner, based on a biological rationale.

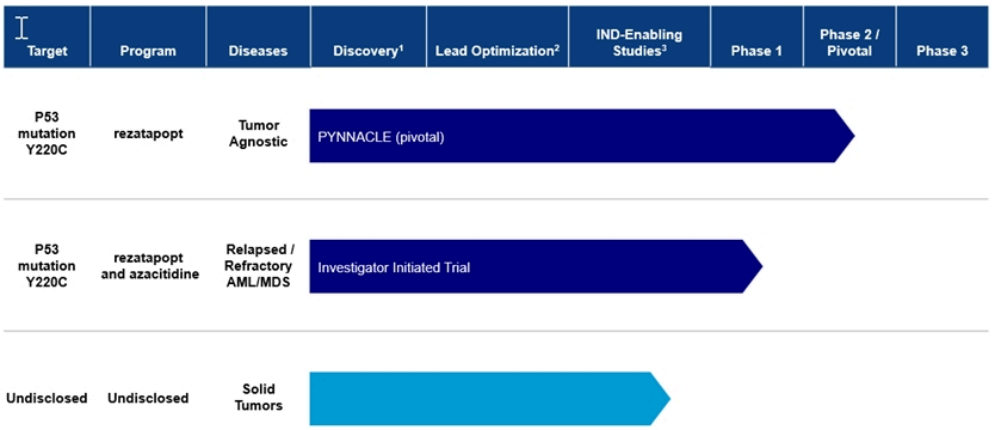
The widespread recognition that cancer is a genomic disease, as much as it is a disease defined by histology or anatomical location, has driven the increased use of genomic sequencing, which is now employed by approximately 75% of oncologists in the United States. As DNA sequencing technology advances, the availability of well-defined genomic sequencing tests increases. With the increasing number of approved targeted therapies, we believe that physicians will seek a better understanding of the underlying genetic and protein abnormalities associated with a specific type of cancer in order to determine the optimal course of treatment. Advances in genomic sequencing are leading to transformations in the discovery and development of new targeted oncology drugs.

We believe p53 mutations are prime targets for precision oncology, as more than 50% of all human cancers contain a p53 mutation. Identifying the specific p53 gene mutation and structurally correcting the corresponding mutant p53 protein can potentially serve as a basis of treatment for these cancers. Diagnostic tests are currently used by physicians in their practice to identify patients with p53 mutations. Given the high prevalence of p53 mutations in cancers, we believe that an effective way to address p53-driven cancers is by targeting individual p53 mutations

using a precision oncology approach and significantly expanding the scope of patients who can benefit from targeted therapies.

Our Product Candidate and Development Programs

We are leveraging our precision oncology platform to develop a pipeline of oral small molecule product candidates. We own worldwide commercial rights to all of our programs. An overview of our development pipeline is shown in the table below.



(1) In Discovery, we screen compounds against biological assays to identify lead compounds.

(2) In Lead Optimization, we modify the lead compound to improve potency, selectivity, pharmacokinetic and toxicity parameters and physical chemical properties important for clinical development.

(3) In IND-Enabling Studies, we conduct preclinical studies, in accordance with GLP required for an IND submission to the FDA.

We expect to initially seek approval of our product candidates in most instances, including with rezatapopt, at least as a second line therapy or for patients with no satisfactory alternative treatments or where the cancer has progressed following other treatment. Subsequently, depending on the nature of the clinical data and experience with any approved products or product candidates, if any, we may pursue approval as an earlier line therapy and potentially as a first line therapy. Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA customarily approves new therapies for a second line or later lines of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapies, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery or a combination of these, proves unsuccessful, second line therapies may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies.

Rezatapopt: A Selective Structural Corrector of p53 Y220C Mutations

P53 is the most widely mutated gene in human cancers. The vast majority of these mutations occur as a result of missense mutations that are found in the DNA binding domain. P53 Y220C mutations are found in approximately 1% of all cancers and approximately 3% of ovarian cancers. This particular mutation is expressed in a large variety of solid tumors, including endometrial, breast, NSCLC, colorectal and pancreatic cancers. Our lead product candidate, rezatapopt, is designed to be an orally available small molecule that structurally corrects a p53 protein containing the Y220C mutation and restores wild-type p53 function.

Wild-type p53 in a normal cell is at low to undetectable levels, but an external insult such as UV radiation or exposure to a carcinogen results in activation and upregulation of the protein. In these instances, wild-type p53 pauses the cell-cycle to survey the integrity of the genome, and if the damage to the genome cannot be repaired, wild-type p53 induces a potent program of cell suicide or programed cell death. Given wild-type p53's profound ability to induce cell death, it is tightly regulated in normal biology by an auto-regulatory loop with MDM2, a downstream induced target of wild-type p53 transcriptional activation. MDM2 production results in degradation of the wild-type p53 protein and re-sets the cell to normal function.

In the case of a mutant p53, there is a loss of p53 wild-type tumor suppression function due to a loss of downstream wild-type p53 transcriptional activation, including MDM2 induction. A consequence of this dysregulation is the inability of the cancer cell to degrade mutant forms of p53, resulting in a profound accumulation of mutant p53 protein in the cancer cell.

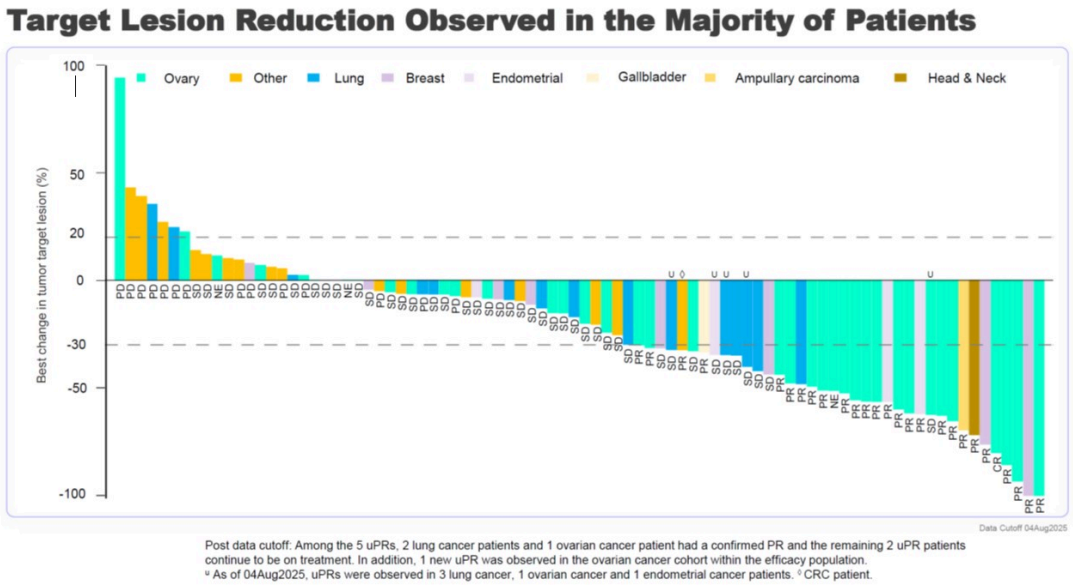
While treatment options such as surgery, chemotherapy, radiotherapy and immuno-therapy are available for endometrial, breast, NSCLC, colorectal, pancreatic and ovarian cancer, there are no approved precision oncology therapies for the subset of patients with the p53 Y220C mutation. The availability of an oral small molecule selective for the p53 Y220C mutation may offer a novel precision therapy for this population, which we believe could potentially change the treatment paradigm for such patients.

Clinical Development Plan of Rezatapopt

We initiated a Phase 1/2 clinical trial, PYNNACLE, for rezatapopt in October 2020. In addition, we were granted FDA Fast Track designation of rezatapopt for the treatment of patients with locally advanced or metastatic solid tumors with a p53 Y220C mutation in October 2020. We dosed our first patient in this clinical trial in the fourth quarter of 2020.

In July 2023, we concluded our End of Phase 1 meeting with the FDA with alignment on the recommended Phase 2 dose and key elements of the single arm, Phase 2 registrational portion of the PYNNACLE study. In October 2023, we presented our updated Phase 1 clinical data for rezatapopt at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics Meeting. We dosed our first patient in the pivotal Phase 2 monotherapy portion of the PYNNACLE study in the first quarter of 2024. In September 2025, we announced interim data from the Phase 2 pivotal portion of the PYNNACLE clinical trial, which was updated in October 2025 in a late-breaking oral presentation and poster presentation at the 2025 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics Meeting.

The updated Phase 2 data, as of a September 4, 2025 data cutoff date, included efficacy population consisting of 103 patients treated with at least one dose of rezatapopt 2000 mg daily, who either had one or more post-baseline tumor assessment or discontinued treatment early. Confirmed responses were observed in patients whose tumors were p53 Y220C mutated and KRAS wild-type in eight tumor types, including ovarian, lung, breast, endometrial, head and neck, colorectal, gallbladder, and ampullary carcinoma. These efficacy evaluable patients had an overall response rate (ORR) of 34% (35/103 patients) per investigator assessment according to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1, including confirmed and unconfirmed responses, and the ovarian cancer cohort ORR was 46% ORR (22/48 patients, including one confirmed complete response, 18 confirmed partial responses, and three unconfirmed partial responses). Across all cohorts, the median time to response was 1.3 months and median duration of response was 7.6 months. In the ovarian cancer cohort, the median time to response was 1.3 months and median duration of response was 8.0 months.



Rezatapopt was observed to be generally well-tolerated (across 112 patients treated with rezatapopt monotherapy as of September 4, 2025). The majority of adverse events were mild or moderate (Grade 1 or 2) in severity with the most frequent adverse events being nausea, vomiting, aspartate transaminase, or AST, alanine transaminase, or ALT, increase, anemia, blood creatinine increase and fatigue.

Other Pipeline Programs

In addition to our rezatapopt program, we are focused on developing a pipeline of product candidates targeting other p53 mutations or p53-related targets. These programs have been developed using our precision oncology platform and expertise.

We are able to utilize the same general principles and similar drug discovery methods developed from our rezatapopt, p53 Y220C, program to facilitate the development of additional new product candidates. We study the structural and functional properties of the target. We use assays, screens, preclinical model systems and biomarkers to assess and optimize selective small molecules. By leveraging our team's depth of expertise around p53, we are positioned to accelerate our efforts to expand the pipeline of therapies that target p53 or other p53-related cancers.

Competition

Our industry is intensely competitive and subject to rapid and significant technological change, as well as strong defense of intellectual property. While we believe that our knowledge, experience, and scientific resources provide us with competitive advantages, we face substantial competition from major pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical, and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license, or commercialize products before or more successfully than we do.

We are a precision oncology company pioneering the discovery and development of small molecule therapies targeting p53 mutations and other p53-related cancers. We are aware of other product candidates that are

in clinical development as potential treatments of various cancers through the modulation of p53. We are aware of molecules in development that also are being explored for p53 upregulation/activation in various stages of preclinical or clinical development being tested by Jacobio Pharmaceuticals, Changchun GeneScience, Frontier Medicines and Nutshell Therapeutics, among others.

We face competition with respect to our current product candidates and will face competition with respect to future product candidates, from segments of the pharmaceutical, biotechnology and other related markets that pursue targeted therapies for patients with genomically-defined cancers. If rezatapopt or our future product candidates do not offer sustainable advantages over competing products, we may otherwise not be able to successfully compete against current and future competitors.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

In addition, we will likely need to develop our product candidates in collaboration with companion diagnostic companies, and we will face competition from other companies in establishing these collaborations. Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, we also face competition more broadly across the market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy or a combination of such methods. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drug and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of our product candidates that we successfully introduce to the market will pose challenges. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

Manufacturing

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates undergoing preclinical and clinical testing, as well as for commercial manufacture if our product candidates receive marketing approval.

All of our product candidates are small molecules manufactured by synthetic processes from readily available starting materials. The chemistry appears amenable to scale up and does not currently require unusual equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

We generally expect to rely on third parties for the manufacture of companion diagnostics for our products, which are assays or tests to identify an appropriate patient population. Depending on the technology solutions we choose, we may rely on multiple third parties to manufacture and sell a single test. In May 2024, we entered into a partnership with Foundation Medicine, Inc. to develop Foundation Medicine’s tissue-based comprehensive genomic profiling test, FoundationOne®CDx, as a companion diagnostic for rezatapopt. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject

to periodic unannounced inspections by the FDA and certain state agencies for compliance with current Good Manufacturing Practice, or cGMP, requirements, which impose certain production, manufacturing, procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP requirements and other aspects of regulatory compliance.

Commercialization

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization to sell our products. We believe that such an organization will be able to address the community of oncologists who are the key specialists in treating the patient populations for which our product candidates are being developed.

We also plan to build a marketing and sales management organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine.

Intellectual Property

We strive to protect the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining and defending patent rights. We also rely on know-how relating to our proprietary technology and product candidates and continuing innovation to develop, strengthen and maintain our proprietary position. We also plan to rely on data exclusivity, market exclusivity and patent term extensions when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to defend and enforce our proprietary rights, including any patents that we may own in the future; and to operate without infringing the valid and enforceable patents and other proprietary rights of third parties. Intellectual property rights may not address all potential threats to our competitive advantage.

With respect to our existing and future product candidates and processes we intend to develop and commercialize in the normal course of business, we intend to pursue further patent protection covering, when possible, compositions, methods of use, dosing and formulations. We also may pursue patent protection with respect to manufacturing and drug development processes and technologies. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies. We may not be able to obtain patent protections for our compositions, methods of use, dosing and formulations, manufacturing and drug development processes and technologies throughout the world. Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for 20 years from the earliest effective filing date. In addition, in certain instances, the term of an issued U.S. patent that is directed to or claims an FDA-approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. This process is called “patent term extension.” The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of biopharmaceuticals has emerged in the United States. The relevant patent laws and their interpretation outside of the United States are also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have, or may obtain, blocking patents of which we are currently unaware that could be used to prevent us from developing or commercializing our product candidates and practicing our proprietary technology. Further, defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties or redesign our products. Doing so may be impossible or require substantial time and monetary expenditure. We may also elect to enter into a license agreement to settle litigation or to resolve disputes prior to litigation. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. Should a license to a third-party patent become necessary, we cannot predict whether we would be able to obtain a license, or if a license were available, whether it would be available on commercially reasonable terms. If such a license is necessary and a license under the applicable patent is unavailable on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed. This scenario could materially adversely affect our business. Even if we obtain a license to third-party intellectual property, we may later decide, or it may later become necessary, to terminate the license. If we do so, we may no longer be free to use the technology protected by the patents no longer under license. Also, if a competitor developed the technology protected by the patents no longer under license, we would not be able to block the competitor's progress. If the competitor's product was competitive with ours, then we may suffer economic harm from the competitive product.

The issuance of a patent is not conclusive as to its scope, validity or enforceability and our issued patents may be challenged, invalidated, deemed unenforceable or circumvented. These scenarios could limit our ability to stop competitors from marketing-related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we do not know whether 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. Moreover, any efforts to enforce our intellectual property rights are likely to be costly and may divert the efforts of our scientific and management personnel. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may also be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims. 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 these claims, litigation could result in substantial costs and be a distraction to our management and employees.

In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent directed to such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

We generally file a provisional patent application with the U.S. Patent and Trademark Office, or USPTO, first and then subsequently file a corresponding non-provisional patent application. This process enables us to establish an earlier effective filing date in the subsequently filed non-provisional patent application. To benefit from the earlier effective filing date, we must file a corresponding non-provisional patent application, such as a utility application in the United States or an international application under the Patent Cooperation Treaty, or PCT, within 12 months of the date of the provisional patent application filing. Based on a PCT filing, we may file national and regional patent applications in the United States or foreign jurisdictions, such as the European Union, China, Japan and possibly others. To date, we have not filed for patent protection in all national and regional jurisdictions where such protection may be available, and we may decide to abandon national and regional patent applications before a patent is granted. In addition, the patent grant proceeding for each national or regional patent application that we file is an independent proceeding. As a result, it is possible for a patent application to be granted in one jurisdiction and denied in another jurisdiction, and depending on the jurisdiction, the scope of patent protection may vary. As of January 27, 2026, we owned 11 issued U.S. patents and 53 granted foreign patents relating to methods of use and composition of matter of PMV compounds, including rezatapopt, at least 10 pending U.S. patent applications, and at least 30 pending foreign patent applications, each of which relates to methods of use and composition of matter of PMV compounds. The 11 issued U.S. patents are expected to expire between 2037 and 2043, without taking into account any possible patent term adjustment or extensions.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, preclinical and clinical testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. Generally, before a new drug can be marketed, considerable data must be generated, which demonstrates the drug's quality, safety and efficacy. Such data must then be organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an new drug application, or NDA, after completion of all pivotal trials;

- determination by the FDA within 60 days of its receipt of an NDA to accept the filing for substantive review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and of selected clinical investigation sites to assess compliance with GCP requirements; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

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 the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB or ethics committee for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, FDA may require, or sponsors may voluntarily pursue, post-approval trials, sometimes referred to as Phase 4 studies, that are conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, such as with accelerated approval drugs, the FDA may mandate the performance of post-approval clinical trials as a condition of approval of an NDA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 1 and Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical trial results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and 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 product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

NDA Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing complies with cGMP requirements to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug to an advisory committee. 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.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application 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. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA to address all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. Further, FDA's "real time" release of newly issued Complete Response Letters associated with withdrawn or abandoned applications, if applicable to any of our product candidates, can materially impact our business and competitive advantage.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Expedited Development and Review Programs

The FDA has various programs, including Fast Track designation, breakthrough therapy designation, accelerated approval and priority review, that are intended to expedite the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions. For example, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life- threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a Fast Track product has opportunities for frequent interactions with the review team during product development and, once a NDA is submitted, the product may be eligible for priority review. With regard to a Fast Track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a Fast Track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review, accelerated approval and breakthrough therapy designation. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product. The Food and Drug Omnibus Reform Act made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

The Food and Drug Administration Safety and Innovation Act established a category of drugs referred to as "breakthrough therapies" that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product candidate as a "breakthrough therapy" if the product is intended, 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 designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated

approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as a breakthrough therapy, the FDA will work to expedite the development and review of such drug.

Fast Track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

In 2025, FDA initiated the Commissioner's National Priority Voucher (CNPV) pilot program, which provides accelerated review and approval of product candidates that address one of the U.S. national health priorities, such as onshoring drug development/manufacturing to strengthen U.S. domestic capacity, large unmet medical needs, and innovative breakthrough therapies that fundamentally change disease management. Vouchers granted by the CNPV pilot program are nontransferable, can accelerate approval to 1-2 months, and provide enhanced interactions with the FDA review team and agency leadership.

Post-approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There are also continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements, which impose certain production, manufacturing, procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may 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 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 studies 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 the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;

- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or 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.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation, or ODD, to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with either a patient population of fewer than 200,000 individuals in the United States, or a patient population greater of than 200,000 individuals in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States of that drug or biologic. ODD must be requested before submitting an NDA. After the FDA grants ODD, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has received ODD and subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same biologic for the same indication for seven years from the approval of the NDA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of ODD are tax credits for certain research and a waiver of the NDA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received ODD. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

In *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an

eligible disease. On January 24, 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. The Consolidated Appropriations Act of 2026, signed into law in February 2026, codified this longstanding FDA interpretation of the Orphan Drug Act, allowing the FDA to approve multiple versions of the same orphan drug for different subindications and subpopulations.

Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission and approval of certain marketing applications for products containing the same active ingredient. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from accepting ANDAs or 505(b)(2) NDAs for drugs referencing the approved application for review. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

In June 2024, the U.S. Supreme Court overruled the Chevron doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies, which could lead to uncertainties in the industry. Further, changes in the leadership of the FDA and other federal agencies under the current administration may lead to new policies, changes in the regulations, or disruptions to the operations of federal agencies, any of which may impact our clinical development plans.

Other Healthcare Laws

Pharmaceutical manufacturers are subject to additional healthcare fraud and abuse laws, regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal anti-kickback, false claims, civil monetary penalty, consumer fraud, pricing reporting, data privacy and security and physician payment transparency laws and regulations as well as similar foreign laws in the jurisdictions outside the U.S. Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers or by patients themselves; 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, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information; state and local laws which require tracking gifts and other remuneration and transfer of value provided to physicians, other healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by the Health Insurance Portability and Accountability Act of 1996, thus complicating compliance efforts.

The risk of being found in violation of these or other laws and regulations is increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts and their provisions are open to various interpretations. These laws and regulations are subject to change, which can increase the resources needed for compliance and delay drug approval or commercialization. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Also, we may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments. Violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, 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, the curtailment or restructuring of operations, exclusion from participation in government healthcare programs and imprisonment.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufacturers to provide scientific, cost-effectiveness and clinical support for the use of a product to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, companion diagnostic tests that are used with applicable pharmaceutical products require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical products, will apply to companion diagnostics.

Moreover, third-party payors are increasingly reducing coverage and reimbursement for pharmaceutical products and related services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for

substitution of generic products. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. 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. 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. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Affordable Care Act, or ACA, was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded eligibility criteria for Medicaid programs; creates a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures under the current administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which will remain in effect through 2032, unless additional Congressional action is taken.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and

proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. Specifically, there have been several recent U.S. Presidential executive orders, Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the American Rescue Plan Act of 2021 eliminated the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of approved products, which could have a material impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D drugs in 2023, negotiations began in 2024, and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of HHS to establish a mechanism through
which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the U.S. In November 2025, CMS announced a voluntary initiative called the GENEROUS Model (GENErating cost Reductions fOr U.S. Medicaid Model) to introduce the option of most-favored-nation pricing to the Medicaid program, whereby a drug manufacturer may voluntarily offer supplemental rebates to participating state Medicaid programs for a manufacturer's covered outpatient drugs. Government agreements with pharmaceutical companies and other measures that use most-favored-nation pricing targets for prescription drugs or that increase generic and biosimilar drug entry sooner than expected can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future, or the pricing of our approved product in the U.S. and in foreign countries. The impact of judicial challenges and future government reform measures on us and the pharmaceutical industry as a whole is unclear.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs.

FDA Approval and Regulation of Companion Diagnostics

We expect that our product candidates may require use of a diagnostic to identify appropriate patient populations for our products. These diagnostics, often referred to as companion diagnostics, are medical devices, often in vitro devices, which provide information that is essential for the safe and effective use of a corresponding drug. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and

promotion, sales and distribution, export and import and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance (or decision to grant a De Novo classification request if there is no predicate device), and premarket approval, or PMA approval. In January 2024, FDA announced its plans to reclassify certain high-risk of *in vitro* diagnostics, including companion diagnostics, as Class II devices. In 2025, FDA issued a proposed rule to reclassify certain class III nucleic acid-based test systems indicated for use with a corresponding approved oncology therapeutic product from class III (premarket approval) into class II (special controls), subject to premarket notification. As such, to the extent we or our collaborators develop a companion diagnostic, it may be regulated as a Class II or Class III medical device, depending on its intended use and technical characteristics, among other factors.

510(k) clearance process

To obtain 510(k) clearance, a pre-market notification is submitted to the FDA demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet required the submission of a PMA application. The FDA's 510(k) clearance process may take three to 12 months from the date the application is submitted and filed with the FDA, but may take longer if FDA requests additional information, among other reasons. In some cases, the FDA may require clinical data to support substantial equivalence. In reviewing a pre-market notification submission, the FDA may request additional information, which may significantly prolong the review process. Notwithstanding compliance with all these requirements, clearance is never assured.

After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or require a PMA. In addition, the FDA may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, which may significantly affect the process.

De novo classification process

If a new medical device does not qualify for the 510(k) pre-market notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. The Food and Drug Administration Modernization Act of 1997 established a different route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification process. This process allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk and requires PMA or that general controls would be inadequate to control the risks and special controls cannot be developed.

Obtaining FDA marketing authorization, de novo down-classification, or approval for medical devices is expensive and uncertain, and may take several years, and generally requires significant scientific and clinical data.

PMA process

The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, a PMA application typically requires data regarding analytical and clinical validation studies. As part of the PMA

review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality Management System Regulation, or QMSR, which went into effect in February 2026, replacing the former Quality System Regulation, and imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards are not maintained, or problems are identified following initial marketing.

In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and *in vitro* companion diagnostics. According to the guidance, if FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic device is not approved or cleared for that indication at the same time. The review of *in vitro* companion diagnostics in conjunction with the review of our therapeutic treatments for cancer will, therefore, likely involve coordination of review by the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health Office of In Vitro Diagnostics. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption, or IDE, regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE. After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QMSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

Employees and Human Capital Resources

As of March 6, 2026, we had 54 full-time employees, including 18 employees with Ph.D., M.D. or Pharm.D. degrees. Of these full-time employees, 41 employees are engaged in research and development activities.

None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees 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 and cash incentive plans are to attract, retain and reward personnel though the granting of stock-based and cash-based compensation awards, to increase stockholder value and our success by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Environmental, Social and Governance (ESG) Initiatives

As a clinical-stage precision oncology company, we are rooted in our mission to fundamentally disrupt the course of cancer for patients with p53 gene mutations and other p53-related cancers. We believe integrating responsible environmental, social, and governance principles into our corporate strategy will drive sustainable value creation for our shareholders, employees, patients, and caregivers over the long term. We have formed an internal ESG Working Group with cross-functional senior leadership that meets periodically, with oversight by the nominating and corporate governance committee of our board of directors. Our ESG Working Group oversees our sustainability efforts, and we have documented our initiatives in our 2024 ESG Highlights Report, which is available on our website at ir.pmvpharma.com. The content provided in our 2024 ESG Highlights Report or accessible through our website is not incorporated by reference as part of this Annual Report on Form 10-K.

Corporate Information

We were incorporated in Delaware in March 2013 under the name "PJ Pharmaceuticals, Inc." In July 2013, we changed our name to "PMV Pharmaceuticals, Inc." Our principal executive offices are located at 400 Alexander Park Drive, Suite 301, Princeton, New Jersey 08540. Our telephone number is (609) 642-6670. Our website address is www.pmvpharma.com. Information contained on, or that can be accessible through, our website is not a part of this Annual Report on Form 10-K and the inclusion of our website address in this Annual Report on Form 10-K is an inactive textual reference only.

We use the name "PMV Pharma," the "PMV Pharma" logo and other marks as unregistered trademarks in the United States and other countries. This Annual Report on Form 10-K contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we or their owners will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable owner to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Available Information

Our Internet address is www.pmvpharma.com. We will file or furnish periodic reports and amendments thereto, including our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K (and amendments to those reports), proxy and information statements and other information filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, with the Securities and Exchange Commission, or the SEC. The SEC maintains a website that contains reports, proxy and information statement, and other information regarding issuers that file electronically, which may be accessed through the SEC at http://www.sec.gov. Our reports, amendments thereto, proxy statements and other information are also made available, free of charge, on our investor relations website at ir.pmvpharma.com as soon as reasonably practicable after we electronically file or furnish such information with the SEC. The information contained on the websites referenced in this Annual Report on Form 10-K is not incorporated by reference into this filing. Further, our references to website URLs are intended to be inactive textual references only. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K and in our other filings with the SEC, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risk Factors Summary

Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as fully described below. The principal factors and uncertainties that make investing in our common stock risky include, among others:

- we have a limited operating history, have not completed any clinical trials, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability;
- we have incurred significant losses since our inception, and we expect to incur significant net losses for the foreseeable future and may not be able to achieve or sustain revenue or profitability in the future;
- we have not generated any revenue from our product candidates and may never generate revenue or be profitable. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of our product candidates;
- we will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and product development programs or future commercialization efforts;
- our discovery and preclinical and clinical development is focused on the development of precision medicines for patients with genomically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs targeting p53 hotspot mutations and other p53-related cancers is novel, may never lead to marketable products and may not ultimately represent a significant market;
- we are substantially dependent on our lead product candidate, rezatapopt. If we are unable to advance rezatapopt or any of our future product candidates through clinical development, obtain regulatory approval and ultimately commercialize rezatapopt or any of our future product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected;
- interim, initial, “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- the subset of cancer patients that we are targeting are expected to have certain p53 mutations and we may not be able to identify a sufficient number of patients whom we can recruit and retain for our clinical trials to obtain approval for our current or future product candidates;
- the regulatory approval processes of the U.S. Food and Drug Administration, or FDA, and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired;

- we currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates;
- if we are unable to obtain and maintain sufficient patent and other intellectual property protection for our product candidates and technology, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any product candidates we may develop; and
- our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to protect our intellectual property rights throughout the world.

Risks Related to Our Limited Operating History, Business, Financial Condition, Results of Operations and Need for Additional Capital

We have a limited operating history, have not completed any clinical trials, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a clinical stage biotechnology company with a limited operating history. We commenced operations in March 2013, and our operations to date have been primarily limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and, more recently, clinical studies, and establishing arrangements with third parties for the manufacture of initial quantities of product candidates. Our lead product candidate, rezatapopt, received authorization to proceed under an IND with the FDA in September 2020 and then received Fast Track designation in October 2020. In the fourth quarter of 2020, we initiated patient dosing in our Phase 1/2 clinical trial of rezatapopt. We announced preliminary results from the Phase 1/2 clinical trial of rezatapopt in June 2022. In October 2023, we announced updated Phase 1 results from the Phase 1/2 clinical trial of rezatapopt, and we dosed our first patient in the pivotal Phase 2 monotherapy portion of the trial in the first quarter of 2024. In September 2025, we announced interim data from the Phase 2 pivotal portion of the PYNNACLE clinical trial, which was updated in October 2025 in a late-breaking oral presentation and poster presentation at the 2025 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics Meeting. In March 2026, rezatapopt was granted ODD from the FDA for the treatment of TP53 Y220C positive ovarian cancer, fallopian tube cancer, and primary peritoneal cancer. We have not demonstrated an ability to successfully complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a company with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We have incurred significant losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain revenue or profitability in the future.

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We are still in the process of developing our product candidates. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We have financed our operations

primarily through private placements of our preferred stock, our initial public offering and our at-the-market equity offering program.

We have incurred significant net losses in each period since we commenced operations in March 2013. Our net losses were $77.7 million and $58.7 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $446.5 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Additionally, the net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indicator of our future performance.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- continue our research and development efforts and submit IND applications for our product candidates;
- conduct preclinical studies and clinical trials;
- fail to demonstrate adequate efficacy or an acceptable safety profile in our clinical trials;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities, whether alone or with third parties, to commercialize any product candidates for which we may obtain regulatory approval, if any;
- obtain, expand, maintain, enforce and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel; and
- operate as a public company.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, seek regulatory approval for and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have not generated any revenue from our product candidates and may never generate revenue or be profitable. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of our product candidates.

Our ability to become profitable depends upon our ability to generate revenue. We have not received marketing approval for any product candidate, and we have not generated any revenue from any product sales. We do not expect to generate revenue unless or until we successfully complete preclinical and clinical development and obtain regulatory approval of, and then successfully commercialize, at least one product candidate. We announced preliminary results for our Phase 1/2 clinical trial of our lead product candidate, rezatapopt, in June 2022, and announced updated Phase 1 results in October 2023 and announced interim data from the Phase 2 pivotal portion
of the PYNNACLE clinical trial, which was updated in October 2025. We are continuing to transition from a company with a research focus to a company capable of supporting clinical development and commercial activities. We have not yet demonstrated our ability to successfully complete large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. In addition, all of our other product candidates are still in preclinical development and have not been evaluated in humans. We face significant translational risk as our product candidates advance to the clinical stage, and promising results in preclinical studies may not be replicated in clinical trials. All of our current and future product candidates will require preclinical and clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- successful enrollment and timely completion of our clinical trials for our lead product candidate, rezatapopt, and timely initiation and completion of our preclinical studies for our future product candidates, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development of rezatapopt and our future product candidates;
- our ability to complete IND-enabling studies and successfully submit and receive authorization to proceed under INDs or comparable applications;
- whether we are required by the FDA or other comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA and comparable foreign regulatory authorities the safety, efficacy, consistent manufacturing quality and acceptable risk-benefit profile of our small molecule product candidates or any future product candidates, and such regulatory authorities' acceptance of our tumor-agnostic development strategy;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA and comparable foreign regulatory authorities;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or future product candidates over alternative or more conventional therapies, such as chemotherapy, to treat solid tumors;
- the actual and perceived availability, cost, risk profile and side effects and efficacy of our product candidates, if approved, relative to existing and future alternative cancer therapies and competitive product candidates and technologies;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP requirements;

- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- patient demand for our product candidates and any future product candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercializing our product candidates. Successful completion of preclinical studies and clinical trials does not mean that any of our current or future product candidates will receive regulatory approval. Even if regulatory approvals are obtained, we could experience significant delays or an inability to successfully commercialize our current and any future product candidates, which would materially harm our business. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and product development programs or future commercialization efforts.

Developing biopharmaceutical products, 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 conduct clinical trials of, and seek marketing approval for, rezatapopt, and advance our future product candidates. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to modify the design of our clinical trials or perform preclinical studies or clinical trials in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of December 31, 2025, we had $112.9 million in cash, cash equivalents, and marketable securities. Although we believe that our available cash, cash equivalents, and marketable securities will be sufficient to fund our planned operations until the end of the second quarter of 2027, this belief is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. This belief also does not reflect the possibility that we may not be able to access a portion of our existing cash and cash equivalents due to market conditions. The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, could adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the United States, or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a failure or liquidity crisis.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates or any future product candidates we choose to pursue, and conducting preclinical studies and clinical trials, including our clinical trials of rezatapopt;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the timing and amount of any milestone, royalty and/or other payments we are required to make pursuant to any future license or collaboration agreements;
- the cost of manufacturing our product candidates or any future product candidates and any products we successfully commercialize;
- the cost of building a sales force in anticipation of product commercialization;
- the cost of commercialization activities of our product candidates, if approved for sale, including marketing, sales and distribution costs;
- our ability to establish future 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 products;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio;
- the timing, receipt and amount of sales of any future approved products; and
- the impact of a global pandemic or other public health emergencies on our operations, which may exacerbate the magnitude of the factors discussed above.

We do not have any committed external source of funds and adequate additional financing may not be available to us on acceptable terms, or at all. In addition, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions, inflation expectations, rising interest rates and the disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from a global pandemic or other public health emergencies, geopolitical tensions (such as the Ukraine-Russia war, the conflict in the Middle East and trade restrictions between the U.S. and China) among other global conditions affecting financial markets. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

Risks Related to Product Development

Our discovery and product development is focused on the development of precision medicines for patients with genomically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs targeting p53 is novel, may never lead to marketable products and may not ultimately represent a significant market.

The discovery and development of precision medicines for patients with genomically defined cancers is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates

based on these discoveries is both preliminary and limited. Further, despite decades of research on p53 as a target for precision medicines, prior product development efforts have been unsuccessful. Although we believe, based on our preclinical work and p53 research generally, that the top ten most frequent, or hotspot, p53 mutations have potential as precision oncology targets, clinical trial results may not confirm this hypothesis or may only confirm it for certain mutations or certain tumor types.

Further, even if our approach is successful in showing clinical benefit for tumors harboring the p53 mutation targeted by our lead product candidate, rezatapopt, we may never successfully identify additional product candidates for targeting p53 through our platform. Therefore, we do not know if our approach of treating patients with genomically defined cancers will be successful, and if our approach is unsuccessful, our business will be materially adversely affected.

In addition, because our approach targets genomically defined cancer patients and not specific tumors based on tumor or cancer types, we are pursuing a tumor-agnostic development strategy (i.e., pursuing approval for a potential indication based on a specific genetic mutation rather than a specific type of tissue). There is currently a limited number of approved tumor-agnostic therapies and we may not receive approval for a broad tumor-agnostic indication or may be delayed in receiving broad tumor-agnostic approval. If our Phase 1/2 trial for rezatapopt does not support a tumor-agnostic indication, but we observe clinical benefit in certain tumor or cancer types, we may decide to pursue a tumor- or cancer-specific indication which may require additional clinical trials. Further, even if our Phase 1/2 trial for rezatapopt is successful, the FDA may not agree that such study can serve as a pivotal study, which would require us to conduct additional clinical trials prior to approval.

We are substantially dependent on our lead product candidate, rezatapopt. If we are unable to advance rezatapopt or any of our future product candidates through clinical development, obtain regulatory approval and ultimately commercialize rezatapopt or any of our future product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.

We allocate the majority of our efforts and financial resources to the development of our lead product candidate, rezatapopt. Our future success is dependent on our ability to timely and successfully complete clinical trials, obtain marketing approval for and successfully commercialize rezatapopt. All of our other product candidates are still in preclinical development and have never been tested in human subjects. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of rezatapopt and one or more of our future product candidates. In addition, our product development programs contemplate the development with third party collaborators of companion diagnostics, which are assays or tests used to identify an appropriate patient population for our product candidates. Companion diagnostics are subject to regulation as medical devices (or *in vitro* diagnostic devices) and must themselves be approved for marketing by the FDA and comparable foreign regulatory agencies before we may commercialize such companion diagnostics with our product candidates. The success of our product candidates will depend on several factors, including the following:

- timely and successful completion of our ongoing clinical trials;
- our ability to continue our business operations and product candidate research and development, and adapt to any changes in the regulatory approval process, manufacturing supply or clinical trial requirements and timing stemming from a global pandemic or other public health emergencies;
- receipt of authorization to proceed under INDs for our planned clinical trials or future clinical trials;
- FDA acceptance of our tumor-agnostic development strategy;
- the initiation and successful patient enrollment in and completion of additional preclinical and clinical trials of our product candidates on a timely basis;
- successful development with third party collaborators of companion diagnostics for use with our product candidates;
- safety, tolerability and efficacy profiles for our product candidates that are satisfactory to the FDA or any foreign regulatory authority for marketing approval;

- receipt of marketing approvals for our product candidates and any companion diagnostics from applicable regulatory authorities, which must be approved contemporaneously;
- completion of any required post-marketing approval commitments to applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates, if any product candidates are approved;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other cancer therapies;
- obtaining and maintaining third-party coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of our products following approval.

Many of these factors are beyond our control, and it is possible that we may never obtain regulatory approval for our product candidates even if we expend substantial time and resources seeking their development and approval. If we do not achieve regulatory approval in a timely manner or at all, we could experience significant delays or an inability to commercialize our current or future product candidates, which would materially adversely affect our business. If we do not receive regulatory approvals for our current or future product candidates, we will not be able to continue our operations.

The success of our business, including our ability to finance our company and generate revenue from products in the future, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the product candidates we develop, which may never occur. Our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating cost-effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production in accordance with cGMP, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenue from product sales. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. Changes in the manufacturing process or facilities will require further comparability analysis and approval by FDA before implementation, which could delay our clinical trials and product candidate development, and could require additional clinical trials, including bridging studies, to demonstrate consistent and continued safety and efficacy.

We have not previously submitted a NDA to the FDA or similar approval filings to a comparable foreign regulatory authority, for any product candidate. An NDA or other relevant regulatory filing must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. We cannot be certain that our current or future product candidates will be successful in clinical trials or receive regulatory approval. Further, even if they are successful in clinical trials, our product candidates or any future product candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights for each product candidate, as well as the availability of competitive products, whether there is sufficient third-party reimbursement and adoption by physicians.

The subset of cancer patients that we are targeting are expected to have certain p53 mutants and we may not be able to identify a sufficient number of patients whom we can recruit and retain for our clinical trials to obtain approval for our current or future product candidates.

The patient populations for our current product candidates are limited to those with specific p53 mutations, which represents a substantially smaller subset of the generally treated cancer patient population. We expect our future product candidates to be similarly limited. We will need to screen and identify patients with these targeted mutations. Further, even if we are successful in identifying patients, we cannot be certain that the resulting patient populations with each p53 hotspot mutation will be large enough to allow us to successfully conduct the requisite clinical trials necessary to obtain marketing approval for each mutation-specific product candidate before we can commercialize our products, if approved, and achieve profitability.

The results of preclinical testing and earlier clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities. Successful preclinical studies and clinical trials cannot provide assurance of successful commercialization.

We are required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective before we can seek marketing approvals for their commercial sale. Success in preclinical studies does not mean that future clinical trials will be successful. For instance, we do not know whether rezatapopt will perform in its clinical trials as rezatapopt has performed in preclinical studies, nor can we predict how our future product candidates will perform in future preclinical studies or clinical trials. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates or prevent regulatory approval. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of our product candidates.

Even if we succeed in developing and commercializing our product candidates, we may never generate sufficient or sustainable revenue to enable us to be profitable.

We may need to use existing commercial diagnostic tests or develop, in collaborations or partnerships with third parties, novel companion diagnostics for some of our current or future product candidates. If we or our collaboration partners are unable to successfully develop, validate and obtain approval for such companion diagnostics, or experience significant delays in doing so, we may not realize the full commercial potential of our future product candidates.

As one of the key elements of our product development strategy, we seek to identify cancer patient populations that may derive meaningful benefit from our current or future product candidates. Because specific genetic mutations will be used to identify the appropriate patients for our programs and our current or future product candidates, we believe that our success may depend, in part, on our ability to use existing diagnostic tests and genomic sequencing, or to develop novel companion diagnostics in collaboration with partners.

Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of our product candidates. In our Phase 1/2 clinical trial, we are working with physicians and leading academic centers to enroll patients with the p53 Y220C mutation identified through next generation sequencing, or NGS. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges.

We have little experience as a company in the development of diagnostics. As such, we expect to rely on partners for the design, development and manufacture of appropriate diagnostics to pair with our current or future product candidates. For example, in May 2024, we entered into a collaboration agreement with Foundation Medicine, Inc. for the development of Foundation Medicine's tissue-based comprehensive genomic profiling test, FoundationOne®CDx, as a companion diagnostic for rezatapopt. We will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities outside the United States as medical devices (or in *vitro* diagnostic devices) and require separate regulatory approval or clearance prior to commercialization. Moreover, the FDA generally requires the contemporaneous approval of companion diagnostics and the associated therapeutic. Changes in the FDA leadership, regulatory actions and other actions under the current administration, including changes in the FDA's regulation of diagnostic tests, may impact our development of a companion diagnostic for our product candidates and result in delays in regulatory approval.

We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we, our partners, or any third parties that we engage to assist us, are unable to successfully develop and supply companion diagnostics for our current product candidates and any future product candidates, or experience delays in doing so:

- the development of our current product candidates and any future product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials; and
- we may not be able to obtain approval of our current product candidates and any future product candidates that require companion diagnostics on a timely basis or at all.

If any of these events were to occur, our business would be adversely impacted.

Global pandemics or other public health concerns and/or emergencies in the United States and the rest of the world that disrupt normal operations could materially adversely impact our business, results of operations and financial condition, including our preclinical studies and clinical trials.

We may experience disruptions that could severely impact our business and clinical trials due to global pandemics, public health concerns or other public emergencies, including:

- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of

clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;

- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption or delays to our sourced discovery and clinical activities; and
- changes in clinical site procedures and requirements as well as regulatory requirements for conducting clinical trials during the pandemic.

The ultimate impact of a global pandemic or other public health emergency on our business operations is difficult to forecast and highly uncertain, and there can be no assurance that we will be able to avoid a material impact on our business from such global pandemic or other public health emergency or their consequences, including disruption to our business and downturns in business sentiment generally or in our industry. To the extent a global pandemic or other public health emergency adversely affects our business, financial condition and results of operations, it may also have the effect of heightening many of the risks described in this "Risk factors" section.

If we experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials on a timely basis or at all for our product candidates if we are unable to recruit and enroll a sufficient number of eligible patients to participate in these trials through completion of such trials as required by the FDA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. For example, our enrollment for clinical trials of rezatapopt will require patients to have the specific p53 Y220C mutation. If we are unable to locate a sufficient number of such patients, our clinical trial and development plans could be delayed.

Patient enrollment may also be affected if our competitors have ongoing clinical trials for programs that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' programs. Patient enrollment for our current or any future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved or future product candidates being investigated for the indications we are investigating;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;

- delays in or temporary suspension of the enrollment of patients in our clinical trials due to a global pandemic or other public health emergencies;
- ability to obtain and maintain patient consents;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion, including as a result of other health conditions, or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

The market opportunities for our product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA customarily approves new therapies only for a second line or later lines of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapies, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. We expect to initially seek approval of our product candidates in most instances at least as a second line therapy. Subsequently, depending on the nature of the clinical data and experience with any approved products or product candidates, if any, we may pursue approval as an earlier line therapy and potentially as a first line therapy. But there is no guarantee that our product candidates, even if approved as a second or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of both the number of people who have the p53 hotspot mutations we are targeting, who may have their tumors genomically sequenced, as well as the subset of people with these mutations in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our assumptions and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved for a second or third line of therapy, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type.

Our business may become subject to economic, political, regulatory, and other risks associated with international operations directly or indirectly. A variety of risks associated with marketing our product candidates, if approved, internationally may materially adversely affect our business.

Our business is subject to risks associated with business operations we conduct internationally, as well as indirect impacts from our relationships with collaborators, partners, or contractors who conduct business internationally. To the extent we seek regulatory approval of any of our product candidates outside of the United States, we expect that we will be subject to additional risks related to our operations in foreign countries. Accordingly, our future results could be harmed directly or indirectly by a variety of factors, including:

- differing regulatory requirements in foreign countries, changes in existing regulatory requirements, or implementation of new regulatory requirements or policies that impact our clinical development and business operations in foreign countries;
- foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials or our interpretation of data from preclinical studies or clinical trials;

- approval policies or regulations of foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- impact of a global pandemic or other public health emergencies on our ability to produce our product candidates and conduct clinical trials in foreign countries;
- sociopolitical instability in particular foreign economies and markets;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- legislation or other measures that restrict business, trade, or use of government funding for any product or service rendered by certain companies based in China or Chinese-owned U.S. companies due to national security concerns or geopolitical issues, and our reliance on such Chinese companies, including CROs, contract manufacturing organization, or CMOs, suppliers, and other vendors or contractors based in China. For example, the President recently signed into law the National Defense Authorization Act of 2026, which includes Section 851 regarding "prohibition on contracting with certain biotechnology providers" ("the BIOSECURE Act"), which restricts federal government contracts, grants, and loans from being issued to companies that use biotechnology equipment or services from any designated "biotechnology company of concern," as part of such companies' performance of those agreements with the U.S. government. Once fully implemented through issuance of regulations, the BIOSECURE Act may ultimately limit certain U.S. biotechnology companies from using equipment or services produced or provided by Chinese biotechnology companies that meet the designation criteria of the new law, or certain affiliated entities. In addition, even if we do not seek any covered federal government contracts, grants, or loans, commercial partners, government agencies, or other third parties may view our business
  less favorably if we contract with entities that ultimately become biotechnology companies of concern;
- regulations or other potentially new measures that arise for national security or geopolitical reasons, including those that would affect the transfer of certain types of data abroad, including China. For example, the Department of Justice issued a final rule which took effect in April 2025 that places limitations, and in some cases prohibitions, on certain transfers of sensitive personal data to business partners located in China and other designated countries, or with other specified links to China and other designated countries. These rules also may broadly require us to extract promises from other third-party service providers that they will not transfer data we share with them onward to parties linked to countries of concern;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments; production or supply shortages resulting directly or indirectly from any events affecting raw material supply or manufacturing capabilities abroad, including, but not limited to, impacts due to the ongoing Ukraine-Russia war or the conflict in the Middle East, addition of certain suppliers or companies to the Unverified List under the Export Administration Regulations, implementation of other export controls, restrictions or sanctions that can impact the supply chain, our business, or business operations of our suppliers, contractors or partners;

- business interruptions resulting directly or indirectly from geo-political actions, conflicts and terrorism; and supply and other disruptions resulting from the impact of public health epidemics on our strategic partners, third-party manufacturers, suppliers and other third parties upon which we rely.

These and other risks associated with international operations may materially adversely affect our business, financial condition, and results of operations.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

Our industry is intensely competitive and subject to rapid and significant technological change as well as strong defense of intellectual property. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face substantial competition from major pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

In particular, we are aware of molecules in development that also are being explored for p53 upregulation/activation in various stages of preclinical or clinical development being tested by Jacobio Pharmaceuticals, Changchun GeneScience, Frontier Medicines, and Nutshell Therapeutics, among others.

We face competition with respect to our current product candidates and will face competition with respect to future product candidates, from segments of the pharmaceutical, biotechnology and other related markets that pursue targeted therapies for patients with genomically-defined cancers. If rezatapopt or our future product candidates do not offer sustainable advantages over competing products, we may otherwise not be able to successfully compete against current and future competitors.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

In addition, we will likely need to develop our product candidates in collaboration with companion diagnostic companies, and we will face competition from other companies in establishing these future collaborations. Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, we also face competition more broadly across the market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy or a combination of such methods. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drug and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of our product candidates that we successfully introduce to the market will pose challenges. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

Product candidates that we may successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products.

Our long-term prospects depend in part upon discovering, developing and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.

Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates beyond our lead product candidate, rezatapopt, and those we currently have in preclinical development. A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of future product candidates we may develop will depend on many factors, including the following and the other factors relating to product development described elsewhere in this "Risk Factors" section:

- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of the product candidate for use in clinical trials; and
- adverse events in the clinical trials.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize additional product candidates, which would materially adversely affect our business, financial condition and results of operations.

Even if we successfully advance any future product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from our future product candidates.

Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may adversely affect our business, financial condition and prospects significantly.

While our lead product candidate, rezatapopt, is still in clinical development and although it has been generally well-tolerated per our preliminary and updated data releases, as is the case with all oncology drugs, it is likely that there may be significant side effects associated with its use. rezatapopt or future product candidates may be used in populations for which safety concerns may be reviewed by regulatory agencies. In addition, we are collaborating with MD Anderson and MSK to support an investigator-initiated Phase 1b study, which is designed to

assess the safety, tolerability, pharmacokinetics, and preliminary efficacy of rezatapopt monotherapy in combination with azacitidine in R/R AML and MDS patients harboring a TP53 Y220C mutation, and we may study rezatapopt in combination with other additional therapies, which may exacerbate adverse events associated with the therapy. Further, our product candidates will be used in patients that have weakened immune systems, which may exacerbate any potential side effects associated with their use. Patients treated with rezatapopt or any of our future product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients enrolled in our rezatapopt clinical trials will die or experience major clinical events either during the course of our clinical trials or after participating in such trials. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects.

If further significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially adversely affect our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early stage clinical trials.

We expect to develop our current or future product candidates in combination with other therapies, which exposes us to additional risks.

In October 2024, we announced that we are collaborating with the MD Anderson Cancer Center and the Memorial Sloan Kettering Cancer Center to support an investigator-initiated Phase 1b study, which is designed to assess the safety, tolerability, pharmacokinetics, and preliminary efficacy of rezatapopt monotherapy in combination with azacitidine in R/R AML and MDS patients harboring a TP53 Y220C mutation. We intend to develop our current or future product candidates in combination with one or more other approved cancer therapies or therapies in development. Patients may not be able to tolerate rezatapopt or any of our future product candidates in combination with other therapies or dosing of rezatapopt or any of our future product candidates in combination with other therapies may have unexpected consequences. Even if any of our current or future product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

We may also evaluate our current or future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or other comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the

therapies we choose to evaluate in combination with rezatapopt or any future product candidate, we may be unable to obtain approval of or successfully market any one or all of the current or future product candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could materially adversely affect our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be adversely affected, which could materially adversely affect our business, financial condition and results of operations.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

The use of precision medicines as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Various factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- our ability to demonstrate the advantages of our product candidates over other cancer medicines;
- the prevalence and severity of any side effects;

- the prevalence and severity of any side effects for other precision medicines and public perception of other precision medicines;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates receive regulatory approval but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

In addition, although our product candidates differ in certain ways from other precision medicine approaches, serious adverse events or deaths in other clinical trials involving precision medicines, even if not ultimately attributable to our product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates and a decrease in demand for any such product candidates.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would adversely affect our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may materially change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage

and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or future product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the 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. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our business, financial condition and results of operations, our ability to raise capital needed to commercialize product candidates and our overall financial condition.

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. Our inability to promptly obtain coverage and profitable reimbursement rates from third-party payors for any approved products that we develop could have a material adverse effect on our business, financial condition and results of operations, our ability to raise capital needed to commercialize products and our overall financial condition.

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. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Additionally, we may develop companion diagnostic tests for use with our product candidates. We, or our collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. Even if we obtain regulatory approval or clearance for such companion diagnostics, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. Medicare reimbursement methodologies, whether under Part A, Part B or clinical laboratory fee schedule may be amended from time to time, and we cannot predict what effect any change to these methodologies would have on any product candidate or companion diagnostic for which we receive approval. Our inability to promptly obtain coverage and adequate reimbursement from both third-party payors for the companion diagnostic tests that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA or other comparable foreign regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA or other comparable foreign regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue arrangements with third-party sales, marketing and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain such arrangements on favorable terms or if at all, or if we are able to do so, that these third-party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

Risks Related to Regulatory Process and Other Legal Compliance Matters

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including our lead product candidate rezatapopt, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for each targeted indication.

Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval.

The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, 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 IND, NDA or equivalent application types, may cause delays in the approval or rejection of an application. For example, the FDA issued various COVID-19 related guidance documents for trial sponsors and manufacturers during the COVID-19 national and public health emergencies, and may do so in response to other public health concerns in the future.

FDA's Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to help develop and implement strategies to support approvals in the early clinical setting, among other goals. How the FDA plans to implement these goals and their impact on specific clinical programs and the industry are unclear. 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 data. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, including our Phase 1/2 clinical trial design for rezatapopt, or require us to modify the design of our clinical trials, including additional procedures and contingency measures in response to the COVID-19 pandemic or as required by clinical sites, IRBs, FDA or other regulatory authorities;
- the FDA or comparable foreign regulatory authorities may disagree with our tumor-agnostic development strategy;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication, or a related companion diagnostic is suitable to identify appropriate patient populations;
- the FDA or other comparable regulatory authorities may fail to approve companion diagnostic tests that may be required for our product candidates;

- 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, or that a product candidate has an acceptable benefit-risk ratio for its proposed indication;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures, specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- our third-party contractors may fail to comply with regulatory requirements or otherwise fail or be unable to adequately perform their obligations to allow for the conduct of our planned or future clinical studies; 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.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would materially adversely affect our business, results of operations and prospects.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, 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.

Although we have received orphan drug designation (ODD) for rezatapopt, we may not be able to maintain the benefits associated with ODD, such as orphan drug exclusivity and, even if we do, that exclusivity may not prevent the FDA or other comparable foreign regulatory authorities from approving competing products.

As part of our business strategy, we sought and received ODD for rezatapopt for the treatment of TP53 Y220C positive ovarian cancer, fallopian tube cancer, and primary peritoneal cancer, and we may seek ODD for any eligible product candidates we develop in the future. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product 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 United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing and making available the drug will be recovered from sales in the United States. Our target indications may include diseases with large patient populations or may include orphan indications. However, there can be no assurances that we will be able to obtain orphan designations for our product candidates.

In the United States, ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has ODD subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the

FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity or if FDA finds that the holder of the orphan exclusivity has not shown that it can ensure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the product was designated. The applicable exclusivity period is 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for ODD or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain ODD for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained ODD for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety 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 or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process.

Further, in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an eligible disease. However, on January 24, 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. The Consolidated Appropriations Act of 2026, signed into law in February 2026, codified this longstanding FDA interpretation of the Orphan Drug Act, allowing the FDA to approve multiple versions of the same orphan drug for different subindications and subpopulations.

We may seek and fail to obtain or maintain breakthrough therapy or Fast Track designations for our current or future product candidates. Even if we are successful, such programs may not lead to a faster development or regulatory review process, and they do not guarantee we will receive approval for any product candidate. We may also seek to obtain accelerated approval for one or more of our product candidates but the FDA may disagree that we have met the requirements for such approval.

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. In October 2020, we received Fast Track designation for rezatapopt from the FDA. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular future product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Further, even though we have received Fast Track designation for rezatapopt, 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 program.

We may also 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. Like Fast Track designation, breakthrough therapy designation 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 a 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.

Separately from Fast Track or breakthrough therapy designation, we may seek accelerated approval for one or more of our product candidates. A product candidate intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval if it is determined to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-approval clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires pre-approval of promotional materials for accelerated approval products, once approved. We cannot guarantee that the FDA will agree any of our product candidates has met the criteria to receive accelerated approval, which would require us to conduct additional clinical testing prior to seeking FDA approval. Even if any of our product candidates received approval through this pathway, the required post-approval confirmatory clinical trials may fail to verify the predicted clinical benefit of the product, and we may be required to remove the product from the market or amend the product label in a way that adversely impacts its marketing. In addition, the Food and Drug Omnibus Reform Act made several changes to the FDA's authorities and its regulatory framework, including reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

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. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from 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 establishing and maintaining 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. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be adversely affected.

Preclinical and clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

Our lead product candidate, rezatapopt, is in clinical development and all of our other product candidates are in discovery or preclinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and a failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Our preclinical studies and clinical trials may not be successful.

We cannot be certain that our preclinical study and clinical trial results will be sufficient to support regulatory approval of our product candidates, or that FDA or other comparable regulatory authorities will find our planned clinical strategy to be acceptable. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Failure or delay can occur at any time during the clinical trial process.

Additionally, our rezatapopt Phase 1/2 clinical trial is, and other clinical trials we conduct in the future may be, open-label in study design and conducted at a limited number of clinical sites on a limited number of patients. 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 typically, 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. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new 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.

We may experience delays in obtaining the FDA’s authorization to initiate clinical trials, completing ongoing clinical trials of rezatapopt and preclinical studies of our other product candidates and initiating our planned preclinical studies and clinical trials. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will begin on time, not require redesign, enroll an adequate number of research subjects or patients on time, or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the availability of financial resources to commence and complete clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing with our tumor-agnostic development strategy;
- delays in obtaining regulatory approval or authorization to commence a clinical trial, including delays or issues relating to any future companion diagnostics which we may develop;

- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB or ethics committee approval at each clinical trial site;
- recruiting an adequate number of suitable patients to participate in a clinical trial;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate, for example, if we experience delays or challenges in identifying patients with the mutations required for our clinical trials, we may have to reimburse sites for genomic sequencing costs in order to encourage sequencing of additional patients;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial;
- having third-party contractors fail to complete their obligations in a timely manner or failing to comply with applicable regulatory requirements;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient product supply of product candidate for use in preclinical studies or clinical trials from third-party suppliers.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or other regulatory authorities. Such authorities may 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 trial 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, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

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

If we experience delays in the completion, or termination, of any preclinical study or clinical trial of our product candidates, the commercial prospects of our product candidates may be adversely affected, and our ability to generate revenue from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our preclinical studies or clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may materially adversely affect our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also

ultimately lead to the denial of regulatory approval of our product candidates. If one or more of our product candidates generally prove to be ineffective, unsafe or commercially unviable, our entire pipeline and platform would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

In addition, the FDA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, such as those implemented by the Department of Government Efficiency, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. In view of the Loper Bright Enterprises v. Raimondo decision, this landmark Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies. Additionally, changes in the leadership of the FDA and other federal agencies under the current administration may also lead to new policies and changes in the regulations and operations of the FDA, which may impact our clinical development plans.

Changes in funding or disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns, government shutdown, or a lapse of U.S. government appropriations could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, 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 and other events that may otherwise affect the FDA's ability to perform routine functions. Changes in the leadership of the FDA and other federal agencies under the current administration, including return-to-office policy, hiring freeze, layoffs, government shutdown, or a lapse of U.S. government appropriations may also lead to changes in the operations of the FDA, which may have a material impact on the industry. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and 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.

If a prolonged government shutdown, furlough or other disruption occurs, including delays or disruptions due to travel restrictions, foreign COVID-19-related policies, staffing shortages or public health reasons, or if global health or other concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities in a timely manner, 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, in our operations as a public company, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Even if we receive regulatory approval of our product candidates, we will be subject to extensive 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.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries.

Following potential approval of any of our current or future product candidates, the FDA or other comparable regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time-consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA may also require a risk

evaluation and mitigation strategy, or REMS, in order to approve our product candidates, which could entail requirements for 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, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements, GLP requirements and good clinical practice, or GCP, requirements, for any clinical trials that we conduct post-approval. 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, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning or untitled 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 revocation 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.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. The U.S. Supreme Court's overturn of the Chevron doctrine in Loper Bright Enterprises v. Raimondo may invite various stakeholders to bring lawsuits against the FDA and other federal agencies to challenge longstanding decisions and policies, which could lead to uncertainty in the industry. Further, changes to the leadership of the FDA and other federal agencies under the current administration may result in changes in agencies' funding, operations, and policies, which may impact our clinical development plans and timelines. 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. FDA's "real-time" release of newly issued Complete Response Letters associated with withdrawn or abandoned applications, if applicable to any of our product candidates, can materially impact our competitive advantage and intellectual property. To the extent any current or future executive or legislative actions impose significant changes in or burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities, such as implementing regulations through rulemaking, issuance of guidance, and agency review and approval of marketing applications on a timely basis, our business and clinical development plans could be negatively impacted. If we, as well as our contractors, are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or are not able to maintain regulatory compliance, we may be delayed in obtaining regulatory approval, lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates, if approved, and generate revenue.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Affordable Care Act, or ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjected biological products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts 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.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the current administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Other legislative changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2032, unless additional Congressional action is taken.

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 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 federal level, for example, the American Rescue Plan Act of 2021 eliminated the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries,

including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, CMS selected 10 high-cost Medicare Part D drugs in 2023 and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act of 2022 are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the current administration us and the pharmaceutical industry as a whole is unclear.

Further, the current administration has issued executive orders focused on decreasing prescription drug prices. Government contracts with pharmaceutical companies and other government measures that use most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the United States, or that increase generic and biosimilar drug entry sooner than expected, can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future. We cannot predict the full impact of the executive orders focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the current administration related to drug pricing, drug supply chain and manufacturing in the United States. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

At the state level, individual states are increasingly aggressive 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. For example, FDA has authorized the state of Florida to develop Section 804 Importation Programs to import certain prescription drugs from Canada for a limited period, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. 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. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. 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 products;
- our ability to obtain coverage and reimbursement approval for a product;
- 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.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and material adversely affect to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by these parties, 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 governmental 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, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

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. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. 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. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- federal civil and criminal false claims laws, including the False Claims Act, or FCA, which can be enforced through civil "qui tam" or "whistleblower" actions, and civil monetary penalty laws, 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. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996, or 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 HIPAA without actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payment Sunshine Act, created under the ACA and its implementing regulations, which require applicable 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 covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other non-physician healthcare providers (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as well as ownership and investment interests held by physicians, as defined by law, and their immediate family members;

- 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.

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, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock or stock options for services provided to us and may be in the position to influence the ordering of or use of our product candidates, if approved, may 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are 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, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant 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.

Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

In connection with our clinical trials or enrollment of patients in any future clinical trials, we will be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European activities. Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated.

In the United States, most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations. HIPAA 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, or 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.

In addition, certain states have enacted additional laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. In November 2020, California passed the California Privacy Rights Act, or CPRA, which amends and expands the CCPA. Although the CCPA includes exemptions for certain clinical trial data, the law may increase our compliance costs and potential liability with respect to other personal information. The CCPA and CPRA may impact our business activities and

exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Further, national security concerns or changing geopolitical tensions could spur regulations that limit our ability to transfer certain types of data abroad. For example, the Department of Justice issued a final rule which took effect in April 2025 that places limitations, and in some cases prohibitions, on certain transfers of sensitive personal data to business partners located in China and other designated countries, or with other specified links to China and other designated countries. These rules also may broadly require us to extract promises from other third-party service providers that they will not transfer data we share with them onward to parties linked to countries of concern.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could materially adversely affect our business, financial condition and results of operations. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could adversely affect our business.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations may also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these 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. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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

We may be subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, foreign investment and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, we may be subject to U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, foreign investment and other trade laws and regulations, which are collectively referred to as Trade Laws. Anti-bribery and anti-corruption laws prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector.

We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Our products candidates and technology, in some cases, may be subject to export control laws and regulations, including the Export Administration Regulations administered by the U.S. Department of Commerce, and our product candidates, technology, and activities are subject to trade and economic sanctions, including those administered by the U.S. Treasury Department's Office of Foreign Assets Control, or OFAC. As such, licenses and notices may be required to export, import or re-export our product candidates or technology to certain countries and end users and for certain end uses. The process for obtaining necessary licenses and making required notices may be time-consuming or unsuccessful, potentially causing delays in sales or losses of sales opportunities. Export controls and sanctions are complex and dynamic regimes and monitoring and ensuring compliance can be challenging. Any failure to comply with these regimes could subject us to both civil and criminal penalties, including substantial fines, possible incarceration of responsible individuals for willful violations, possible loss of our export or import privileges, and reputational harm. In addition, investigating or defending against any such allegations, actions or investigations will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees.

We also may be subject to review under U.S. or other national-security or foreign-investment laws and regulations when foreign persons invest in us or when we engage in certain cross-border transactions. Such review may delay or prevent proposed investments or transactions, impose material conditions or require divestiture, and failure to comply with or to obtain required clearance could have a material adverse effect on our business, financial condition and results of operations.

Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our Chief Executive Officer and President, our Chief Financial Officer, our Chief Development Officer and our General Counsel and Chief Operating Officer. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could materially adversely affect our business, financial condition and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be adversely affected.

Additionally, we rely on our founders, members of our board of directors, and other scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. These advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are unable to maintain consulting relationships with our scientific founders or if they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be materially adversely affected.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of March 6, 2026, we had 54 full-time employees, including 41 employees engaged in research and development activities. In order to successfully implement our development and commercialization plans and strategies, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and other comparable foreign regulatory agencies' review process for rezatapopt and any future product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize rezatapopt and future product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of rezatapopt and any future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize rezatapopt and future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems, and those of our third-party CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from

service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. We cannot assure you that our data protection efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties, will prevent significant breakdowns or breaches in systems or other cyber incidents that cause loss, destruction, unavailability, alteration or dissemination of, or damage to, our data that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, data (including trade secrets or other confidential information, intellectual property, proprietary business information and personal information), which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Notifications and follow-up actions related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security incident were to result in a loss, destruction or alteration of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in or, failure or security breach of our systems or third-party systems where information important to our business operations or commercial development is stored. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

Business disruptions could materially adversely affect our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CMOs and other contractors, consultants and third parties could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, pandemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously adversely affect our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited.

As of December 31, 2025, we had federal and state net operating loss, or NOL, carryforwards of $290.0 million and $109.3 million, respectively, and federal and state research and development credit carryforwards of approximately $14.1 million and $2.0 million, respectively. Our federal NOLs generated in tax years beginning before January 1, 2018 are only permitted to be carried forward for 20 taxable years, and therefore could expire unused. Under the Tax Cuts and Jobs Act of 2017, or TCJA, as modified by the Coronavirus Aid, Relief, and Economic Stability Act, our federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but for taxable years beginning after December 31, 2020, the deductibility of federal NOLs generated in tax years beginning after December 31, 2017 is limited to 80% of current year taxable income. Our federal NOL carryforwards will begin to expire in 2033, and our federal research and development credit carryforwards will begin to expire in 2034, if not fully utilized. Some of our state NOL carryforwards and state credit carryforwards may also expire unused.

In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change" (generally defined as a cumulative change (by value) in the corporation's ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change taxable income or tax liabilities may be limited. Similar rules or other limitations may apply under state tax laws. We have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. At this time, we have not conducted any studies to determine the annual limitations, if any, that resulted from such an ownership change. Our ability to utilize our NOLs and certain other tax attributes could be limited by an ownership change as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations. There is also a risk that due to federal or state regulatory changes, such as suspensions on the use of NOLs, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Changes in tax laws or regulations that are applied adversely to us could have a material adverse effect on our business, financial condition and results of operations.

New income, sales, use or other tax laws or regulations could be enacted at any time, which could affect our tax profile and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the TCJA eliminated the option to deduct research and development expenditures currently and requires taxpayers to capitalize and amortize such expenditures over five or 15 years pursuant to Section 174 of the Code, beginning in 2022. On July 4, 2025, the U.S. federal tax legislation commonly referred to as the One Big Beautiful Bill Act, or the OBBB Act, was enacted, which makes a number of changes to U.S. federal income tax law, including permanently suspending the
requirement to capitalize and amortize domestic research and development expenditures and permitting such deductions on a current basis. We are currently evaluating the full impact of the OBBB Act on us. Further, the Inflation Reduction Act of 2022, among other changes, imposes a one-percent excise tax on stock repurchases made on or after January 1, 2023. Any further changes in tax laws or regulations that are applied adversely to us could have a material adverse effect on our business, financial condition and results of operations.

A portion of our chemistry-based product development and sourcing of certain manufacturing raw materials for our product candidates takes place in China through third-party manufacturers. A significant disruption in the operation of those manufacturers, a trade war or political unrest in China could materially adversely affect our business, financial condition and results of operations.

We currently contract certain product development and manufacturing operations to third parties outside the United States, including in China, and we expect to continue to use such third-party manufacturers for such product candidates. Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes could impair our ability to operate our business on a day-to-day basis and to continue our development of our product candidates. Furthermore, since these manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China. For example, a trade war could lead to tariffs on the chemical intermediates and active pharmaceuticals ingredients we use that are manufactured in China. Beginning in February 2025, the United States imposed an additional 10-20% tariff on most imports from China. Since April 2025, the United States and China have imposed significant additional reciprocal tariffs of 10-125% on a large proportion of imports from the respective trading partner; though currently these reciprocal tariffs are limited to 10% through November 2026, both countries may continue to pursue new and/or retaliatory tariff and trade policies as bilateral trade negotiations progress. Moreover, the United States also implemented additional reciprocal tariffs of 10% on the import of a large proportion of imports from most U.S. trading partners beginning in April 2025, and which increased to elevated, country-specific rates for certain trading partners beginning in August 2025. Although certain products have been exempted from some of these reciprocal tariffs, including many pharmaceutical products, these policies are subject to change. In addition, the United States initiated an investigation into pharmaceuticals and pharmaceutical products in April 2025, the results of which could result in additional tariffs on pharmaceutical and pharmaceutical products under authorities provided in Section 232 of the Trade Expansion Act of 1962; whether, when, which products, and at what level such items may become subject to these additional tariffs is uncertain. Though announcements in September 2025 indicated that a 100% Section 232 tariff on branded or patented pharmaceutical products would be forthcoming, with a possible exemption for manufacturers who have broken ground or begun construction on U.S. manufacturing facilities, this policy has not been formalized in an executive action and details and timing are currently unclear. These and other changes in tariffs and trade policies of the United States or its trading partners may affect our products or our customers, and could materially adversely affect our business, financial condition and results of operations. Any recall of the manufacturing lots or similar action regarding our product candidates used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in China.

In addition to the use of tariffs and other traditional trade tools, the U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. In particular, the U.S. has made or considered making a broad set of trade-related or security-related policy changes with respect to specific counterparty countries, most significantly China, to create various limitations on cross-border operations. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, financial condition, and results of operations would be materially adversely affected.

Risks Related to Reliance on Third Parties

We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners to conduct and support our preclinical studies and clinical trials under agreements with us. We are continuing to build our internal chemistry, manufacturing and controls, biology and preclinical development capabilities to supplement activities conducted by third parties on our behalf. As part of this personnel build out, we may incur additional costs or experience delays in engaging directly with other third-party CROs and CMOs.

We expect to have to negotiate budgets and contracts with CROs, trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with pharmaceutical product produced under cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our product candidates. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be adversely affected, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or on third parties to manufacture our product candidates, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture our product candidates. We have not yet caused our product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates. We will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates and we may not be able to do so on favorable terms. We have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other comparable foreign regulatory authorities following inspections that will be conducted after we submit an application to the FDA or other comparable foreign regulatory authorities. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially adversely affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, if any third-party manufacturers on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially adversely affected.

Our anticipated reliance on a limited number of third-party manufacturers exposes us to a number of risks, including the following:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must inspect any manufacturers for cGMP compliance as part of our marketing application;
- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates;
- our third-party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards and we have no control over third-party manufacturers' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- our third-party manufacturers could breach or terminate their agreements with us;

- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel.

Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on our company until deficiencies are remedied.

We currently, and may in the future, depend on single-source suppliers for some of the ingredients, components and materials used in, and the manufacturing processes required to develop, our product candidates.

We currently, and may in the future, depend on single-source suppliers for some of the ingredients, components and materials used in, and manufacturing processes required to develop, our product candidates. There are, for certain of these components, relatively few alternative sources of supply and there is limited need for multiple suppliers at this stage of our business. We cannot ensure that these suppliers or service providers will remain in business, have sufficient capacity or supply to meet our needs or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of raw materials, ingredients, components, key processes and finished goods exposes us to several risks, including disruptions in supply, price increases or late deliveries. These suppliers may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single-source supplier or service provider could lead to supply delays or interruptions which would materially adversely affect our business, financial condition and results of operations.

If we have to switch to a replacement supplier, the manufacture and delivery of our product candidates may be interrupted for an extended period, which could materially adversely affect our business. Establishing additional or replacement suppliers for any of the components or processes used in or for our product candidates, if required, may not be accomplished quickly and would create increased cost. If we are able to find a replacement supplier, the replacement supplier would need to be qualified, would need to process our technology transfer and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single-source ingredients, components and materials used in our products, any interruption or delay in the supply of ingredients, components or materials or our inability to obtain ingredients, components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our product candidates.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure by us or our third-party manufacturers to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce our products either at our own facility or at a third party's facility, we will need to comply with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of our precision medicines as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our precision medicines for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

We may, in the future, form or seek collaborations or strategic alliances or enter into licensing arrangements, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We may, in the future, form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into future collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into future collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

If conflicts arise between us and our future 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 future corporate or academic collaborators 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. Future collaborators or strategic partners may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. 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 our current or future product candidates. Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient

resources to the development and commercialization of products. Any of these developments could adversely affect our product development efforts.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and/or acquire intangible assets that could result in significant future amortization expense.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient patent and other intellectual property protection for our product candidates and technology, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any product candidates we may develop.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. We will only be able to protect our product candidates, proprietary technologies and their uses from unauthorized use by third parties to the extent that valid and enforceable patents or trade secret protections cover them. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Composition-of-matter patents on the active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. 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 products 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 these 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.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own may fail to result in issued patents in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability, inventorship or scope thereof. Such a challenge may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. This will require us to be cognizant of the time from invention to filing of a patent application.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially-viable terms, then we may not be able to launch our product. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, and this scenario could materially adversely affect our business, financial condition and results of operations.

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to protect our intellectual property rights throughout the world.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates. These candidates include rezatapopt and others, their respective components, formulations, methods used to manufacture them and methods of treatment. Our commercial success will also depend on successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Our pending and future patent applications may not result in issued patents that protect our technology or products, in whole or in part. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies.

If we delay in filing a patent application, and a competitor files a patent application on the same or a similar technology before we do, we may face a limited ability to secure patent rights. We may not be able to patent the technology at all. Even if we can patent the technology, we may be able to patent only a limited scope of the technology, and the limited scope may be inadequate to protect our products, or to block competitor products that are similar or adjacent to ours. Our earliest patent filings have been published. A competitor may review our published patents and arrive at the same or similar technology advances for our products as we developed. If the competitor files a patent application on such an advance before we do, then we may no longer be able to protect the technology, we may require a license from the competitor, and if the license is not available on commercially-viable terms, then we may not be able to launch our product.

In the future we may in-license intellectual property from licensors. We may rely on these licensors to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be in-licensed. For example, we cannot be certain that such activities by licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. For example, our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties. Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. These pharmaceutical compounds may be covered by intellectual property rights held by others. We may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates. These diagnostic test or tests may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would adversely affect our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, and may allow our competitors access to the same technologies licensed to us.

Additionally, we may sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. These institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive for commercializing our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

During the course of business we have decided not to pursue certain products or processes and have terminated certain corresponding intellectual property license agreements, and we may do so again in the future. If it is later determined that our activities or product candidates infringe this intellectual property we may be liable for damages, enhanced damages or subjected to an injunction, any of which could have a material adverse effect on our business.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years, patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries 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 as the laws of the United States. 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 be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, the U.S. Patent and Trademark Office, or USPTO, might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Even if our patent applications issue as patents, they may not issue in a form that will 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 owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, we may become involved in opposition, interference, derivation, *inter partes* review or other proceedings challenging our patent rights, and the outcome of any proceedings are highly uncertain. Such challenges may result in the patent claims of our owned or in-licensed patents being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors or use such information to compete with us. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be adversely affected and this would have a material adverse effect on our business.

If any of our patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates. Likewise, our current patents covering our proprietary technologies and our product candidates are expected to expire through 2037, without taking into account any possible patent term adjustments or extensions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects.

Filing, prosecuting and defending patents on 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. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other countries. Competitors may use our technologies in countries where we have not obtained patent protection to develop their own products and further, may infringe our patents in territories where we have patent protection, but enforcement is not as strong as in the United States. 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.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain countries. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement or protection of patents, trade secrets and other intellectual property, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign countries could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could 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. We have contract research and manufacturing relationships with contract organizations that operate in certain countries that are at heightened risk of theft of technology, data and intellectual property through direct intrusion by private parties or foreign actors, including those affiliated with or controlled by state actors. Accordingly, our efforts to protect or enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment (such as annuities) 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 noncompliance 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-compliance 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. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Any issued patents we may own covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO.

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the U.S. and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have

conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable.

With respect to challenges to the validity of our patents, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

We may become involved in lawsuits or litigation at the USPTO to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our future licensors is threatened, it could dissuade other companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

We may be required to protect our patents through procedures created to attack the validity of a patent at the USPTO. The USPTO hears post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO 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 possibility of post-grant proceedings could have a material adverse effect on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates 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. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new 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 sufficient rights to exclude others from commercializing product candidates similar or identical to ours for a meaningful amount of time, or at all.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union and certain other countries. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be expected, and our competitive position, business, financial condition, results of operations and prospects could be materially adversely affected.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate. Any of the foregoing could adversely affect our competitive position, business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase

the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. United States Congress has in recent years considered legislation to reduce the term of certain drug patents in order to ease generic entry and increase competition. Evolving judicial interpretation of patent law could also adversely affect our business. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, 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 we might obtain in the future.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Also, former employees may become employed by competitors who develop similar technology, and could assist the competitor in designing around our patents. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our patents, trade secrets or other 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, intellectual property that is important to 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 and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We use and will continue to use registered and/or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among 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 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. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain. Defending against such

lawsuits will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our product candidates infringe the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to: infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business; substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees; a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us; however, the third party is not required to grant the license; if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and redesigning our product candidates or processes so they do not infringe; redesign may not be possible or may require substantial monetary expenditures and time.

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

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office, or EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non-competition or non-solicitation agreements with our competitors or their former employers.

As is common in the biotechnology and pharmaceutical industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

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 licensors, we could lose license rights that are important to our business.

We may in the future enter into license agreements with third parties under which we receive rights to intellectual property that are important to our business. These intellectual property license agreements may impose on us various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

We may also in the future enter into license agreements with third parties under which we are a sublicensee. If our sublicensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize our product candidates incorporating the relevant intellectual property.

We may need to obtain licenses in the future from third parties to advance our research or allow commercialization of our product candidates, and we cannot provide any assurances that there are no third-party patents which might be enforced against our product candidates in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may 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;

- whether and the extent to which our technology and processes infringe on 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 with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- 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.

If disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business.

In addition, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place.

Risks Related to Ownership of Our Common Stock

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors include:

- the results of our ongoing, planned or any future preclinical studies, clinical trials or clinical development programs;
- the commencement, enrollment, or results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results or delays in preclinical studies and clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial, including due to the suspension of a clinical trial by the FDA or other regulatory authorities;
- any delay in our regulatory filings or any adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers or our manufacturing plans;
- our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;

- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to intellectual property or proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property or stockholder litigation;
- the impact of any natural disasters or public health emergencies;
- general economic, political, industry and market conditions, including the Ukraine-Russia war and the conflict in the Middle East, the impact of other disruptions resulting from public health epidemics, macroeconomic events such as future changes in trade regulations, tariff structures, global supply chain challenges, elevated inflation and interest rates and monetary policy changes (including the impact of changes to U.S. federal income tax law), instability in the global banking system; and
- other events or factors, many of which are beyond our control.

The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and adverse impact on the market price of our common stock.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In addition, broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management’s attention and resources, which would materially adversely affect our business, financial condition and results of operation.

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

Prior to the closing of our initial public offering in September 2020, there was no public trading market for our common stock. Although our common stock is listed on the Nasdaq Global Select Market, the market for our shares has demonstrated varying levels of trading activity. Furthermore, an active trading market for our common stock may not be sustained in the future. The lack of an active market may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable may reduce the market value of their shares and may impair our ability to raise capital.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. We do not have any control over these analysts. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. 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 may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships, alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

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 intend to sell shares, could reduce the market price of our common stock.

We do not intend to pay dividends on our capital stock, so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our capital stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our capital stock. Any return to stockholders will therefore be limited to any appreciation in the value of their stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan (also known as a "poison pill");
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware, or DGCL, prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

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

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction):

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and

- any action asserting a claim against us that is governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, or Securities Act, the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find these types of provisions to be inapplicable or unenforceable, and if a court were to find the exclusive forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could materially adversely affect our business.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would materially adversely affect our business and the trading price of our common stock.

We are subject to Section 404 of the Sarbanes-Oxley Act and the related rules of the SEC and Nasdaq, which, among other things, require that we maintain effective internal control over financial reporting. In addition, Section 404 requires our management to report on the effectiveness of our internal control over financial reporting. We are also required to disclose changes made in our internal controls and procedures on a quarterly basis.

The requirements of these rules and regulations are difficult, time-consuming and costly, and place significant strain on our personnel, systems and resources. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we have expended and anticipate we will continue to expend significant resources, including accounting-related costs, and provide significant management oversight. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the Nasdaq Global Select Market.

Any testing by us conducted in connection with Section 404, or any subsequent testing, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. In addition, undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

If we are unable to assert that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC.

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.

We are subject to increased risk of securities class action litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could materially adversely affect our business.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current product candidates and any future product candidates and research-stage programs, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets;

- the timing and outcomes of clinical trials for our future product candidates, or competing product candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- competition from existing and potential future products that compete with our product candidates and any of our future product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of our product candidates;
- the level of demand for our future product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with our product candidates;
- our ability to commercialize our product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain future collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic and political environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity or availability of our information systems or any information residing therein.

We conduct periodic risk assessments to identify cybersecurity threats and assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include the identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems and safeguards in place to manage such risks.

Following these risk assessments, we re-design, implement, and maintain reasonable safeguards to minimize identified risks, reasonably address any identified gaps in existing safeguards, and regularly monitor the

effectiveness of our safeguards. We devote significant resources and designate high-level personnel, including our VP of Information Technology, who reports to our General Counsel & Chief Operating Officer, to manage the risk assessment and mitigation process.

As part of our overall risk management system, we monitor and test our safeguards and train our employees on these safeguards in collaboration with management. Personnel at all levels and departments know our cybersecurity policies through training. Random attack simulations are conducted monthly to familiarize all personnel with various phishing methods with positive reinforcement on identifying and reporting suspicious content to the IT Department.

We engage third parties like a penetration testing firm and our managed service provider in connection with our risk assessment processes. These service providers assist us in identifying vulnerabilities to design and implement, suggesting remediation of our cybersecurity policies and procedures, as well as monitor and test our safeguards. We require each third-party service provider to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect our company.

For additional information regarding whether any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect our company, including our business strategy, results of operations, or financial condition, please refer to "Item 1A. Risk Factors," in this Annual Report on Form 10-K, including the risk factors entitled "Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operation."

Governance

One of the key functions of our board of directors is oversight of our risk management process, including risks from cybersecurity threats. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers manage the material risks we face. Our board of directors administers its cybersecurity risk oversight function directly as a whole and through the audit committee.

Our VP of Information Technology, and our management committee on cybersecurity, which includes our audit committee, are primarily responsible for assessing and managing our material risks from cybersecurity threats. The VP of Information Technology has twenty years of experience in IT on-premise and cloud infrastructure, enterprise applications, and operations across large and mid-size life science companies with a focus on IT controls for compliance and security.

Our VP of Information Technology oversees our cybersecurity policies and processes, including those described in "Risk Management and Strategy" above. The processes by which our VP of Information Technology or department designee are informed about and monitor the prevention, detection, mitigation and remediation of cybersecurity incidents include weekly assessments for all endpoints and real-time notifications from security solutions, which include a combination of cloud and client-based applications.

Our VP of Information Technology provides annual briefings to the audit committee regarding our cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like. Our audit committee provides regular updates to the board of directors on such reports. In addition, our VP of Information Technology or department designee provides annual briefings to the board of directors on cybersecurity risks and activities.

Item 2. Properties.

Our corporate headquarters is located at 400 Alexander Park Drive, Suite 301, Princeton, New Jersey 08540, where we sublease 14,201 square feet of office space. This lease term extends through February 2027.

We also sublease 3,205 square feet of laboratory space located at 311 Pennington Rocky Hill Road, Hopewell, New Jersey 08534. This lease term extends through 2029, and has a three-year extension option.

We believe that our current facilities are suitable and adequate for our current and near term conduct of our business operations and 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 legal proceedings arising in the ordinary course of our business. As of March 6, 2026, we were not a party to any legal matters or claims that, in the opinion of management, are likely to have a material effect on our business. In the future, we may become party to legal matters and claims in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows. Regardless of outcome, litigation, or other legal proceedings can have an adverse impact on us because of legal fees and settlement costs, diversion of management resources, and other factors.

Item 4. Reserved.

PART II

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

Market Information

Our common stock has been listed on the Nasdaq Global Select Market under the symbol "PMVP" since September 25, 2020. Prior to that date there was no public trading market for our common stock.

Holders

As of March 6, 2026, there were approximately 6 holders of record of our common stock. We believe the actual number of stockholders is greater than this number of record holders. The approximate number of holders includes holders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose share may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors might deem relevant.

Recent Sales of Unregistered Securities

There were no unregistered sales of our equity securities during the fiscal year ended December 31, 2025.

Use of Proceeds

Our initial public offering of our common stock was effected pursuant to a registration statement on Form S-1 (File No. 333-248627), which was declared effective by the SEC on September 24, 2020. There has been no material change in the planned use of proceeds from our initial public offering as described our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on September 24, 2020.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

None.

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 the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed in "Part I, Item 1A. Risk Factors" and in other parts of this Annual Report on Form 10-K.

A discussion of our financial performance for the year ended December 31, 2025 as compared to the year ended December 31, 2024 appears below under the captions "Results of Operations" and "Liquidity and Capital Resources." A discussion of our financial performance for the year ended December 31, 2024 compared to the year ended December 31, 2023 can be found in our Annual Report filed on Form 10-K, in the "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations", under the same captions, filed with the SEC on March 3, 2025, which is available free of charge on the SEC's website at *www.sec.gov* and our Investor Relations website at *ir.pmvpharma.com/financial-information/sec-filings*. These website addresses are intended to be inactive, textual references only. None of the materials on, or accessible through, these websites are part of this report or are incorporated by reference herein.

Overview

We are a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53. p53 is a well-defined tumor suppressor protein known as the "guardian of the genome," and normal, or wild-type, p53 has the ability to eliminate cancer cells. However, mutant p53 proteins can be misfolded and lose their wild-type tumor suppressing function. These p53 mutations are found in approximately half of all cancers. The field of p53 biology was established by our co-founder Dr. Arnold Levine when he discovered the p53 protein in 1979. We have leveraged more than four decades of research experience and developed unique insights into p53 to create a precision oncology platform designed to generate selective, small molecule, tumor-agnostic therapies that structurally correct specific mutant p53 proteins to restore their wild-type function. We are deploying our precision oncology platform to target p53 mutations and other p53-related cancers.

Since our formation in March 2013, we have devoted substantially all of our time and efforts to performing research and development activities and raising capital. We are not profitable and have incurred losses in each year since our inception. Our net losses were $78.0 million, $58.7 million, and $69.0 million for the years ended December 31, 2025, 2024, and 2023, respectively. As of December 31, 2025, we had an accumulated deficit of $446.7 million. We do not currently have any product candidates approved for sale, and we continue to incur significant research and development and general administrative expenses related to our operations. We initiated a Phase 1/2 clinical trial, PYNNACLE, in October 2020 for our lead product candidate, rezatapopt. Our strategy is to seek approval under an accelerated pathway, and we believe the Phase 2 portion of the PYNNACLE clinical trial has the potential to serve as a pivotal study. In October 2020, we were granted FDA Fast Track designation of rezatapopt for the treatment of patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation. In July 2023, we met with the FDA at an End of Phase 1 meeting where alignment was obtained on the recommended Phase 2 dose and key elements of the single arm, Phase 2 registrational portion of the PYNNACLE study. In October 2023, we presented our updated Phase 1 clinical data for rezatapopt at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics Annual Meeting. We dosed our first patient in the pivotal Phase 2 monotherapy portion of the PYNNACLE study in the first quarter of 2024. In September 2025, we announced interim data from the Phase 2 pivotal portion of the PYNNACLE clinical trial, which was updated in October 2025 in a late-breaking oral presentation and poster presentation at the 2025 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics Meeting. In March 2026, rezatapopt was granted ODD from the FDA for the treatment of TP53 Y220C positive ovarian cancer, fallopian tube cancer, and primary peritoneal cancer. We plan to submit a New Drug Application, or NDA, for the treatment of patients with platinum-resistant/refractory ovarian cancer harboring a TP53 Y220C mutation to the FDA for rezatapopt in the first quarter of 2027.

We expect that our operating expenses will increase significantly as we advance our product candidates through preclinical and clinical development, seek regulatory approval, and prepare for and, if approved, proceed to commercialization; acquire, discover, validate, and develop additional product candidates; obtain, maintain, protect,

and enforce our intellectual property portfolio; and hire additional personnel. We expect to continue to incur significant losses for the foreseeable future.

Our ability to generate product revenue will depend on the successful development, regulatory approval, and eventual commercialization of one or more of our product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through private or public equity or debt financings, collaborative, or other arrangements with corporate sources, or through other sources of financing. Adequate funding may not be available to us on acceptable 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, scale back or discontinue the development and commercialization of our product candidates.

We plan to continue to use third-party service providers, including clinical research organizations, or CROs, and contract manufacturing organization, or CMOs, to carry out our preclinical and clinical development and to manufacture and supply the materials to be used during the development and commercialization of our product candidates. We do not currently have a sales force.

Components of Results of Operations

Revenue

To date, we have not generated any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, or result in license agreements with third parties, we may generate revenue in the future from product sales or license agreements. However, there can be no assurance as to when we will generate such revenue, if at all.

Operating Expenses

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred to conduct research, such as the discovery and development of our product candidates as well as the development of future product candidates. Research and development expenses include personnel costs, including stock-based compensation expense, third-party contractor services, laboratory materials and supplies, and depreciation and maintenance of research equipment. We expense research and development costs as they are incurred.

We do not allocate our costs by product candidate or development program, as a significant amount of research and development expenses include compensation costs, materials, supplies, depreciation on and maintenance of research equipment, and the cost of services provided by outside contractors, which are not tracked by product candidate or development program. In particular, with respect to internal costs, several of our departments support multiple product candidate research and development programs, and therefore the costs cannot be allocated to a particular product candidate or development program. Substantially all of our research and development costs are associated with our lead product candidate, rezatapopt. We initiated our Phase 1/2 PYNNACLE clinical trial in October 2020, and on that date, we were granted FDA Fast Track designation of rezatapopt for the treatment of patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation. In October 2023, we presented our updated Phase 1 clinical data for rezatapopt at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics Meeting. In September 2025, we announced interim data from the Phase 2 pivotal portion of the PYNNACLE clinical trial, which was updated in October 2025 in a late-breaking oral presentation and poster presentation at the 2025 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics Meeting. In March 2026, rezatapopt was granted ODD from the FDA for the treatment of TP53 Y220C positive ovarian cancer, fallopian tube cancer, and primary peritoneal cancer. We plan to submit an NDA for the treatment of patients with platinum-resistant/refractory ovarian cancer harboring a TP53 Y220C mutation to the FDA for rezatapopt in the first quarter of 2027.

We expect our research and development expenses to increase substantially in absolute dollars in the future as we advance our product candidates into and through clinical trials and pursue regulatory approval of our product

candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors including: the safety and efficacy of our product candidates, clinical data, investment in our clinical program, the ability of any future collaborators to successfully develop our licensed product candidates, competition, manufacturing capability, and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects.

General and Administrative Expenses

General and administrative expenses include personnel costs, expenses for outside professional services and other allocated expenses. Personnel costs consist of salaries, bonuses, benefits, and stock-based compensation. Outside professional services consist of legal, accounting and audit services and other consulting fees. Allocated expenses consist of rent expense related to our office and research and development facilities. We have incurred expenses related to compliance with the rules and regulations of the SEC, and those of any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to increase our general and administrative expenses as we advance our product candidates through preclinical research and development, manufacturing, clinical development, and commercialization.

Interest Income, Net

Interest income, net, primarily consists of interest income from our interest-bearing cash, cash equivalents, and marketable securities, and interest costs related to accretion and amortization of discounts and premiums on marketable securities.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations (in thousands):

	Year Ended December 31,		
Statement of operations data:	**2025**	**2024**	**Change**
Operating expenses:			
Research and development	$ 69,877	$ 58,527	$ 11,350
General and administrative	16,329	26,921	(10,592)
Total operating expenses	86,206	85,448	758
Loss from operations	(86,206)	(85,448)	(758)
Other income (expense):			
Interest income, net	6,337	10,655	(4,318)
Other income (expense), net	(45)	(16)	(29)
Total other income (expense)	6,292	10,639	(4,347)
Loss before (benefit) provision for income taxes	(79,914)	(74,809)	(5,105)
(Benefit) provision for income taxes	(2,172)	(16,100)	13,928
Net loss	$ (77,742)	$ (58,709)	$ (19,033)

Research and Development Expenses

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

Statement of operations data:	Year Ended December 31, 2025	2024	Change
Research	$ 5,232	$ 5,914	$ (682)
Development	48,370	35,295	13,075
Personnel related	13,668	13,662	6
Stock-based compensation	2,607	3,656	(1,049)
Total	$ 69,877	$ 58,527	$ 11,350

Research and development expenses were $69.9 million for the year ended December 31, 2025, compared to $58.5 million for the year ended December 31, 2024. The increase of $11.4 million was primarily due to the following:

- $13.1 million increase in development and personnel related expenses, largely driven by increased CRO costs for advancing our lead product candidate, rezatapopt, through the Phase 2 clinical trial; offset by
- $0.7 million decrease in research related costs driven by decreased pre-clinical CRO costs; and
- $1.0 million decrease for stock-based compensation.

General and Administrative Expenses

General and administrative expenses were $16.3 million for the year ended December 31, 2025, compared to $26.9 million for the year ended December 31, 2024. The decrease of $10.6 million was primarily due to the following:

- $7.7 million decrease in facility related costs due to the termination of our lease for our prior headquarters located at One Research Way in Princeton, New Jersey; and
- $0.4 million decrease in general and administrative consulting costs, $0.1 million decrease in director and officer insurance fees, and $2.4 million decrease in expenses for personnel related costs and stock-based compensation.

Interest Income, Net

Interest income, net, primarily consists of interest income from our interest-bearing cash, cash equivalents, and marketable securities and interest costs related to amortization of premiums and discounts on marketable securities. Interest income, net was $6.4 million for the year ended December 31, 2025, compared to $10.7 million for the year ended December 31, 2024. The decrease of $4.3 million was primarily due to the amount of, and reduction of interest rates with respect to, our cash investments in marketable securities and U.S. treasuries.

Liquidity and Capital Resources

Our financial condition is summarized as follows (in thousands):

	As of December 31,		
	2025	2024	Change
Financial assets:			
Cash and cash equivalents	$ 37,983	$ 40,876	$ (2,893)
Marketable securities – current	74,960	128,578	(53,618)
Marketable securities – noncurrent	—	13,843	(13,843)
Total financial assets	$ 112,943	$ 183,297	$ (70,354)
Working capital:			
Current assets	$ 115,227	$ 175,658	$ (60,431)
Current liabilities	11,415	14,370	(2,955)
Total working capital	$ 103,812	$ 161,288	$ (57,476)

Sources of Liquidity

Since our inception, we have not generated any revenue from any product sales or any other sources and have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. As of December 31, 2025, we had cash, cash equivalents, and marketable securities of $112.9 million and an accumulated deficit of $446.5 million. We have financed our operations primarily through issuance and sales of our equity securities.

On November 20, 2024 we filed a shelf registration statement on Form S-3 (File No. 333-283349) with the SEC and a prospectus supplement, which registered the offering, issuance and sale of up to $200,000,000 of various equity and debt securities and up to $113.8 million of common stock pursuant to an at-the-market equity offering program with Jefferies LLC, dated October 4, 2021, or the ATM Program. The SEC declared the registration statement effective on November 27, 2024. During the year ending December 31, 2025, we did not sell any shares of our common stock pursuant to the ATM Program. As of December 31, 2025, we had approximately $113.8 million remaining in gross proceeds available for future issuances of common stock under the ATM Program.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with CROs and other vendors to assist in the performance of our research and development activities and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments.

In September 2024, we signed two subleases, one for 14,201 square feet of office space at 400 Alexander Park Drive, Suite 301, in Princeton, New Jersey, to be used as our new headquarters, or the 400 Alexander Sublease, and the other for 3,205 square feet of office and laboratory space at 311 Pennington Rocky Hill in Hopewell, New Jersey, to be used for our new laboratory space, or the 311 Pennington Sublease. The 400 Alexander Sublease term extends until February 2027, and the 311 Pennington Sublease term extends until December 2029 and has a three-year extension option. Amounts related to future lease payments for 311 Pennington Sublease as of December 31, 2025, totaled $0.6 million with $0.1 million to be paid within the next 12 months. Amounts related to future lease payments for 400 Alexander Sublease as of December 31, 2025, totaled $0.4 million with $0.3 million to be paid within the next 12 months.

Plan of Operation and Future Funding Requirements

We use our capital resources primarily to fund operating expenses, mainly research and development expenditures. At this time, due to the inherently unpredictable nature of preclinical and clinical development, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval and commercialize our current product candidates or any future product candidates, if at all. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Due to our significant research and development expenditures, we have generated substantial operating losses in each period since inception. We have incurred an accumulated deficit of $446.5 million through December 31, 2025. We expect to incur substantial additional losses in the future. Our cash operating expenditures were $73.6 million in 2025 and $51.3 million in 2024. Based on our research and development plans, we expect that our cash, cash equivalents, and marketable securities balances as of December 31, 2025 will be sufficient to fund our planned operations until the end of the second quarter of 2027.

We have based this estimate on assumptions that may prove to be wrong, however, and we could use our capital resources sooner than we expect.

The timing and amount of our operating expenditures will depend largely on:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the timing and amount of milestone payments we may receive under any future collaboration agreements;
- our ability to maintain future licenses and research and development programs and to establish new collaboration and/or in-licensing arrangements;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the cost and timing of regulatory approvals; and
- our efforts to manage our office and laboratory headquarters, enhance operational systems and hire additional personnel to support development of our product candidates and satisfy our obligations as a public company.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to fund our operations and capital funding needs through equity and/or debt financing. We may also consider entering into collaboration arrangements or selectively partnering for clinical development and commercialization. The sale of additional equity would result in additional dilution to our stockholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations or our ability to incur additional indebtedness or pay dividends, among other items. If we raise additional funds through governmental funding, collaborations, strategic partnerships and 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 not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially and adversely affect our business, financial condition, results of operations and prospects.

Cash Flows

The following table summarizes our cash flows for the period indicated (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Cash used in operating activities	$ (73,577)	$ (51,282)	$ (55,657)
Cash provided by (used in) investing activities	70,172	53,352	(50,545)
Cash provided by (used in) financing activities	505	313	35,577
Impact of exchange rates on cash, cash equivalents, and restricted cash	7	(35)	34
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (2,893)	$ 2,348	$ (70,591)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2025, was $73.6 million, which consisted primarily of net loss of $77.7 million decreased by non-cash charges of $3.3 million and increased by a net change of $0.9 million in our net operating assets and liabilities. The non-cash charges primarily consisted of stock-based compensation of $5.9 million; offset by accretion of discounts on marketable securities of $2.8 million. The change in our net operating assets and liabilities was primarily due to a decrease in other assets and an increase in accrued expenses.

Net cash used in operating activities for the year ended December 31, 2024, was $51.3 million, which consisted primarily of net loss of $58.7 million decreased by non-cash charges of $9.0 million and decreased by a net change of $1.6 million in our net operating assets and liabilities. The non-cash charges primarily consisted of stock-based compensation of $8.9 million, depreciation of $1.1 million, and accretion of discounts on marketable securities of $5.4 million. The change in our net operating assets and liabilities was primarily due to an increase in operating lease liabilities and other assets and an increase in accrued expenses.

Investing Activities

Our investing activities provided $70.2 million of cash during the year ended December 31, 2025, which consisted primarily of maturities of marketable securities of $158 million, offset by purchases of marketable securities of $88.2 million.

Our investing activities provided $53.4 million of cash during the year ended December 31, 2024, which consisted primarily of maturities of marketable securities of $202 million, offset by purchases of marketable securities of $148.3 million, along with purchase of property and equipment of $0.7 million.

Financing Activities

Our financing activities provided $0.5 million of cash during the year ended December 31, 2025 which consisted of $0.5 million of proceeds from the exercise of stock options and issuance of common stock under the 2020 ESPP.

Our financing activities provided $0.3 million of cash during the year ended December 31, 2024 which consisted of $0.3 million of proceeds from the exercise of stock options and issuance of common stock under the 2020 ESPP.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and judgments that affect the amounts reported in those consolidated financial statements and accompanying notes. Although we believe that the estimates we use are reasonable, due to the inherent uncertainty involved in making those estimates, actual results reported in future periods could differ from those estimates.

We believe that the accounting policies described below involve a high degree of judgment and complexity. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our financial condition and results of our operations. The following summary should be read in conjunction with Note 2 of the notes to our audited consolidated financial statements for the year ended December 31, 2025 included elsewhere in this Annual Report on Form 10-K.

Research and Development Costs, Accrued Research and Development Costs and Related Prepaid Expenses

Research and development costs are expensed as incurred. Research and development expenses consist principally of personnel costs, including salaries, stock-based compensation and benefits for employees, third-party license fees and other operational costs related to our research and development activities, including sourcing of raw materials and manufacturing of our product candidates, allocated facility-related expenses and external costs of outside vendors, and other direct and indirect costs. Non-refundable research and development advance payments are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or services are performed.

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors, including research laboratories, in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical studies and clinical trials; and
- CMOs in connection with drug substance and drug product formulation of preclinical studies and clinical trial materials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that supply, conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Recent Accounting Pronouncements

For a description of recent accounting pronouncements, see Note 2 of the notes to our audited consolidated financial statements for the year ended December 31, 2025 included elsewhere in this Annual Report on Form 10-K.

Item 7A. Reserved.

Item 8. Consolidated Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Audited Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of PMV Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of PMV Pharmaceuticals, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for Research and Development Expenses

Description of the Matter	As disclosed in Note 2 to the consolidated financial statements, the Company is required to estimate research and development expenses from its obligations under contracts and purchase orders with vendors, clinical research organizations, clinical manufacturing organizations and others and for clinical site agreements at each balance sheet date. The Company recorded accrued expenses for the research and development expenses, which are included in accrued expenses on the December 31, 2025 consolidated balance sheet, and prepaid research and development expenses, which are included in prepaid expenses and other current assets on the December 31, 2025 consolidated balance sheet. The amounts recorded for accrued research and development expenses and for the prepaid research and development expenses, within the aforementioned balance sheet captions, represent the Company's estimate of the unpaid and prepaid research and development expenses based on the progress of the research and development services compared to the amounts paid for those services through December 31, 2025. Auditing the Company's accrued research and development expenses and related prepaid expenses involved a high degree of subjectivity due to the estimation required by management in determining the progress to completion of services that have been performed that will be invoiced by the vendors, clinical research organizations and consultants and under clinical site agreements subsequent to the date that the consolidated financial statements are issued.
How We Addressed the Matter in Our Audit	To test the research and development accruals and prepaid expenses, our audit procedures included, among others, reviewing a sample of agreements with the service providers to corroborate key financial and contractual terms, and testing the accuracy and completeness of the underlying data used in the accrual and prepaid expense computations. We also evaluated management's estimates of the progress of a sample of research and development activities by making inquiries of the Company's operations personnel that oversee the external research and development activities and obtaining information directly from the Company's clinical research organization. To evaluate the completeness of the accruals, we also examined subsequent invoices from the service providers and cash disbursements to the service providers, to the extent such invoices were received, or payments were made prior to the date that the consolidated financial statements were issued.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

Philadelphia, Pennsylvania
March 6, 2026

PMV Pharmaceuticals, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 37,983	$ 40,876
Marketable securities, current	74,960	128,578
Prepaid expenses and other current assets	2,284	6,204
Total current assets	115,227	175,658
Property and equipment, net	237	409
Marketable securities, noncurrent	—	13,843
Right-of-use assets	801	1,143
Other assets	297	235
Total assets	$ 116,562	$ 191,288
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,155	$ 6,579
Accrued expenses	7,857	7,439
Operating lease liabilities, current	403	352
Total current liabilities	11,415	14,370
Operating lease liabilities, noncurrent	435	838
Total liabilities	11,850	15,208
Commitments and contingencies (see Note 6)		
Stockholders' equity:		
Preferred stock, $0.00001 par value, 5,000,000 shares authorized as of December 31, 2025 and December 31, 2024. No shares issued or outstanding as of December 31, 2025 and December 31, 2024.	—	—
Common stock, $0.00001 par value, 1,000,000,000 shares authorized as of December 31, 2025 and December 31, 2024; 53,331,766 and 51,935,134 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively.	—	—
Additional paid-in capital	551,082	544,653
Accumulated deficit	(446,454)	(368,712)
Accumulated other comprehensive income	84	139
Total stockholders' equity	104,712	176,080
Total liabilities and stockholders' equity	$ 116,562	$ 191,288

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

PMV Pharmaceuticals, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Years ended December 31,		
	2025	2024	2023
Operating expenses:			
Research and development	$ 69,877	$ 58,527	$ 55,885
General and administrative	16,329	26,921	24,247
Total operating expenses	86,206	85,448	80,132
Loss from operations	(86,206)	(85,448)	(80,132)
Other income:			
Interest income, net	6,337	10,655	11,171
Other (expense) income, net	(45)	(16)	3
Total other income	6,292	10,639	11,174
Loss before provision (benefit) for income taxes	(79,914)	(74,809)	(68,958)
Provision (benefit) for income taxes	(2,172)	(16,100)	2
Net loss	(77,742)	(58,709)	(68,960)
Unrealized (loss) gain on available for sale investments, net of tax	(63)	(50)	635
Foreign currency translation (loss) gain	8	(35)	34
Total other comprehensive (loss) income	(55)	(85)	669
Total Comprehensive loss	$ (77,797)	$ (58,794)	$ (68,291)
Net loss per share -- basic and diluted	$ (1.48)	$ (1.14)	$ (1.44)
Weighted-average common shares outstanding	52,541,613	51,578,807	48,014,645

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

PMV Pharmaceuticals, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
(in thousands except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2022	45,771,332	$ —	$ 487,516	$ (445)	$ (241,043)	$ 246,028
Exercise of stock options and common stock issued under the 2020 ESPP	525,084	—	456	—	—	456
Issuance of common stock, net of issuance costs	5,149,446		35,121			35,121
Stock-based compensation expense	—	—	12,375	—	—	12,375
Net loss	—	—		—	(68,960)	(68,960)
Unrealized gain on investments	—	—	—	635	—	635
Foreign currency translation gain	—	—	—	34	—	34
Balance at December 31, 2023	51,445,862	$ —	$ 535,468	$ 224	$ (310,003)	$ 225,689
Exercise of stock options, common stock issued under the 2020 ESPP, and release of vested restricted stock units	489,272	—	313	—	—	313
Stock-based compensation expense	—	—	8,872	—	—	8,872
Net loss	—	—	—	—	(58,709)	(58,709)
Unrealized loss on investments	—	—	—	(50)		(50)
Foreign currency translation loss	—	—	—	(35)		(35)
Balance at December 31, 2024	51,935,134	$ —	$ 544,653	$ 139	$ (368,712)	$ 176,080
Exercise of stock options, common stock issued under the 2020 ESPP, and release of vested restricted stock units	1,396,632	—	505	—	—	505
Stock-based compensation expense	—	—	5,924	—	—	5,924
Net loss	—	—	—	—	(77,742)	(77,742)
Unrealized loss on investments on available for sale investments	—	—	—	(63)	—	(63)
Foreign currency translation gain	—	—	—	8		8
Balance at December 31, 2025	53,331,766	$ —	$ 551,082	$ 84	$ (446,454)	$ 104,712

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

PMV Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Years ended December 31,		
	2025	2024	2023
Cash flows from operating activities:			
Net loss	$ (77,742)	$ (58,709)	$ (68,960)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	5,924	8,872	12,375
Depreciation	133	1,144	1,257
Accretion of discounts on marketable securities	(2,771)	(5,371)	(5,386)
Non-cash lease income	(10)	(248)	(370)
Loss on termination of lease, net	—	4,604	—
Loss on sales and disposals of fixed assets, net	37	62	—
Other, net	(62)	(44)	—
Change in operating assets and liabilities:			
Prepaid expenses and other assets	3,920	(2,674)	1,723
Operating lease right-of-use assets and liabilities	—	241	837
Accounts payable	(3,424)	3,342	235
Accrued expenses	418	(2,501)	2,632
Net cash used in operating activities	(73,577)	(51,282)	(55,657)
Cash flows from investing activities:			
Purchases of property and equipment	(29)	(655)	(962)
Proceeds from sale of property and equipment	31	251	—
Purchases of marketable securities	(88,203)	(148,286)	(220,539)
Maturities of marketable securities	158,373	202,042	170,956
Net cash provided by investing activities	70,172	53,352	(50,545)
Cash flows from financing activities:			
Issuance of common stock, net of issuance costs	—	—	35,121
Proceeds from the exercise of stock options and common stock issued under the 2020 EIP	505	313	456
Net cash provided by financing activities	505	313	35,577
Impact of exchange rates on cash, cash equivalents, and restricted cash	7	(35)	34
Net (decrease) increase in cash and cash equivalents	(2,893)	2,348	(70,591)
Cash, cash equivalents, and restricted cash			
Cash, cash equivalents, and restricted cash - beginning of period	40,876	38,528	109,119
Cash, cash equivalents, and restricted cash - end of period	$ 37,983	$ 40,876	38,528
Supplemental disclosures of noncash investing activities			
Accrued purchases of property and equipment	$ —	$ —	$ 6

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

PMV Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements

1. Formation and Business of the Company

Organization and Liquidity

PMV Pharmaceuticals, Inc. (the "Company") was incorporated in the state of Delaware in March 2013. Since inception, the Company has devoted substantially all of its time and efforts to performing research and development activities and raising capital. The Company is a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53. The Company's headquarters are located at 400 Alexander Park Drive, Suite 301, Princeton, New Jersey.

The Company is subject to risks and uncertainties common to clinical stage companies in the biotechnology industry including, but not limited to, technical risks associated with the successful research, development and manufacturing of product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Current and future programs will require significant research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The Company has incurred net losses and negative cash flows from operations since its inception. During the year ended December 31, 2025, the Company incurred a net loss of $77,742 and used $73,577 of cash for operations. As of December 31, 2025, the Company had an accumulated deficit of $446,454. Cash, cash equivalents, and marketable securities were $112,943 as of December 31, 2025. Management expects to incur substantial additional operating losses for the next several years and may need to obtain additional debt or equity financings in order to complete development of its products, obtain regulatory approvals, launch and commercialize its products and continue research and development programs. The Company believes it has adequate cash, cash equivalents, and marketable securities to operate for the next 12 months from the date of issuance of these consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The audited consolidated financial statements are prepared in accordance with United States generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated financial statements include the Company's accounts and the accounts of its wholly owned subsidiary, PMV Pharma Australia Pvt Ltd. All significant intercompany transactions and balances have been eliminated upon consolidation. These consolidated financial statements are presented in United States ("U.S.") Dollars, which is also the functional currency of the Company.

These consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has limited operating history and its prospects are subject to risks, expenses and uncertainties frequently encountered by companies in the biotechnology industry.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of revenues and expenses during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances.

Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, research and development costs, accrued research and development costs and related prepaid expenses, and stock-based compensation. Actual results could differ materially from those estimates.

Fair Value of Financial Instruments

The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

- Level 1 - Inputs that reflect unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- Level 2 - Inputs other than quoted prices that are observable for the asset or liability either directly or indirectly, including inputs in markets that are not considered to be active.
- Level 3 - Inputs are unobservable in which there is little or no market data available, which require the reporting entity to develop its own assumptions that are unobservable.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

Cash, Cash Equivalents, and Marketable Securities

Management considers all highly liquid investments with original maturities of three months or less to be cash equivalents.

The Company's marketable debt securities have been classified and accounted for as available-for-sale. The Company classifies its marketable debt securities as either short-term or long-term based on each instrument's underlying contractual maturity date. Marketable debt securities with maturities of 12 months or less are classified as short-term and marketable debt securities with maturities greater than 12 months are classified as long-term. The Company's marketable debt securities are carried at fair value, with unrealized gains and losses, net of taxes, reported as a component of accumulated other comprehensive loss in stockholders' equity. Premiums and discounts on marketable debt securities are amortized into earnings over the life of the security and recorded on the interest income, net line of the income statement. For the years ended December 31, 2025, 2024, and 2023, the Company recorded $2,771 of accretion, $5,371 of accretion, and $5,386 of accretion, respectively.

Comprehensive Loss and Accumulated Other Comprehensive Income (Loss)

Other comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on investments and foreign currency translation gains and losses.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the circumstances present. The Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset's economic benefits. The Company determines the initial classification and measurement of its operating right-of-use ("ROU") assets and operating lease liabilities at the lease commencement date, and thereafter if modified. The lease term includes any renewal options that the Company is reasonably certain to exercise. The Company's policy is to not record leases with a

lease term of 12 months or less on its balance sheets. The Company's only existing leases are for office and laboratory space.

The ROU asset represents the right to use the leased asset for the lease term. The lease liability represents the present value of the lease payments under the lease. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term.

Lease expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expense in the statements of operations.

Payments due under each lease agreement include fixed and variable payments. Variable payments relate to the Company's share of the lessor's operating costs associated with the underlying asset and are recognized when the event on which those payments are assessed occurs. Variable payments have been excluded from the lease liability and associated right-of-use asset. Neither of the Company's leases contain residual value guarantees.

The interest rate implicit in lease agreements is typically not readily determinable, and as such, the Company utilizes the incremental borrowing rate to calculate lease liabilities, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

Property and Equipment

Property and equipment are recorded at cost net of accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, generally five years, except for leasehold improvements, which are amortized over the shorter of the useful life of the asset or the remaining term of the lease. Upon retirement or sale of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations. Repairs and maintenance costs are charged to operations as incurred.

Impairment of Long-Lived Assets

Long-lived assets, are tested for recoverability whenever events or changes in the business environment indicate that the carrying amount of the assets may not be fully recoverable. Factors considered by the Company when deciding when to perform an impairment review include significant underperformance of the business against expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows resulting from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows resulting from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its current fair value.

Research and Development Expenses

All costs associated with research and development are expensed as incurred. Research and development expenses include costs directly attributable to the conduct of research and development programs, including compensation costs, which includes allocated stock-based compensation, salary payroll taxes, employee benefits; materials; supplies; depreciation on and maintenance of research equipment; the cost of services provided by outside contractors; and the allocable portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, and general support services. The Company records accruals for estimated research and development expenses, comprising payments for work performed by third party vendors, clinical research organizations, clinical manufacturing organizations and others. Some of these vendors bill monthly based on actual services performed, while others bill periodically based upon achieving certain contractual milestones. For the latter, the Company accrues the expenses as goods or services are used or rendered. Research and development activities related to patient enrollment are accrued as patients enter and progress through the trial. In the event that the Company prepays

fees, the Company records the prepayment as a prepaid asset and periodically evaluate the prepaid asset in conjunction with the related accrued research and development expenses.

Stock-Based Compensation

The Company's share-based compensation program allows for grants of stock options and restricted stock units. Grants are awarded to employees and non-employees, and directors.

The Company accounts for stock-based employee compensation arrangements in accordance with provisions of ASC 718, *Compensation – Stock Compensation* ("ASC 718"). ASC 718 requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. ASC 718 requires companies to estimate the fair value of share-based payment awards on the date of grant using an option pricing or equity valuation model that is applied in a manner consistent with the fair value measurement objectives of ASC 718, is based on established principles of financial theory and reflects all of the substantive terms and conditions of the award. The Company uses the Black-Scholes option-pricing model ("Black-Scholes") to value stock option grants to employees, non-employees and directors. The fair value of the Company's common stock at the grant date is used to determine the fair value of restricted stock units and stock options.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. The historical volatility is calculated based on a period of time commensurate with expected term assumption. The Company uses the simplified method to calculate the expected term for options granted to employees whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the options due to its lack of sufficient historical data, except for when awards are determined to be out-of-the-money, as was the case for when applying modification accounting related to the stock option exchange in August 2024. Refer to Note 8 for details on the stock option exchange. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock. The Company recognizes forfeitures as they occur.

The Company's stock-based compensation awards are subject to service-based vesting conditions. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is typically the vesting term.

Net Loss per Share

Basic net income (loss) per share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding for the years ended December 31, 2025 and 2024. Diluted net income (loss) per share is computed by dividing the diluted net income (loss) by the weighted average number of shares of common stock, including potential dilutive common shares assuming the dilutive effect of outstanding stock options and unvested restricted common stock, as determined using the treasury stock method. For periods in which the Company has reported net losses, diluted net loss per share is the same as basic net loss per share, since dilutive shares of common stock are not assumed to have been issued if their effect is antidilutive.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, *Income Taxes* ("ASC 740"), which requires that deferred tax assets and liabilities be recognized using enacted tax rates for the effect of temporary differences between the book and tax bases of recorded assets and liabilities. Under ASC 740, the liability method is used in accounting for income taxes. Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax basis of assets and liabilities and are measured using the enacted tax rates and law that will be in effect when the differences are expected to reverse. ASC 740 also requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some or all of the deferred tax assets will not be realized. The Company evaluates annually the realizability of the deferred tax assets by assessing the valuation allowance and by adjusting the amount of such allowance, if necessary. The factors used to assess the likelihood of realization include forecast of future taxable income and available tax planning strategies that could be

implemented to realize the net deferred tax assets. In 2025 and 2024, the Company recorded a full valuation allowance for the deferred tax assets based on the historical loss and the uncertainty regarding the ability to project future taxable income. In future periods if the Company is able to generate income, the Company may reduce or eliminate the valuation allowance.

The Company accounts for uncertain tax positions in accordance with ASC 740. ASC 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax provision that an entity takes or expects to take in a tax return. Additionally, ASC 740 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosures, and transition. Under ASC 740, an entity may only recognize or continue to recognize tax positions that meet a "more likely than not" threshold. In accordance with this accounting policy, the Company recognizes accrued interest and penalties related to unrecognized tax benefits as a component of income tax.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash, cash equivalents, and marketable securities. Cash and cash equivalents were held at primarily two financial institutions. At times, such deposits may be in excess of insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents. The Company's marketable securities are carried at fair value and include any unrealized gains and losses. Any investments with unrealized losses are considered to be temporarily impaired.

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, rapid technological change, uncertainty of market acceptance of the product, competition from substitute products and larger companies, protection of proprietary technology, any future strategic relationships and dependence on key individuals.

Products developed by the Company require clearances from the U.S. Food and Drug Administration or other international regulatory agencies prior to commercial sales. There can be no assurance the Company's product candidates will receive the necessary clearances. If the Company is denied clearance, clearance is delayed or it is unable to maintain clearance, it could have a materially adverse impact on the Company.

Subsequent Events

The Company considered events or transactions occurring after the balance sheet date, but prior to the issuance of the consolidated financial statements, for potential recognition or disclosure in its consolidated financial statements. All significant subsequent events have been properly disclosed in the consolidated financial statements.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The amended guidance enhances income tax disclosures primarily related to the effective tax rate reconciliation and income taxes paid information. This guidance requires disclosure of specific categories in the effective tax rate reconciliation and additional information on reconciling items meeting a quantitative threshold. In addition, the amended guidance requires disaggregating income taxes paid (net of refunds received) by federal, state, and foreign taxes. It also requires disaggregating individual jurisdictions in which income taxes paid (net of refunds received) are equal to or greater than 5 percent of total income taxes paid (net of refunds received). The amended guidance is effective for annual periods beginning after December 15, 2024. We adopted this guidance prospectively for the annual period ending December 31, 2025. For additional information, see "Note 9 — Income Taxes."

Recent Accounting Pronouncements Not Yet Adopted

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". This amended guidance requires disaggregation of specific expense categories in the notes to the financial

statements and a qualitative description of the remaining expense amounts not separately disaggregated. This standard becomes effective for reporting companies with annual reporting periods beginning after December 15, 2026, and requires prospective application with an option to apply it retrospectively. The Company anticipates adopting this standard in its Annual Report on Form 10-K for the year ending December 31, 2027. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements.

In September 2025, the FASB issued ASU No. 2025-07 ("ASU 2025-07"), Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606). The guidance refines the scope of Topic 815 to clarify which contracts are subject to derivative accounting. The guidance also provides clarification under Topic 606 for share-based payments from a customer in a revenue contract. The amendments in ASU 2025-07 are effective for fiscal years beginning after December 15, 2026, and interim reporting periods, with early adoption permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements.

3. Financial Instruments and Fair Value Measurements

The Company's financial instruments consist of money market funds, U.S. government debt securities and corporate debt securities. Cash and cash equivalents includes money market funds and certain corporate securities, which are measured at fair value on a recurring basis using quoted prices and are classified as Level 1. Marketable securities are measured at fair value based on inputs other than quoted prices that are derived from observable market data and are classified as Level 2 inputs, except for investments in U.S. treasury securities which are classified as Level 1. There were no Level 3 assets or liabilities at December 31, 2025 or 2024.

The following tables show the Company's cash equivalents and available-for-sale securities' carrying amounts and fair values as of December 31, 2025 and 2024:

	As of December 31, 2025 (in thousands)						
	Carrying Amount	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Quoted priced in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Financial assets							
Money market funds	$ 29,909	$ —	$ —	$ 29,909	$ 29,909	$ —	$ —
Corporate securities	30,636	12	(4)	30,644	—	30,644	—
Government securities	52,229	68	—	52,297	52,297	—	—
Total financial assets	$ 112,774	$ 80	$ (4)	$ 112,850	$ 82,206	$ 30,644	$ —

	As of December 31, 2024 (in thousands)						
	Carrying Amount	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Quoted Priced in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets							
Money market funds	$ 40,790	$ —	$ —	$ 40,790	$ 40,790	$ —	$ —
Corporate securities	32,941	34	(26)	32,949	2,148	30,801	—
Government securities	109,341	153	(22)	109,472	73,339	36,133	—
Total financial assets	$ 183,072	$ 187	$ (48)	$ 183,211	$ 116,277	$ 66,934	$ —

Cash and Cash Equivalents – As of December 31, 2025, the Company had aggregate cash and cash equivalents of $37,983, including cash equivalents of $37,890 consisting of $29,909 of money market funds and $7,981 of corporate securities. As of December 31, 2024, the Company had aggregate cash and cash equivalents of $40,876, including cash equivalents of $40,790, consisting of money market funds and government securities.

Marketable Securities – Marketable securities of $74,960 as of December 31, 2025, consisted of corporate debt securities of $22,663 and government debt securities of $52,298. There were $74,960 current marketable securities and no noncurrent marketable securities as of December 31, 2025. Marketable securities of $142,421 as of

December 31, 2024, consisted of corporate debt securities of $32,949 and government debt securities of $109,472. There were $128,578 current marketable securities and $13,843 noncurrent marketable securities as of December 31, 2024.

As of December 31, 2025 and 2024, aggregated gross unrealized losses of available-for-sale investments were not material, and accordingly, no allowance for credit losses was recorded.

4. Property and Equipment, Net

(in thousands)	December 31, 2025	December 31, 2024
Machinery & equipment	$ 1,447	$ 1,782
Computers	13	13
Furniture & fixtures	23	23
Leasehold improvements	81	51
Total property and equipment	1,564	1,869
Less: Accumulated depreciation	(1,327)	(1,460)
Property and equipment, net	$ 237	$ 409

The Company terminated a lease in 2024 resulting in an abandonment and write-off of the leasehold improvements of $9,454. Refer to Note 6 for more details on the lease termination. Depreciation expense for the years ended December 31, 2025, 2024, and 2023 was $133, $1,144, and $1,257, respectively.

5. Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	December 31, 2025	December 31, 2024
Accrued compensation	$ 4,532	$ 5,005
Accrued research and development costs	3,130	2,177
Accrued legal and professional services	195	257
Total	$ 7,857	$ 7,439

6. Commitments and Contingencies

Operating Leases

In January 2021, the Company signed a lease for 50,581 square feet of office and laboratory space (the "One Research Way Lease") at One Research Way in Princeton, New Jersey (the "Premises"). The lease term initially extended through 2032, had a five-year extension option, and replaced the Company's two prior facilities as the Company's headquarters in March 2023. The Company estimated that payments under the One Research Way Lease would be $19,889 through May 2032. The Company received a lease incentive of $4,046 from the lessor for a buildout of laboratory, vivarium, and office space. Management estimated the timing and amounts of reimbursements and included them as a reduction of lease payments when initially measuring the lease liability and right-of-use asset upon commencement. Since the inception date of the lease, $4,046 reimbursements were received from the lessor.

In August 2024, the Company entered into a Lease Termination Agreement with BMR-One Research Way LLC (the "Landlord"), in connection with the termination of the One Research Way Lease (the "Termination Agreement"). The Termination Agreement was contingent on the sale of the Premises by the Landlord to a prospective new buyer, which was met on October 1, 2024, and, as a result, there was no modification in August 2024.

Pursuant to the Termination Agreement, and subject to the Contingency, the Company agreed to surrender the Premises and paid a total termination fee of approximately $1,420, consisting of (i) a cash payment in the

amount of approximately $798 and (ii) a release of a security deposit from the Company's existing letter of credit in the amount of approximately $622. The transaction was accounted for as an immediate termination of an operating lease before the expiration of the lease term in accordance with ASC 842. The Company derecognized the lease-related asset and liability resulting in a gain of $4,850. Since the termination fee of $1,420 was not already included in the lease payments, the termination fee was recognized as a loss on termination of the lease. Further, the Company abandoned and wrote-off all the related leasehold improvements totaling $9,454 held at the Premises. This net activity totaling $6,024 was recorded as a loss within General and Administrative expense in the Statement of Operations for the year ended December 31, 2024. As of December 31, 2025 and 2024, respectively, the Company has no commitments or contingencies related to the Lease.

In August 2024, the Company signed a sublease for 14,201 square feet of office space at 400 Alexander Park Drive, Suite 301, in Princeton, New Jersey, to be used as its new headquarters ("400 Alexander Sublease"). The 400 Alexander Sublease commenced on October 1, 2024 and extends until February 28, 2027. Payments under the 400 Alexander Sublease will total $789 through February 2027.

In September 2024, the Company signed a sublease agreement for 3,205 square feet of office and laboratory space at 311 Pennington Rocky Hill Road in Hopewell, New Jersey. The Company utilizes the premises as laboratory space for research and development activities. The sublease term extends through 2029 and provides the Company with the option to extend the term for an additional three year period. Payments under this sublease will total $768 through December 2029.

The components of lease cost for the years ended December 31, 2025, 2024, and 2023 are as follows:

	Year Ended December 31,		
(in thousands)	**2025**	**2024**	**2023**
Operating lease cost	$ 471	$ 1,194	$ 1,913
Variable lease cost	73	517	914
Total lease cost	$ 544	$ 1,711	$ 2,827

Amounts reported in the balance sheet for leases where the Company is the lessee as of December 31, 2025, and 2024, were as follows:

	As of December 31,	
Operating Leases (in thousands):	**2025**	**2024**
Right-of-use assets, operating leases	$ 801	$ 1,143
Operating lease liabilities, current	$ 403	$ 352
Operating lease liabilities, non-current	435	838
Total operating lease liabilities	$ 838	$ 1,190
Weighted-average remaining lease term (years)	2.76	3.47
Weighted-average discount rate	13.70%	13.70%

Other information related to leases for the years ended December 31, 2025, 2024, and 2023, respectively, were as follows:

	Year Ended December 31,		
(in thousands)	**2025**	**2024**	**2023**
Net cash paid for amounts included in the measurement of lease liabilities	$ 480	$ 1,202	$ 1,447
Leased assets (derecognized) in exchange for new or modified operating lease liabilities	—	(11,524)	—

Future minimum lease payments, net of reimbursements, remaining as of December 31, 2025, under operating leases by fiscal year were as follows:

Fiscal year	(in thousands)
2026	$ 483
2027	205
2028	152
2029	155
Thereafter	—
Total minimum lease payments	$ 995
Less: Amounts representing imputed interest	(157)
Present value of lease liabilities	$ 838

Rent expense recorded for the years ended December 31, 2025, 2024, and 2023, were $471, $1,194, and $1,913 respectively.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when future expenditures are probable and such expenditures can be reasonably estimated.

7. Stockholders' Equity

The Company is authorized to issue up to 1,000,000,000 shares of common stock with a par value of $0.00001 per share, and 5,000,000 shares of preferred stock with a par value of $0.00001 per share. As of December 31, 2025 and 2024, there were 53,331,766 and 51,935,134 shares of common stock issued and outstanding, respectively.

Common stockholders are entitled to receive dividends if and when declared by the board of directors subject to the rights of any preferred stockholders. As of December 31, 2025, no dividends on common stock had been declared by the Company.

As of December 31, 2025 and 2024, the Company had reserved shares of common stock for issuance as follows:

	December 31,	
	2025	2024
Options issued and outstanding	11,990,688	8,653,913
Shares available for future stock option and RSU grants	4,338,125	5,321,104
Shares available for employee stock purchase plan	1,162,196	1,408,321
Total	17,491,009	15,383,338

ATM Program

On October 4, 2021, the Company entered into an at-the-market offering program (the "ATM Program") pursuant to which, the Company may offer and sell shares of its common stock having aggregate gross sales proceeds of up to $150.0 million from time to time. During the year ended December 31, 2025, the Company did not sell any shares of its common stock under the ATM Program. As of December 31, 2025, the Company had approximately $113.8 million remaining in gross proceeds available for future issuances of common stock under the ATM Program.

8. Stock Plan

2020 Equity Incentive Plan

The 2020 Equity Incentive Plan (the "2020 Plan") was approved by the Company's board of directors on September 24, 2020. The 2020 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights to the Company's officers, employees, directors and consultants. The number of shares of common stock initially reserved for issuance under the 2020 Plan was 4,406,374, which shall be increased, upon approval by the Company's board of directors, on January 1, 2021 and each January 1 thereafter, in an amount equal to the least of (i) 4,406,374 shares of common stock, (ii) five percent (5%) of the outstanding common stock on the immediately preceding December 31, or (iii) such number of common stock determined by the board of directors no later than the immediately preceding December 31. For 2022, the board's compensation committee, as the 2020 Plan administrator, exercised its discretion under clause (iii) to increase the number of shares of common stock reserved for issuance under the 2020 Plan by a lesser amount of 1,363,084 shares, effective as of January 1, 2022. For 2023, the board's compensation committee, as the 2020 Plan administrator, exercised its discretion under clause (iii) to increase the number of shares of common stock reserved for issuance under the 2020 Plan by a lesser amount of 1,830,853 shares, effective as of January 1, 2023. For 2024, the board's compensation committee, as the 2020 Plan administrator, exercised its discretion under clause (ii) to increase the number of shares of common stock reserved for issuance under the 2020 Plan by 2,572,174 shares, effective as of January 1, 2024. For 2025, the board's compensation committee, as the 2020 Plan administrator, exercised its discretion under clause (ii) to increase the number of shares of common stock reserved for issuance under the 2020 Plan by 2,596,638 shares, effective as of January 1, 2025. For 2026, the board's compensation committee, as the 2020 Plan administrator, exercised its discretion under clause (ii) to increase the number of shares of common stock reserved for issuance under the 2020 Plan by 2,666,470 shares, effective as of January 1, 2026. As of December 31, 2025, there were 4,338,125 shares available for issuance under the 2020 Plan.

On September 9, 2022, the Company granted 374,899 Restricted Stock Units ("RSUs") to employees pursuant to an employee retention program approved by the compensation committee of the Company's board of directors. The RSUs have graded vesting on an annual basis for two years of continuous service, as per the 2020 Plan. As of December 31, 2025, such RSUs were fully vested and common stock was issued upon the settlement of the RSUs.

On January 18, 2024, the Company granted 952,665 RSUs to employees VP-level or higher, pursuant to an employee retention program approved by the compensation committee of the Company's board of directors. As of December 31, 2025 such RSUs were fully vested and common stock was issued upon settlement of the RSUs.

The table below summarizes the annual grant activity under the 2020 Plan as of December 31, 2025:

	Shares Available for Grant
Balances December 31, 2024	5,321,104
Shares reserved for issuance	2,596,638
Options granted	(3,784,840)
Options forfeited / cancelled	205,223
Balances December 31, 2025	4,338,125

2020 Employee Stock Purchase Plan

The 2020 Employee Stock Purchase Plan (the "2020 ESPP") was approved by the Company's board of directors on September 24, 2020. A total of 400,752 shares of common stock were initially reserved for issuance under this plan, which shall be increased, upon approval by the Company's board of directors, on January 1, 2021 and each January 1 thereafter, to the lesser of (i) 801,504 shares of common stock, (ii) 1% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (iii) an amount determined by the board of directors or any of its committees no later than the last day of the immediately preceding fiscal year. For 2022, the Company's board of directors waived the annual increase to the shares reserved under the 2020 ESPP. For 2023, the 2020 ESPP reserved shares were increased under clause (ii) by 457,713 shares, effective as of January 1,

2023. For 2024, the 2020 ESPP reserved shares were increased under clause (ii) by 514,434 shares, effective as of January 1, 2024. For 2025 and 2026, the Company's board of directors waived the annual increase to the shares reserved under the 2020 ESPP.

On May 20, 2025, employees of the Company exercised their right to purchase 128,240 shares under the 2020 ESPP. On November 21, 2025, employees of the Company exercised their right to purchase 117,885 shares under the 2020 ESPP. As of December 31, 2025, 611,415 shares are issued or outstanding, and there were 1,162,196 shares available for issuance, under the 2020 ESPP.

Stock Options

On July 16, 2024, the Company filed with the Securities and Exchange Commission a Tender Offer Statement on Schedule TO defining the terms and conditions of a one-time voluntary stock option exchange to its employees of certain options to purchase up to an aggregate of 2,820,491 shares of the Company's common stock (the "Option Exchange"). On August 13, 2024, the completion date of the Option Exchange, stock options covering an aggregate of 2,786,691 shares of common stock were tendered by eligible employees, and the Company granted new options at an exercise price of $1.48, the Company's closing stock price on August 13, 2024, covering an aggregate of 2,786,691 shares of common stock under the 2020 Plan in exchange for the tendered options. The new options are subject to a new three or four-year vesting schedule, vesting in equal annual installments over the vesting term. Each new option has a maximum term of ten years. The Option Exchange was treated as a modification for accounting purposes. As a result of the Option Exchange, the Company will recognize incremental stock-based compensation expense of $1,370 over the requisite service period of the new stock options, which is three or four years. The Company will recognize the sum of the incremental stock-based compensation expense and the remaining unrecognized compensation expense for the original awards on the modification date, over the requisite service period of the new stock options.

The following table summarizes option activity for the year ended December 31, 2025:

	Options Outstanding			
	Number of Options	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in 000s)
Balances December 31, 2024	8,653,913	$ 2.87	7.72	$ 162
Options granted	3,784,840	$ 1.29		
Options forfeited / cancelled	(205,223)	$ 1.64		
Options exercised	(242,842)	$ 1.29		
Balances December 31, 2025	11,990,688	$ 2.43	7.74	86
At December 31, 2025				
Vested and expected to vest	11,990,688	$ 2.43	7.74	$ 86
Exercisable	5,513,338	$ 3.56	6.52	$ -

The weighted average grant date fair value of stock options granted during the years ended December 31, 2025, 2024, and 2023, was $0.92, $4.94, and $4.03, respectively.

The aggregate intrinsic value of options vested and exercisable as of December 31, 2025 and 2024 is calculated based on the difference between the exercise price and the fair value of the Company's common stock. The intrinsic value of options exercised in 2025, 2024, and 2023, was $66, $107, and $892, respectively.

As of December 31, 2025, the total compensation cost related to nonvested awards not yet recognized was $11,185. The weighted-average period over which the nonvested awards will be recognized is 2.5 years.

The Company estimated the fair value of stock options using the Black-Scholes options valuation model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of employee stock options was estimated using the following assumptions:

	Year Ended December 31,		
	2025	2024	2023
Risk-free interest rate	3.89% - 4.48%	3.57% - 4.69%	3.45% - 4.65%
Expected life (in years)	5.50 - 6.25	5.50 - 6.25	5.50 - 6.25
Dividend yield	0%	0%	0%
Expected volatility	78.67% - 80.22%	85.55% - 127.07%	75.21% - 77.72%

The weighted average assumptions used to estimate the fair value of stock purchase rights under the 2020 ESPP are as follows:

	Year Ended December 31,		
	2025	2024	2023
Risk-free interest rate	4.07%	5.43%	5.41%
Expected life (in years)	0.5	0.5	0.49
Dividend yield	0%	0%	0%
Expected volatility	78.51%	85.55%	76.27%

Risk Free Interest Rate: The risk-free rate is based on the U.S. Treasury yields in effect at the time of grant for periods corresponding with the expected term of the option.

Expected Term: The Company uses the simplified method to calculate expected term described in the SEC's Staff Accounting Bulletin No. 107, which takes into account vesting term and expiration date of the options.

Dividend Yield: The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and therefore, used an expected dividend yield of zero in the valuation model.

Volatility: Volatility is based on the historical volatility of the Company's publicly traded shares for the expected term.

Restricted Stock Units

The following table presents RSU activity under the 2020 Plan as of December 31, 2025:

	Number of Stock Units	Weighted-Average Grant Date Fair Value
Unvested shares December 31, 2024	907,665	$ 1.80
Granted	—	—
Vested	(907,665)	(1.80)
Forfeited	—	—
Unvested shares December 31, 2025	—	—

As of December 31, 2025, there was no unrecognized compensation cost related to RSUs that are expected to vest.

Stock-based compensation expense recorded under ASC 718 related to stock options granted and common stock issued under the 2020 ESPP were allocated to research and development and general and administrative expense as follows:

(in thousands)	For the Year Ended December 31, 2025	2024	2023
Research and development	$ 2,607	$ 3,656	$ 5,518
General and administrative	3,317	5,216	6,857
Total stock-based compensation	$ 5,924	$ 8,872	$ 12,375

Stock-based compensation expense by award type included within the consolidated statements of operations is as follows:

(in thousands)	For the Years Ended December 31, 2025	2024	2023
Stock options	$ 5,172	$ 6,732	$ 9,745
Restricted stock units	559	1,939	2,413
Employee stock purchase plan	193	201	217
Total stock-based compensation	$ 5,924	$ 8,872	$ 12,375

9. Income Taxes

The income/(loss) from operations before tax (expense) benefit was as follows:

	For the Years Ended December 31, 2025	2024	2023
Pre-Tax Book Income/(Loss)			
Domestic	(79,937)	(74,905)	(68,925)
Foreign	23	96	(33)
Total Pre-Tax Income/(Loss)	$ (79,914)	$ (74,809)	$ (68,958)

The income tax (benefit) provision for the years ended December 31, 2025, 2024, and 2023 are as follows (in thousands):

	For the Years Ended December 31, 2025	2024	2023
Current:			
Federal	$ -	$ -	$ -
State	(2,194)	(16,170)	2
Foreign	22	70	-
Total current	(2,172)	(16,100)	2
Deferred:			
Federal	$ -	$ -	$ -
State	-	-	-
Foreign	-	-	-
Total deferred	-	-	-
Total (benefit) provision	$ (2,172)	$ (16,100)	$ 2

A reconciliation of the provision for income to the amount computed by applying the 21% statutory U.S federal income tax rate to income before income taxes after the adoption of ASU 2023-09 as follows:

	Year Ended December 31, 2025		
	(in thousands)		Percent
U.S. Federal Statutory Tax Rate	$ (16,782)		21%
State and Local Income Taxes, Net of Federal Income Tax Effect	(1,843)	(a)	2%
Foreign Tax Effect			
Australia - statutory tax rate differential	6		0%
Tax Credits	(2,542)		3%
Nontaxable or nondeductible items	992		-1%
Change in unrecognized tax benefits	745		0%
Change in valuation allowance	17,252		-22%
Effective tax rate	$ (2,172)		3%

(a) State taxes in New Jersey made up the majority (greater than 50 percent) of the tax effect in this category, inclusive of the benefit from the sale of NOLs in 2025 under the New Jersey Technology Business Tax Certificate Transfer Program.

As previously disclosed for the years ended December 31, 2024 and 2023 prior to the adoption of ASU 2023-09, the following is a reconciliation of the difference between the effective income tax rate and federal statutory rate:

	For the Years Ended	
	December 31, 2024	December 31, 2023
Income tax provision at statutory rate	21%	21%
State income taxes, net of federal benefit	5%	6%
Tax credits	3%	3%
Stock compensation	-3%	-1%
Executive compensation limitation	-1%	-1%
Proceeds from sale of tax attributes	17%	0%
Change in valuation allowance, excluding impact of the sale of tax attributes	-21%	-28%
Effective income tax rate	21%	0%

For the years ended December 31, 2025 and 2024, the Company generated a state tax benefit from the sale of net operating losses (“NOLs”) under the New Jersey Technology Business Tax Certificate Transfer Program. For the years ended December 31, 2025 and 2024, the Company’s effective tax rate was 3% and 21%, respectively, primarily due to the income tax benefit recognized for the sale of state tax attributes and the Company’s position to establish a full valuation allowance on its deferred tax assets. For the year ending December 31, 2023, the Company’s effective tax rate was below the federal statutory income tax rate of 21% primarily due to state income taxes, net of federal benefit and the Company’s position to establish a full valuation allowance on its deferred tax assets.

The tax effect of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets and liabilities are presented below:

(in thousands)	As of December 31, 2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 68,592	$ 49,729
Stock compensation	3,681	3,610
Capitalized research expenditures	32,309	32,514
Research and development credits	11,788	9,554
Accrued expenses and other	1,209	1,230
Operating lease liabilities	228	338
Total deferred tax assets	117,807	96,975
Valuation allowance	(117,542)	(96,606)
Deferred tax assets recognized	265	369
Deferred tax liabilities:		
Right-of-use assets	(238)	(325)
Fixed assets and depreciation	(27)	(44)
Total deferred tax liabilities	(265)	(369)
Net deferred tax assets	$ —	$ —

The Company has recorded a valuation allowance for its deferred tax assets that it does not believe will be realizable at a more likely than not level based on analysis of all available sources of taxable income.

As of December 31, 2025 and 2024, the Company had federal net operating loss carryforwards of $289,964 and $214,652, respectively. As of December 31, 2025, the Company had state net operating loss carryforwards for New Jersey, California, Massachusetts, and Arizona of approximately $97,539, $4,912, $6,342, and $543, respectively. At December 31, 2024, the Company had state net operating loss carryforwards for New Jersey, California, Massachusetts, and Arizona of approximately $54,685, $4,912, $6,542, and $192, respectively. Federal net operating loss carryforwards of $27,500 expire beginning in the year 2033. State net operating loss carryforwards begin to expire in the year 2033. Net operating loss carryforwards related to tax years after 2017 of $262,464 do not expire. The Company also has federal and state research and development credit carryforward of approximately $16,129 and $13,034 as of December 31, 2025 and 2024, respectively. The federal credits will begin to expire in 2034 if not utilized. The California state credits carryforward indefinitely and the New Jersey state credits expire starting in 2030. The above net operating losses and research and development credits are subject to Sections 382 and 383 of the Internal Revenue Code. In the event of a change in ownership as defined by these code sections, the usage of the net operating losses and research and development credits may be limited.

The Company accrues interest and penalties related to unrecognized tax benefits in the (benefit) provision for income taxes line item in the consolidated statements of operations and comprehensive loss. As of December 31, 2025 and 2024, the Company had not accrued any interest or penalties related to uncertain tax positions.

If the ending balance of $4,032 and $3,259 of unrecognized tax benefits as of December 31, 2025 and 2024, respectively, were recognized, none of the recognition would affect the income tax rate. The following table summarized the activity related to the Company's unrecognized tax benefits:

	For the Year Ended December 31, 2025	December 31, 2024
Unrecognized tax benefits, beginning of year	$ 3,259	$ 3,173
Decreases related to prior year tax positions	—	(586)
Increases related to current year tax positions	773	672
Unrecognized tax benefits, end of year	$ 4,032	$ 3,259

The Company files U.S. federal and state income tax returns with varying statutes of limitations. The Company's tax years 2013 to 2024 will remain open for examination by the federal and state authorities for three and four years, respectively, from the date of utilization of any net operating losses and research and development credits.

The State of New Jersey's Technology Business Tax Certificate Program allows certain high technology and biotechnology companies to sell unused NOL carryforwards and research and development ("R&D") tax credits to other New Jersey-based corporate taxpayers. As of December 31, 2025 and 2024, the Company received $2,196 and $16,176, respectively, of cash for the NOL and R&D tax credit sales related to the tax years ended December 31, 2015 through 2024. The sale of the NOLs and R&D tax credits has been recorded as an income tax benefit within the consolidated statement of operations.

For the year ended December 31, 2025, income taxes paid, net of refunds, by jurisdiction were immaterial both individually and in the aggregate and, accordingly, have not been separately disclosed. This is exclusive of the benefit from the sale of NOLs in 2025 under the New Jersey Technology Business Tax Certificate Transfer Program.

10. Net Loss per Share

The Company excluded all outstanding stock options and RSUs at each period end from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect. The following common stock equivalents were excluded from the calculation of diluted net loss per share:

	For the Years Ended December 31,		
	2025	2024	2023
Options to purchase common stock	11,990,688	8,653,913	6,973,464
Unvested restricted stock units	—	907,666	236,296
Expected shares to be purchased under 2020 ESPP	6,417	3,944	2,237
Total	11,997,105	9,565,523	7,211,997

11. Related Parties

The Company has consulting agreements with three members of its board of directors; one of which waived his consulting fees starting as of September 2021. Total consulting fees paid during the years ended December 31, 2025, 2024, and 2023 were $200, $187, and $92, respectively. There were no amounts owed under the consulting agreements as of December 31, 2025.

12. Restructuring

On January 18, 2024, the Company announced a restructuring plan involving the reduction of its workforce by approximately 30% of the Company's employees. The Company undertook these steps in order to streamline operations, reduce costs and preserve capital as it advances into late-stage development for its lead product candidate, rezatapopt. All of the costs under the restructuring plan were incurred and paid in full during the fiscal year ending December 31, 2024.

As a result of the reduction in force, the Company incurred an aggregate non-recurring charge of $597 for the fiscal year ending December 31, 2024, consisting primarily of employee severance and benefit costs associated with the restructuring. The Company has recorded these charges in research and development expenses in the accompanying consolidated statement of operations based on responsibilities of the impacted employees.

The Company accounts for employee termination benefits that represent a one-time benefit in accordance with ASC Topic 420, Exit or Disposal Cost Obligations. It records such costs into expense over the employee's future service period, if any.

13. Segment Information

The Company has viewed its operations and manages its business as one operating and reporting segment. Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the Company's chief operating decision maker ("CODM") to make decisions with respect to resource allocation and assessment of performance. The Company's CODM is its Chief Executive Officer (the "CEO"), who reviews and evaluates consolidated net loss for purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods. The determination of a single segment is consistent with the financial information regularly reviewed by the CEO.

The CEO regularly reviews the consolidated statement of operations and a disaggregation of operating expenses, of which the significant expenses are related to research and development. The following table represents the significant segment expenses regularly provided to the CEO:

	For the year ended December 31,		
	2025	2024	2023
Research and Development			
Research	$ 5,232	$ 5,914	$ 5,307
Development	48,370	35,295	31,740
Personnel related	13,668	13,662	13,320
Stock-based compensation	2,607	3,656	5,518
Total research and development	69,877	58,527	55,885
General and administration			
Personnel related	$ 5,485	$ 5,849	$ 6,748
Stock-based compensation	3,317	5,216	6,857
External	7,527	15,856	10,642
Total general and administrative	16,329	26,921	24,247
Loss from Operations	$ 86,206	$ 85,448	$ 80,132

14. Subsequent Events

The Company has evaluated subsequent events through March 6, 2026, the date these financial statements were issued. The Company determined that there were no subsequent events that required adjustment to or disclosure in the financial statements.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of December 31, 2025, the Company conducted an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15(d)-15(e) promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of the end of the period covered by this Annual Report on Form 10-K.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) promulgated under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, our management assessed and conducted an evaluation of the effectiveness of our internal control over financial reporting based on the Internal Control—Integrated Framework (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Changes in Internal Control Over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any changes in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting during the fourth quarter of the year ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Securities Trading Plans of Directors and Executive Officers

During the three months ended December 31, 2025, no director or officer, as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," each as defined in Regulation S-K Item 408.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be included under the caption “Directors and Corporate Governance” and “Executive Compensation” in our definitive proxy statement to be filed with the SEC on or before April 30, 2026, or the Proxy Statement, and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be included under the captions “Executive Compensation” and “Directors and Corporate Governance” in the Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be included under the captions “Beneficial Ownership of Shares of Common Stock” and “Executive Compensation—Equity Compensation Plan Information” in the Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be included under the captions “Certain Relationships and Related Person Transactions” and “Directors and Corporate Governance” in the Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be included under the captions “Ratification of Appointment of Independent Registered Public Accounting Firm” in the Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

EXHIBIT INDEX

Exhibit Number	Description	Form	File No.	Number	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended, as currently in effect.	8-K	001-39539	3.1	September 29, 2020
3.2	Amended and Restated Bylaws of the Registrant, as currently in effect.	10-Q	001-39539	3.3	May 10, 2023
4.1	Description of Securities of the Registrant.	10-K	001-39539	4.1	March 3, 2021
4.2	Specimen common stock certificate of the Registrant.	S-1/A	333-248627	4.2	September 21, 2020
4.3	Form of Indenture.	S-3	333-283349	4.5	November 20, 2024
10.1+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-248627	10.1	September 4, 2020
10.2+	2013 Equity Incentive Plan, as amended, and forms of agreement thereunder.	S-1/A	333-248627	10.2	September 21, 2020
10.3+	2020 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	333-248627	10.3	September 21, 2020
10.4+	2020 Employee Stock Purchase Plan and forms of agreements thereunder.	10-Q	001-39539	10.4	May 9, 2024
10.5+	Employment Offer Letter, dated August 17, 2020, by and between the Registrant and David H. Mack, Ph.D.	S-1	333-248627	10.5	September 4, 2020
10.6+	Employment Offer Letter, dated February 22, 2021, by and between the Registrant and Deepika Jalota, Pharm.D.	10-K	001-39539	10.8	March 1, 2022
10.7+	Employee Incentive Compensation Plan.	S-1	333-248627	10.9	September 4, 2020
10.8+	Change in Control and Severance Policy.	S-1	333-248627	10.10	September 4, 2020
10.9+	Amended and Restated Change in Control and Severance Policy Participation Agreement, dated August 17, 2020, by and between the Registrant and David H. Mack, Ph.D.	S-1	333-248627	10.11	September 4, 2020
10.10+	Amended and Restated Change in Control and Severance Policy Participation Agreement, dated March 23, 2022, by and between the Registrant and Deepika Jalota, Pharm.D.	10-Q	001-39539	10.14	May 10, 2022
10.11+*	Amended Outside Director Compensation Policy.				

10.12+	Consulting Agreement, dated January 1, 2016, by and between the Registrant and Arnold Levine, Ph.D.	S-1	333-248627	10.16	September 4, 2020
10.13+	Consulting Agreement, dated May 21, 2021, by and between the Registrant and Richard Heyman, Ph.D., as amended on July 16, 2021.	10-K	001-39539	10.17	March 1, 2022
10.14	Open Market Sale Agreement, dated as of October 4, 2021, between the Registrant and Jefferies LLC.	S-3ASR	333-260012	1.2	October 4, 2021
10.15+	Amended and Restated Employment Letter, dated January 5, 2024, by and between the Registrant and Michael Carulli.	10-K	001-39539	10.22	February 29, 2024
10.16+	Amended and Restated Change in Control and Severance Policy Participation Agreement, dated January 5, 2024, by and between the Registrant and Michael Carulli.	10-K	001-39539	10.24	February 29, 2024
10.17+	Amended and Restated Employment Offer Letter, dated November 5, 2024, by and between the Registrant and Robert Ticktin.	10-Q	001-39539	10.2	May 9, 2025
10.18+	Amended and Restated Change in Control and Severance Policy Participation Agreement, dated November 5, 2024, by and between the Registrant and Robert Ticktin.	10-Q	001-39539	10.3	May 9, 2025
10.19+*	Consulting Agreement, dated January 1, 2026, by and between the Registrant and Charles Baum, MD., Ph.D.				
19.1	Insider Trading Policy.	10-K	001-39539	19.1	March 3, 2025
21.1	List of Subsidiaries.	10-K	001-39539	21.1	March 1, 2022
23.1*	Consent of Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (contained in the signature page to this Annual Report on Form 10-K).				
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 Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*#	Certification of 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+	Compensation Recovery Policy.	10-K	001-39539	97.1	February 29, 2024
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 Document				
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101)				

* Filed herewith.

+ Indicated management contract or compensatory plan.

The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary

The Company has elected not to include summary information.

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 Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

PMV PHARMACEUTICALS, INC.

By: /s/ David H. Mack
David H. Mack, Ph.D.
President and Chief Executive Officer

Date: March 6, 2026

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David H. Mack, Ph.D. and Michael Carulli, jointly and each one of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents 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 he or she might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ David H. Mack David H. Mack, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 6, 2026
/s/ Michael Carulli Michael Carulli	Chief Financial Officer (Principal Financial and Accounting Officer)	March 6, 2026
/s/ Richard Heyman Richard Heyman, Ph.D.	Director and Chairman of the Board of Directors	March 6, 2026
/s/ Arnold Levine Arnold Levine, Ph.D.	Director	March 6, 2026
/s/ Carol Gallagher Carol Gallagher, Ph.D.	Director	March 6, 2026
/s/ Laurie Stelzer Laurie Stelzer	Director	March 6, 2026
/s/ Charles M. Baum Charles M. Baum, MD., Ph.D.	Director	March 6, 2026
/s/ Kirsten Flowers Kirsten Flowers	Director	March 6, 2026

Exhibit 10.11

Reviewed & Updated by PMV Board as of:
February 25, 2026 ("Updated Effective Date")

PMV PHARMACEUTICALS, INC.

OUTSIDE DIRECTOR COMPENSATION POLICY

PMV Pharmaceuticals, Inc. (the "**Company**") believes that providing cash and equity compensation to its members of the Board of Directors (the "**Board**," and members of the Board, the "**Directors**") represents an effective tool to attract, retain and reward Directors who are not employees of the Company (the "**Outside Directors**"). This Outside Director Compensation Policy (the "**Policy**") is intended to formalize the Company's policy regarding the compensation to its Outside Directors. Unless otherwise defined herein, capitalized terms used in this Policy will have the meaning given to such terms in the Company's 2020 Equity Incentive Plan (the "**Plan**"), or if the Plan is no longer in place, the meaning given to such terms or any similar terms in the equity plan then in place. Each Outside Director will be solely responsible for any tax obligations incurred by such Outside Director as a result of the equity and cash payments such Outside Director receives under this Policy.

Subject to Section 6 of this Policy, this Policy will be effective as of the effective date of the first registration statement that is filed by the Company and declared effective pursuant to Section 12(b) of the Exchange Act, with respect to any class of the Company's securities (the "**Registration Statement**").

1. CASH COMPENSATION

Annual Cash Retainer

Each Outside Director will be paid an annual cash retainer of $40,000. There are no per-meeting attendance fees for attending Board meetings. This cash compensation will be paid quarterly in arrears on a prorated basis.

Committee Annual Cash Retainer

Each Outside Director who serves as the chair of the Board, the lead Outside Director, or the chair or a member of a committee of the Board listed below will be eligible to earn additional annual cash fees (paid quarterly in arrears on a prorated basis) as follows:

Chair of the Board	$35,000
Chair of Audit Committee:	$15,000
Member of Audit Committee:	$7,500
Chair of Compensation Committee:	$10,000
Member of Compensation Committee:	$5,000
Chair of Nominating and Governance Committee:	$8,000
Member of Nominating and Governance Committee:	$4,000

For clarity, each Outside Director who serves as the chair of a committee shall receive only the

additional annual cash fee as the chair of the committee, and not the additional annual cash fee as a member of the committee.

2. EQUITY COMPENSATION

Outside Directors will be eligible to receive all types of Awards (except Incentive Stock Options) under the Plan (or the applicable equity plan in place at the time of grant), including discretionary Awards not covered under this Policy. All grants of Awards to Outside Directors pursuant to Section 2 of this Policy will be automatic and nondiscretionary, except as otherwise provided herein, and will be made in accordance with the following provisions:

a. No Discretion. No person will have any discretion to select which Outside Directors will be granted any Awards under this Policy or to determine the number of Shares to be covered by such Awards.

b. Initial Award. Following the Updated Effective Date, each individual who becomes a newly appointed Outside Director will be granted an award of stock options (an "**Initial Award**") covering 84,000 Shares (subject to adjustment for changes in capitalization under the Plan). The Initial Award will be made on the first trading date on or after the date on which such individual first becomes an Outside Director, whether through election by the stockholders of the Company or appointment by the Board to fill a vacancy. If an individual was a member of the Board and also an employee, becoming an Outside Director due to termination of employment will not entitle the Outside Director to an Initial Award.

Subject to Section 3 of this Policy, each Initial Award will vest in equal amounts on the same day of the month as the date the individual first becomes an Outside Director over the 36 months following the month during which the individual first becomes an Outside Director, subject to the Outside Director continuing to be a Service Provider through the applicable vesting date.

c. Annual Award. On the date of each annual meeting of the Company's stockholders following the Updated Effective Date (each, an "**Annual Meeting**"), each Outside Director will be automatically granted an award of stock options (an "**Annual Award**") covering 42,000 Shares (subject to adjustment for changes in capitalization under the Plan).

Subject to Section 3 of this Policy, each Annual Award will vest on the earlier of (i) the one-year anniversary of the date the Annual Award is granted or (ii) the day prior to the date of the Annual Meeting next following the date the Annual Award is granted, in each case, subject to the Outside Director continuing to be a Service Provider through the applicable vesting date.

3. CHANGE IN CONTROL

In the event of a Change in Control, each Outside Director outstanding Company equity awards will accelerate and vest.

4. TRAVEL EXPENSES

Each Outside Director's reasonable, customary and documented travel expenses to Board or Board committee meetings will be reimbursed by the Company.

5. ADDITIONAL PROVISIONS

All provisions of the Plan not inconsistent with this Policy will apply to Awards granted to Outside Directors.

6. SECTION 409A

In no event will cash compensation or expense reimbursement payments under this Policy be paid after the later of (i) 15th day of the 3rd month following the end of the Company's fiscal year in which the compensation is earned or expenses are incurred, as applicable, or (ii) 15th day of the 3rd month following the end of the calendar year in which the compensation is earned or expenses are incurred, as applicable, in compliance with the "short-term deferral" exception under Section 409A of the Internal Revenue Code of 1986, as amended, and the final regulations and guidance thereunder, as may be amended from time to time (together, "**Section 409A**"). It is the intent of this Policy that this Policy and all payments hereunder be exempt from or otherwise comply with the requirements of Section 409A so that none of the compensation to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities or ambiguous terms herein will be interpreted to be so exempt or comply. In no event will the Company reimburse an Outside Director for any taxes imposed or other costs incurred as a result of Section 409A.

7. REVISIONS

The Board may amend, alter, suspend or terminate this Policy at any time and for any reason. No amendment, alteration, suspension or termination of this Policy will materially impair the rights of an Outside Director with respect to compensation that already has been paid or awarded, unless otherwise mutually agreed between the Outside Director and the Company. Termination of this Policy will not affect the Board's or the Compensation Committee's ability to exercise the powers granted to it under the Plan with respect to Awards granted under the Plan pursuant to this Policy prior to the date of such termination.

Exhibit 10.19

PMV PHARMACEUTICALS, INC.

CLINICAL ADVISORY BOARD CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (the "Agreement") is made and entered into by and between **PMV PHARMACEUTICALS, INC.,** a Delaware corporation (the "Company"), and **Charles Baum, M.D., Ph.D.**, an individual ("Consultant"), effective as of January 01, 2026 ("Effective Date").

RECITALS

WHEREAS, Consultant and the Company have previously entered into a Consulting Agreement, dated as of February 13, 2024 (the "Prior Agreement"), pursuant to which Consultant agreed to provide the Company with senior clinical advisory services, including service as the Chair on the Company's Clinical Advisory Board (the "CAB"); and

WHEREAS, PMV Pharma and Consultant desire to terminate the Prior Agreement as of the Effective Date, and replace it with this Agreement to provide the on-going terms and conditions for Dr. Baum's continued services as Chair of the CAB;

NOW THEREFORE, in consideration of the mutual obligations specified in this Agreement, the parties agree that the Prior Agreement is hereby terminated, and the parties agree to the following:

1. CONSULTING SERVICES ENGAGEMENT. The Company hereby retains Consultant, and Consultant hereby accepts such retention, to perform consulting services for the Company as set forth herein.

1.1. SERVICES. Consultant shall provide services described in Exhibit 1 ("Services") for the Company.

1.2. COMPENSATION. Company agrees to pay Consultant the compensation set forth in Exhibit 1.

1.3. TERM AND TIME COMMITMENT. This Agreement will commence on the Effective Date and will continue from the Effective Date for the remainder of the current three (3)-year CAB term expiring on May 15, 2027, unless terminated earlier by either party according to section 1.6 below.

1.4. PAYMENT TERMS AND EXPENSE REIMBURSEMENT:

1.4.1. PAYMENT. Company shall pay Consultant on a quarterly basis, effect on the first day of each calendar quarter.

1.4.2. EXPENSES. The Company shall reimburse Consultant for expenses actually incurred by Consultant in performing the Services, including but not limited to travel and accommodation expenses, so long as such expenses are reasonable and necessary as determined by the Company and, where such policies exist, comply with the

Company's expense policies. Consultant shall maintain adequate books and records

relating to any expenses to be reimbursed. Consultant shall submit in a timely manner original receipts along with invoices and summarize expenses in a form acceptable to the Company.

1.5. INDEPENDENT CONTRACTOR STATUS. It is understood and agreed that Consultant is an independent contractor, is not an agent or employee of the Company, and is not authorized to act on behalf of the Company. Consultant agrees not to hold himself or herself out as, or give any person any reason to believe that he or she is an employee, agent, joint venturer or partner of the Company. Consultant will not be eligible for any employee benefits, nor will the Company make deductions from any amounts payable to Consultant for taxes or insurance. All payroll and employment taxes, insurance, and benefits shall be the sole responsibility of Consultant. Consultant retains the right to provide services for others during the term of this Agreement and is not required to devote his or her services exclusively for the Company.

1.6. TERMINATION. The Company or Consultant may terminate this Agreement at any time by giving ten (10) business days' written notice. Company may terminate this Agreement immediately upon written notice and without prior notice if Consultant refuses to or is unable to perform the Services or is in breach of any material provision of this Agreement. In the event of such termination, Consultant shall cease work immediately after receiving such notice of termination, unless otherwise agreed to in writing with the Company. At the time of termination of this Agreement for any reason, Consultant shall return to the Company all Confidential Information, Service Product, and other materials belonging to the Company, and shall notify the Company of any compensation earned and expenses incurred up to the termination date, which compensation and expenses shall be paid by the Company within 30 days of the Company's receipt of Consultant's invoice for same.

2. CONFIDENTIALITY AND ASSIGNMENT OF INVENTIONS. As a condition of this Agreement, Consultant agrees to all the terms of Section 1, Exhibit 2 (Confidentiality) and Section 2, Exhibit 2 (Assignment of Inventions).

3. SURVIVING SECTIONS. Sections 1 (Confidentiality), 2 (Ownership of Inventions) of Exhibit 2 of the Agreement shall survive any termination of this Agreement for the period of five (5) years from the execution of this Agreement.

4. ASSIGNMENT; BENEFIT. This Agreement is for the personal services of Consultant and may not be assigned by him or her, nor shall it be assignable by operation of law, without the prior written consent of the Company. This Agreement may not be assigned by the Company, nor shall it be assignable by operation of law, without the prior written consent of Consultant. The parties' rights and obligations under this Agreement will bind and inure to the benefit of their respective successors, heirs, executors, and administrators and permitted assigns.

5. GOVERNING LAW; SEVERABILITY. This Agreement shall be governed by and construed according to the laws of the State of New Jersey without regard to its conflict of laws rules. If any provision of this Agreement is found by a court of competent jurisdiction to be

unenforceable, that provision shall be severed and the remainder of this Agreement shall continue in full force and effect.

6. **COMPLETE UNDERSTANDING; MODIFICATION**. This Agreement, together with any Exhibits attached hereto, constitutes the final, exclusive and complete understanding and agreement of the Company and Consultant with respect to the subject matter hereof. Any waiver, modification or amendment of any provision of this Agreement shall be effective only if in writing and signed by Consultant and a Company officer.

7. **LIABILITY**. Consultant represents that he or she is experienced and qualified to perform the Services hereunder and shall use his or her best efforts to provide the Services with the highest level of skill and professionalism. Except for the foregoing, Consultant makes no warranties with regard to the Services and none shall be implied. In no event shall Consultant be liable for special or consequential damages, either in contract or tort, whether or not the possibility of such damages has been disclosed to Consultant in advance or could have been reasonably foreseen by Consultant. In the event this limitation of damages is held unenforceable, the parties agree that because of the difficulty in foreseeing possible damages, Consultant's liability to the Company shall not exceed the amount of any payments made by the Company to Consultant under this Agreement, any such liability for payment to be construed as liquidated damages and not as a penalty.

8. **NOTICES.** Any notices required or permitted hereunder shall be given to the appropriate party at the address specified below or at such other address as the party shall specify in writing. Such notice shall be deemed given upon personal delivery to the appropriate address or sent by certified or registered mail, three days after the date of mailing.

   If to the Company: If to the Consultant:

   David Mack,Ph.D. Charles Baum, M.D., Ph.D
   President and CEO 6960 The Preserve Way
   PMV Pharmaceuticals, Inc. San Diego, CA 92130 400 Alexander Park Drive, Suite 301
   Princeton, NJ 08540

[remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Effective Date.

PMV PHARMACEUTICALS, INC.	**CHARLES BAUM, M.D., PH.D.**
President & CEO	Consultant

PMV Pharma, Inc. CAB Consulting Agreement

Exhibit 1

1. **SERVICES**: Advise and consult with the Company as chair of its Clinical Advisory Board (CAB) and as to such matters as may be mutually agreed by the Company and Consultant.

2. COMPENSATION:

2.1. **Cash**. Consultant will be paid $20,000 per year for Services provided under the Agreement, in quarterly installments at the beginning of each quarter.

3. **EXPENSES:** Consultant shall be reimbursed for reasonable expenses incurred in performance of Consultants' obligations; provided these expenses shall be invoiced on a monthly basis and are approved by the Company. Domestic air travel, if approved by the Company, shall be reimbursed at business or comparable rate; international air travel, if approved by the Company, shall be reimbursed at business or comparable rate.

4. **TIME COMMITMENT**: Consultant shall provide consulting services to the Company at Company's reasonable request (not to exceed 5 days per year during the term of the Agreement without prior consent of the Company) for the term of the Agreement, or as agreed between Consultant and Company.

5. **CONTACT PERSON**: David Mack, CEO (dmack@pmvpharma.com; 650-224-8240)

PMV Pharma CAB Consulting Agreement

Exhibit 2

Confidentiality and Assignment of Invention

1. Confidential Information.

1.1. Subject to the limitations set forth in Paragraph 1.2, all information disclosed by Company to Consultant or generated by Consultant in the course of performing the Services shall be "Confidential Information." In particular, Confidential Information shall include, but not be limited to, information relating to any compound, chemical, peptide, protein, complex, conjugate, assay, biological material, virus, extract, media, vector, gene sequence, cell, cell component, cell line, formulation or sample; any procedure, discovery, invention, formula, data, result, process, idea or technique; any trade secret, trade dress, copyright, patent or other intellectual property right, or any registration or application therefore, or materials relating thereto; and any information relating to any of the foregoing or to any research, development (including pre-clinical and clinical development), manufacturing, engineering, marketing, servicing, sales, financing, legal or other business activities or to any present or future products, prices, plans, forecasts, suppliers, clients, customers, employees, consultants or investors; whether in oral, written, graphic or electronic form.

1.2. The term "Confidential Information" shall not include information which Consultant can demonstrate by competent written proof: (a) is now, or hereafter becomes, through no act or failure to act on the part of Consultant, generally known or available in the public domain; (b) is known by Consultant at the time of receiving such information as evidenced by his/her records or other reasonable proof; (c) is independently developed by Consultant, or for the Consultant by others, without reference to or reliance on the Confidential Information; (d) is developed from the use of Howard Hughes Medical Institute or Memorial Sloan-Kettering Cancer Center resources, proprietary intellectual property, or materials; or (e) is hereafter furnished to Consultant by a third party, as a matter of right and without restriction on disclosure.

1.3. Consultant shall maintain all Confidential Information received from Company in trust and confidence and shall not disclose without the prior written permission of the Company any such Confidential Information to any third party or use any such Confidential Information for any unauthorized purpose. In particular and without limitation, Consultant shall not use any Confidential Information to support any patent application or related filing. Consultant may use such Confidential Information only to the extent required to perform the Services. Consultant shall not use Confidential Information for any purpose or in any manner, which would constitute a violation of any laws or regulations, including without limitation the export control laws of the United States. Nothing in this Agreement shall be construed to grant Consultant any rights or licenses (a) under Company's trade secrets, trademarks, inventions, copyrights, patents or other

intellectual property rights, or (b) to retain, distribute or commercialize any Confidential Information belonging to Company, in either case, except as necessary to perform the Services.

1.4. Other Employer Information. Consultant agrees that he or she will not, during his or her engagement with the Company, improperly use or disclose any proprietary information or trade secrets of his or her former or concurrent employers, companies or clients, if any, and that he or she will not bring onto the premises of the Company any unpublished documents or any property belonging to his or her former or concurrent employers, companies or clients unless consented to in writing by said employers, companies or clients.

1.5. Third Party Information. Consultant recognizes that the Company has received and in the future will receive from third parties their confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and, in some cases, to use it only for certain limited purposes. Consultant agrees that he or she owes the Company and such third parties, both during the term of his or her engagement and thereafter, a duty to hold all such confidential or proprietary information in the strictest confidence and not to disclose it to any person, firm or corporation (except in a manner that is consistent with the Company's agreement with the third party) or use it for the benefit of anyone other than the Company or such third party (consistent with the Company's agreement with the third party).

1.6. Consultant acknowledges that his or her breach of this Agreement may cause the Company irreparable damage for which recovery of damages would be inadequate, and that the Company shall therefore be entitled to seek timely injunctive relief under this Agreement, as well as such further relief as may be granted by a court of competent jurisdiction in connection with any breach or enforcement of the Company's obligations hereunder o the unauthorized use or release of any such Confidential Information.

2. Assignment of Inventions.

2.1. Disclosure of Inventions. Consultant shall promptly and fully disclose to the Company any and all ideas, improvements, inventions, know-how, techniques and works of authorship developed by Consultant during his or her performance of the Services for the Company (the "Service Product"). Consultant agrees to keep and maintain adequate and current records (in the form of notes, sketches, drawings or in any other form that may be required by the Company) of all work performed relating to the Services, including all proprietary information developed relating thereto, and such records shall be available to and remain the sole property of the Company at all times.

2.2. Inventions Assigned to the Company. Consultant agrees that any and all Service Product shall be the sole and exclusive property of the Company. Consultant hereby assigns to the Company all his or her right, title and interest in and to any and all Service Product. Consultant explicitly acknowledges and agrees that all works of authorship contained in the Service Product are "works for hire" under the copyright laws of the

United States, and that the Company shall own the copyright in all such works of

authorship.

Consultant further agrees that the Company is and shall be vested with all rights, title and interests, including patent, copyright, trade secret and trademark rights, in all of Consultant's Service Product under this Agreement.

2.3. Obtaining Intellectual Property Protection. Consultant agrees to provide reasonable assistance to the Company to obtain and enforce United States and foreign proprietary rights relating to the Service Product in any and all countries. To that end, Consultant agrees to execute, verify and deliver such factually accurate documents and perform such other reasonable acts as the Company may reasonably request for use in applying for, obtaining, perfecting and evidencing such proprietary rights and the assignment thereof. In addition, Consultant agrees to execute, verify and deliver assignments of such proprietary rights to the Company or its designee. Consultant's obligation to assist the Company with respect to proprietary rights in any and all countries shall continue beyond the termination of his or her engagement, but the Company shall compensate Consultant at a reasonable rate after such termination for the time actually spent by Consultant at the Company's request on such assistance.

In the event the Company is unable for any reason, after reasonable effort, to secure Consultant's signature on any document needed in connection with the actions specified in the preceding paragraph, Consultant hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as his or her agent and attorney in fact, to act for and in his or her behalf to execute, verify and file, with the same legal force and effect as if executed by him or her, any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph. Consultant hereby waives and quitclaims to the Company any and all claims of any nature whatsoever which Consultant now or may hereafter have for infringement of any proprietary rights assigned to the Company.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-283349) of PMV Pharmaceuticals, Inc.,

(2) Registration Statement (Form S-8 No. 333-249094) pertaining to the 2013 Equity Incentive Plan, 2020 Equity Incentive Plan and 2020 Employee Stock Purchase Plan of PMV Pharmaceuticals, Inc.,

(3) Registration Statement (Form S-8 Nos. 333-256346, 333-269394 and 333-276667) pertaining to the 2020 Equity Incentive Plan and 2020 Employee Stock Purchase Plan of PMV Pharmaceuticals, Inc.,

(4) Registration Statement (Form S-8 No. 333-262308 and 333-284560) pertaining to the 2020 Equity Incentive Plan of PMV Pharmaceuticals, Inc.;

of our report dated March 6, 2026, with respect to the consolidated financial statements of PMV Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of PMV Pharmaceuticals, Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 6, 2026

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a),
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David H. Mack, certify that:

1. I have reviewed this Annual Report on Form 10-K of PMV Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 6, 2026

PMV PHARMACEUTICALS, INC.

By: /s/ David H. Mack

Name: David H. Mack, Ph.D.

Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a),
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Carulli, certify that:

1. I have reviewed this Annual Report on Form 10-K of PMV Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 6, 2026

PMV PHARMACEUTICALS, INC.

By: /s/ Michael Carulli

Name: Michael Carulli

Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of PMV Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David H. Mack, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 6, 2026

PMV PHARMACEUTICALS, INC.

By: /s/ David H. Mack
Name: David H. Mack, Ph.D.
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of PMV Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Carulli, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 6, 2026

PMV PHARMACEUTICALS, INC.

By: /s/ Michael Carulli
Name: Michael Carulli
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)