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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: 001-40675

Immuneering Corporation

(Exact name of registrant as specified in its charter)

Delaware	**26-1976972**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
245 Main St **Second Floor** **Cambridge, MA**	**02142**
(Address of Principal Executive Offices)	**(Zip Code)**

(617) 500-8080
(Registrant's telephone number, including area code)

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

Title of Each Class	Trading symbol	Name of Exchange on which registered
Class A common Stock, par value $0.001 per share	**IMRX**	**The Nasdaq Global 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 Section 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, a 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 ☒

As of June 30, 2025, the aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant was approximately $101.1 million (based upon a $3.37 closing sale price of the Class A common stock on that date on the Nasdaq Global Market).

As of March 3, 2026, the registrant had 64,652,926 shares of Class A common stock, $0.001 par value per share, issued and outstanding and 0 shares of Class B common stock, $0.001 par value per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements including within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact contained in this Annual Report on Form 10-K, including without limitation statements regarding our plans to develop, manufacture and commercialize our product candidates (including whether as potential monotherapies or in combination with other therapeutic agents), the design, timing, disclosure of data, or outcome of our ongoing or planned preclinical studies or clinical trials involving atebimetinib (also referred to as IMM-1-104), any of our other pipeline product candidates and any future product candidates, the clinical utility of our product candidates when administered alone or in combination with other therapeutic agents, the filing with, and approval by, regulatory authorities of our product candidates, the sufficiency of funds to operate the business of the Company and related expected cash runway, and our plans regarding raising additional capital, are forward-looking statements.

The forward-looking statements in this Annual Report on Form 10-K are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from those projected in the forward-looking statements, including, but not limited to, those described in the sections of this Annual Report on Form 10-K entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." These risks and uncertainties include, but are not limited to:

- our limited operating history;
- our history of operating losses;
- our ability to raise the substantial additional capital that will be required to finance our operations;
- the difficulty of obtaining regulatory approval for any of our current or future product candidates;
- our limited experience in designing and conducting clinical trials;
- the timing of the initiation, progress and potential results of our ongoing and planned clinical trials and our research programs, including our ongoing Phase 1/2a clinical trial of atebimetinib and planned registrational trial of atebimetinib in combination with modified gemcitabine/nab-paclitaxel in first-line pancreatic cancer;
- our ability to successfully complete our clinical trials, including our ongoing Phase 1/2a clinical trial of atebimetinib and planned registrational trial of atebimetinib in combination with modified gemcitabine/nab-paclitaxel in first-line pancreatic cancer;
- the risk of substantial delays in completing, if at all, the development and commercialization of our current or future product candidates;
- risks related to adverse events, toxicities or other undesirable side effects caused by our current or future product candidates;
- the risk of delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, including in our planned registrational trial of atebimetinib in combination with modified gemcitabine/nab-paclitaxel in first-line pancreatic cancer;
- our ability to submit an Investigational New Drug application ("IND"), or IND amendments or comparable documents in foreign jurisdictions in order to commence clinical trials on the timelines we expect;
- our substantial reliance on the successful development of our current and future product candidates, as well as our platform, including our proprietary technologies;

- risks related to competition in our industry;
- the market opportunity for our product candidates, if approved;
- risks related to manufacturing;
- risks related to our reliance on third parties;
- risks related to our intellectual property;
- risks related to ongoing and future pandemics, or other widespread adverse health events; and
- other important risk factors that could affect the outcome of the events set forth in these statements and that could affect our operating results and financial condition described in Part I, Item 1A. “Risk Factors” of this Annual Report on Form 10-K.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. 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, changed circumstances or otherwise.

Unless otherwise stated or the context requires otherwise, references to “Immuneering,” the “Company,” “we,” “us,” and “our,” refer to Immuneering Corporation and its subsidiaries.

Risk Factors Summary

We are subject to numerous risks and uncertainties, including those further described below in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K, that represent challenges that we face in connection with the successful implementation of our strategy and the growth of our business. In particular, the following are principal factors that may offset our competitive strengths or have a negative effect on our business strategy, which could materially adversely affect our business, financial conditions, results of operations, future growth prospects, or cause a decline in the price of our common stock:

- We are a late-stage clinical oncology company with a limited operating history in developing pharmaceutical products, have not completed any registrational clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We have incurred significant net losses for the past several years and we expect to continue to incur significant net losses for the foreseeable future and may never obtain profitability.
- We will require substantial additional capital to finance our operations. 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 drug development programs or future commercialization efforts.
- The regulatory approval processes of the U.S. Food and Drug Administration ("FDA") and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable with respect to outcomes. If we are ultimately unable to obtain regulatory approval for our product candidates, or to obtain regulatory approval to treat the indications we seek to treat with our product candidates, we will be unable to generate product revenue or the level of planned product revenue and our business will be substantially harmed.
- We may encounter substantial delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- The outcome of preclinical studies 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.
- Our current or future product candidates may cause 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 inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.
- Our business is substantially dependent on the successful development of our current and future product candidates. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval to treat the indications that we seek to treat with our product candidates, and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- We are substantially dependent on our platform, including our proprietary technologies, which are supported by our information technology systems. Any failure of these or other elements of our platform will materially harm our business.
- Our long-term prospects depend in part upon discovering, developing and commercializing product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.
- Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to use and expand our platform and capabilities to build a pipeline of product candidates with commercial value.
- We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

- We substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations ("CROs"), to conduct certain aspects of our preclinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

- We contract with third parties, including contract manufacturing organizations ("CMOs") and consultants, for the manufacture of our product candidates for preclinical studies and clinical trials, and expect to continue to do so for commercialization of any approved product candidate. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or be able to acquire such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

- The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

- If we are unable to obtain and maintain patent and/or other intellectual property protection for our product candidates and technologies, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully develop and commercialize our product candidates, products (if any) and technology may be impaired, and we may not be able to compete effectively in our market.

- Acquisitions, joint ventures or other transactions involving third parties could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

PART I

Item 1. Business

We are a late-stage clinical oncology company focused on keeping cancer patients alive and helping them thrive. We are developing and seeking to commercialize an entirely new category of anti-cancer medicines, Deep Cyclic Inhibitors, which we believe have the potential to be more effective and better tolerated targeted therapies.

Deep Cyclic Inhibitors

Deep Cyclic Inhibition® ("DCI") is a novel mechanism that aims to deprive tumor cells of the sustained proliferative signaling required for rapid growth, while sparing healthy cells through a cadenced, normalized level of signaling. Our Deep Cyclic Inhibitors inhibit clinically-validated core signaling pathways, such as the mitogen-activated protein kinase ("MAPK") pathway. Our novel approach is designed to improve durability and tolerability, and differentiates us from chronically targeted precision therapies, which are generally limited by toxicity, resistance and/or application to specific mutations only.

Atebimetinib (IMM-1-104)

Our lead product candidate, atebimetinib (IMM-1-104), is an oral, once-daily Deep Cyclic Inhibitor of mitogen-activated protein kinase kinase ("MEK"), designed to improve durability and tolerability across many cancer indications, including MAPK pathway-driven tumors such as pancreatic cancer. We are currently in the process of initiating a Phase 3 clinical trial of atebimetinib, which we call the MAPKeeper 301 trial, to evaluate atebimetinib in combination with modified gemcitabine/nab-paclitaxel ("mGnP") in first-line pancreatic cancer patients. We expect to dose the first patient in the MAPKeeper 301 trial in mid-2026.

MAPKeeper 301 is designed as a global Phase 3 registrational trial that will evaluate atebimetinib (320 mg QD) in combination with mGnP, compared to standard of care gemcitabine/nab-paclitaxel ("GnP") alone, in first-line metastatic pancreatic ductal adenocarcinoma ("PDAC"). The primary endpoint of MAPKeeper 301 is overall survival, and secondary endpoints include progression-free survival, overall response rate, disease control rate, and quality of life measurements. We plan to enroll a total of approximately 510 patients in MAPKeeper 301, divided equally across the two arms.

In January 2026, we announced positive interim response and safety data from our ongoing Phase 2a clinical trial arm evaluating atebimetinib in combination with mGnP in first-line pancreatic cancer patients, which is part of our ongoing Phase 1/2a clinical trial of atebimetinib in patients with advanced solid tumors. We also announced that we expect the following near-term milestones related to atebimetinib: presenting further updated circulating tumor DNA data on acquired alterations from cancer patients treated with atebimetinib at a major scientific meeting, in the second quarter of 2026; announcing further updated survival data from over 50 first-line pancreatic cancer patients treated with atebimetinib in combination with mGnP in our ongoing Phase 1/2a clinical trial, in the first half of 2026; and dosing the first patient in a planned clinical trial of atebimetinib in combination with Libtayo® in non-small cell lung cancer patients, in the second half of 2026.

Our DCI Pipeline

Our development pipeline also includes our additional clinical-stage product candidate envometinib (IMM-6-415) and other early-stage research programs, including research focused on validated core cancer-signaling pathways outside of the MAPK pathway.

Overview

Our DCI platform is enabled by two key elements:

- **Bioinformatics:** our ability to efficiently analyze high-throughput molecular-level biochemical assays, including transcriptomics, genomics and/or proteomics, collectively referred to as Omics data; and
- **3D Tumor Modeling:** our ability to conduct *in vitro* studies in our own labs using proprietary humanized 3D tumor growth assays that we believe predict *in vivo* activity more accurately than traditional 2D cell culture models.

These different types of biochemical and 3D tumor growth assays each provide us with unique information about the molecular mechanisms of disease biology and drug response and help to guide our translational planning and development.

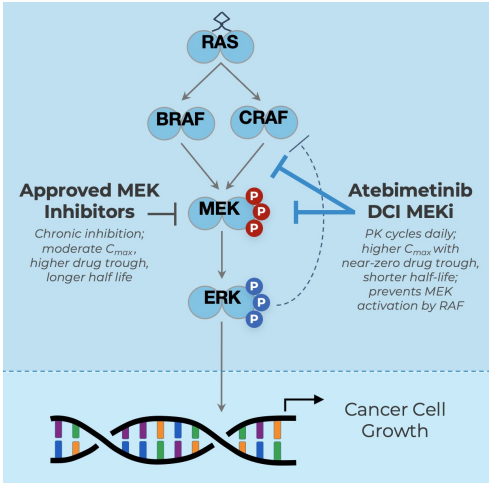
Since our inception, we have partnered with industry-leading pharmaceutical and biotechnology companies to perform a variety of analyses that utilize our expertise in translational bioinformatics. Examples publicly disclosed by our partners include our analyses of ibrutinib, ipilimumab, daratumumab, glatiramer acetate and pridopidine.

We began applying our proprietary platform and approach to internally develop our wholly owned pipeline of Deep Cyclic Inhibitors, orally administered small molecule drug programs. Our approach played a critical role in determining the most important characteristics for, and the creation of, atebimetinib and envometinib. Specifically, our platform enables us to:

- leverage insights from human data to compare distinct groups who differ in a certain aspect of disease or response to a particular therapy, in order to identify disease transcriptional profiles we aim to counteract;
- identify novel targets and new ways to drug existing targets using our technology and insights into mechanisms of response;
- generate novel chemistry that is designed to overcome MAPK-feedback loops and other adaptive resistance mechanisms to achieve optimal signaling dynamics; and
- profile product candidates in a large number of proprietary humanized 3D tumor growth assays using our proprietary translational planning to more accurately predict drug response compared to standard models and identify the types of cancer we believe most likely to be sensitive to such product candidates.

Our current programs are focused on tumors driven by mutations of the MAPK signaling pathway (i.e., RAS/RAF/MEK/ERK), and other relevant signaling pathways outside of the MAPK pathway. Existing drugs targeting the MAPK pathway are generally limited by toxicity, resistance and/or are narrowly focused on subpopulations with specific mutations. The MAPK pathway functions to drive cell proliferation, differentiation, survival and a variety of other cellular functions that are critical for the formation and progression of tumors.

Fundamental Cancer Signaling Cellular Pathways

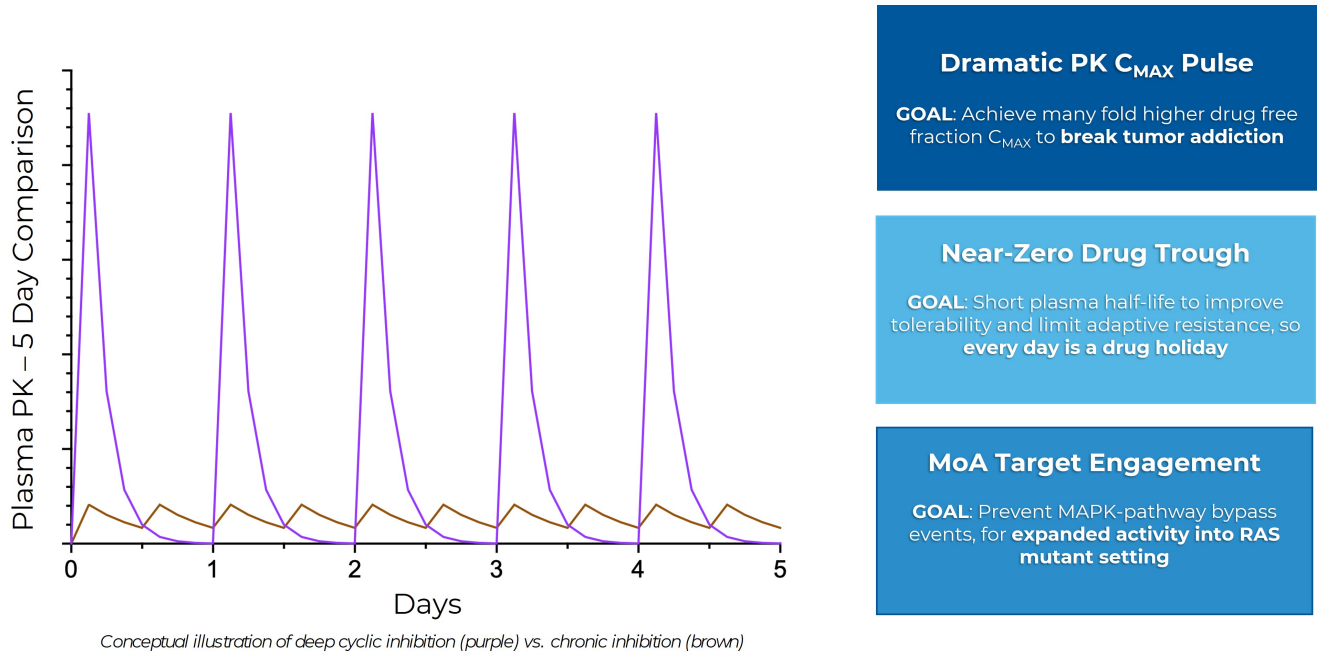


Deep Cyclic Inhibition of Cancer Signaling Pathways Challenges the Prevailing Chronic Ablation Approach

Each of the programs in our pipeline of Deep Cyclic Inhibitors is designed to drive cyclical disruption of abnormal activation of the MAPK signaling pathway or other relevant core signaling pathways outside the MAPK pathway, with the goal of maximizing antitumor therapeutic effects while limiting drug-related toxicity and adaptive resistance.

Traditional targeted oncology drug development generally seeks to chronically sustain pathway inhibition, by prioritizing drugs with long to moderate half-lives and dosing them at intervals that maintain a sufficient level of drug, even at trough, to maintain target occupancy. This prevailing chronic ablation approach can cause on-target drug-related toxicity and limit clinical durability as a result of extended drug holidays, treatment discontinuation, and/or adaptive resistance. By contrast, our differentiated approach, based on counterintuitive insights derived from our translational bioinformatics platform, is to design novel drugs with at least three key aims: (1) achieve a manyfold higher C_{Max}, (2) display a short plasma drug half-life, and (3) endow drugs with the ability to block feedback loops that would otherwise be susceptible to pathway reactivation. This design aims to provide enhanced mechanistic control of the target of interest and break tumor addiction, to prevent tumors from indefinitely self-replicating, metastasizing and evading the host's immune system, among other capabilities. By cyclically disrupting these core oncogenic signaling pathways in cancer cells (i.e., imposing normalized signaling dynamics), we believe we can create novel therapeutics that maximize therapeutic activity in broad patient populations while providing an improved tolerability profile and improved durability through reduced pressure stemming from adaptive resistance. We believe we are pioneers in this unique approach of therapeutically leveraging signaling dynamics against tumor addiction.

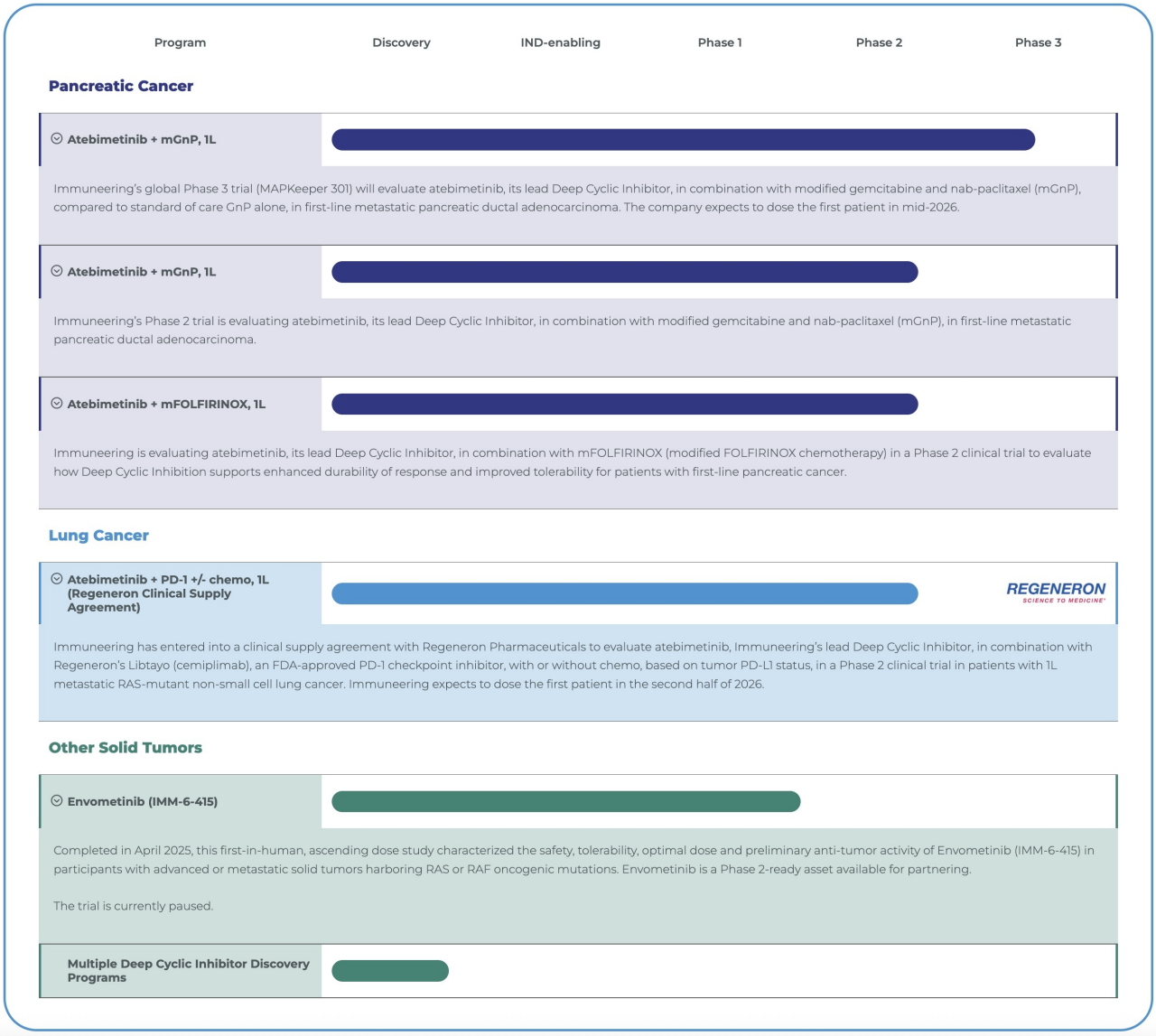
Atebimetinib's Deep Cyclic Inhibition of MEK is Designed to Improve Tolerability and Broaden Activity vs. Chronic Inhibition of MEK



Conceptual illustration of deep cyclic inhibition (purple) vs. chronic inhibition (brown)

Our Wholly-Owned Deep Cyclic Inhibitor Pipeline

Our Deep Cyclic Inhibitor programs target clinically validated pathways while seeking to improve patient outcomes across a wide range of solid tumor types through our differentiated programs. Our current pipeline of product candidates and discovery programs is depicted below.



Our Lead Clinical Program: Atebimetinib (IMM-1-104)

Our lead product candidate, atebimetinib, is an oral, once-daily Deep Cyclic Inhibitor of MEK, designed to improve durability and tolerability across many cancer indications, including MAPK pathway-driven tumors such as pancreatic cancer. Atebimetinib is designed to achieve a unique pharmacokinetic ("PK") profile: it aims for a manyfold higher C_{Max} to provide stronger inhibition of the MAPK pathway than has been observed with first and second generation MEK inhibitors, followed by a complete release of the MAPK pathway through a near-zero drug trough. We believe this deep cyclic inhibition may enable broad activity with improved tolerability and limit the development of adaptive resistance.

Atebimetinib was observed to bind to MEK and acts as a highly selective inhibitor of mitogen-activated protein kinase kinase kinase ("ERK") activation (i.e., phosphorylation), with a “Dual MEK” function that is designed to block the CRAF-bypass feedback to prevent MAPK pathway reactivation. Atebimetinib is designed with a short plasma half-life that reduces sustained pathway inhibition (as depicted above). Atebimetinib is also designed to prevent RAF-mediated activation of MEK, such as CRAF-bypass, by engagement of the RAF activation loop on MEK, and at elevated levels further disrupt the kinase suppressor of RAS 1 and 2 ("KSR"). We believe this innovative method of pathway inhibition has the ability to normalize cancer cell signaling dynamics and limits unnecessary harm to normal healthy cells. Collectively, we believe these qualities differentiate atebimetinib from other treatment options for RAS or RAF mutant and other MAPK-addicted tumors, as well as from known MEK inhibitors, by potentially enabling atebimetinib to reduce drug resistance while improving tolerability.

In preclinical studies, we observed that atebimetinib inhibited MEK and ERK across a wide range of human and murine solid tumor models, including those with activating mutations in KRAS, NRAS, HRAS, and BRAF. In addition, in head-to-head preclinical studies, we evaluated atebimetinib in murine-based KRAS, NRAS, and BRAF mutant solid tumor models representing lung, colon, pancreas, and skin cancer, and observed tumor stasis or regression with insignificant body weight loss ("BWL") when compared to certain FDA-approved MEK inhibitors at reported human dose equivalent dose and schedules. Given the data observed in these preclinical studies, we believe that atebimetinib has the potential to deliver clinical benefit for patients across many cancer indications, including MAPK pathway-driven tumors such as pancreatic cancer. who currently have limited treatment options.

In November 2022, we commenced dosing in our ongoing Phase 1/2a clinical trial for atebimetinib in patients with advanced solid tumors. The ongoing Phase 1/2a clinical trial is designed to assess the safety, tolerability, PK, pharmacodynamic ("PD"), and preliminary anti-tumor activity of atebimetinib, alone or in combination with other agents.

In February 2024, July 2024 and December 2024, respectively, we announced that the FDA granted Fast Track designation for atebimetinib for the treatment of patients: with PDAC who have failed one line of treatment; with PDAC in the first-line setting; and with unresectable or metastatic NRAS-mutant melanoma who have progressed on or are intolerant to PD-1/PD-L1 based immune checkpoint inhibitors.

In October 2024, we announced that the FDA granted orphan drug designation for atebimetinib for the treatment of pancreatic cancer.

In January 2025, we announced positive interim response and safety data from multiple Phase 2a pancreatic cancer arms of our ongoing Phase 1/2a clinical trial of atebimetnib, including:

- *Atebimetinib in combination with modified FOLFIRINOX ("mFFX")*: as of January 6, 2025, of the six evaluable patients in the ongoing Phase 2a arm evaluating atebimetinib with mFFX in first-line pancreatic cancer, three patients achieved a partial response (one unconfirmed) and three patients achieved stable disease, collectively representing an interim 50% (3/6) overall response rate ("ORR"), in each case as measured by the Response Evaluation Criteria in Solid Tumors ("RECIST"). The three patients that achieved partial responses, and one of the patients that achieved stable disease, remained on treatment as of the cutoff date. We also announced that, as of January 6, 2025, atebimetinib in combination with mFFX was observed to be generally well tolerated.

- *Atebimetinib Monotherapy*: as of December 5, 2024, of the twenty-one evaluable patients in the ongoing Phase 2a arm evaluating atebimetinib monotherapy in second-line pancreatic cancer, eleven patients achieved disease control, including one patient that achieved a partial response with a sixty-seven percent (67%) target lesion reduction, in each case as measured by RECIST. The patient that achieved the forementioned partial response, and eight of the patients that achieved stable disease, remained on treatment as of the cutoff date. We also announced that, as of December 5, 2024, atebimetinib monotherapy was observed to be very well tolerated. As of December 5, 2024, treatment-related adverse events ("TRAEs") observed in ten-percent (10%) or greater of evaluable patients dosed with atebimetinib at 320mg (n=21) were mostly Grade 1 events, with some Grade 2 events observed, including for: Rash (1 patient or 5%), Diarrhea (2 patients or 10%), Fatigue (1 patient or 5%) and Blurred Vision (1 patient or 5%); no Grade 3, Grade 4 or Grade 5 TRAEs were observed in this subset of the patient population.

In February 2025, we announced entry into a clinical supply agreement with Regeneron Pharmaceuticals for its anti-PD-1 therapy, Libtayo® (cemiplimab), which intends to support the evaluation of atebimetinib in combination with Libtayo in a planned clinical trial of patients with unresectable or metastatic RAS-mutant non-small cell lung cancer. We expect to dose the first patient in this planned clinical trial in the second half of 2026.

In June 2025 and again in September 2025, we announced positive interim response and safety data from our ongoing Phase 2a clinical trial arm evaluating atebimetinib in combination with mGnP in first-line pancreatic cancer patients.

In August 2025, we announced a clinical supply agreement with Eli Lilly and Company for its second-generation KRAS G12C inhibitor, olomorasib (LY3537982), which intends to support the evaluation of atebimetinib in combination with olomorasib in a planned clinical trial of patients with locally advanced or metastatic KRAS G12C-mutant non-small cell lung cancer who have progressed on prior therapy.

In January 2026, we announced further updated positive interim data from our ongoing Phase 2a clinical trial arm evaluating atebimetinib in combination with mGnP in first-line pancreatic cancer patients. As of a cutoff date of December 15, 2025 (the "Cutoff Date"), 64% overall survival ("OS") at 12 months (with median follow-up time of 13.4 months) was observed in the initial intent-to-treat population of 34 patients dosed at the 320 mg once-daily dose level of atebimetinib in combination with mGnP (the "320 mg ITT Population"). The standard of care (described below) reported a 35% OS at twelve months. As of the Cutoff Date, the median OS of the 320 mg ITT Population had not been reached and the median progression free survival ("PFS") was 8.5 months. Also as of the Cutoff Date, 94% OS and 83% OS were observed in the 320 mg ITT Population at six months and at nine months, respectively. The standard of care (described below) reported a 67% OS at six months; estimates of standard of care (described below) suggest a ~47% OS at nine months. As of the Cutoff Date, atebimetinib in combination with mGnP continued to be generally well tolerated. As of the Cutoff Date, Grade $\geq$ 3 treatment-emergent adverse events ("TEAEs") observed in 10% or greater of patients in the 320 mg ITT Population consisted of Anemia (six patients or 18%) and Neutropenia (six patients or 18%). Grade $\geq$ 3 TEAEs observed in less than 10% of patients in the 320 mg ITT Population included Fatigue (6%), Leukopenia (3%), Vomiting (3%), Febrile Neutropenia (3%), Hypokalemia (3%) and Nausea (3%). No Grade 5 TEAEs were observed in this patient population and no new safety signals were identified.

The estimates of (and other references to) standard of care set forth above with respect to the six month and twelve month follow-up data were reported out directly from the publicly available third-party MPACT pivotal trial data for gemcitabine/nab-paclitaxel. The estimates of (and other references to) standard of care set forth above with respect to the nine month follow-up data were extrapolated and reconstructed by us based on the publicly available third-party MPACT pivotal trial data for gemcitabine/nab-paclitaxel. Our Phase 1/2a clinical trial of atebimetinib does not include a head-to-head comparison against any other agents, and caution should be exercised when comparing data across trials.

We are currently in the process of initiating a Phase 3 clinical trial of atebimetinib, which we call the MAPKeeper 301 trial, to evaluate atebimetinib in combination with mGnP in first-line pancreatic cancer patients. MAPKeeper 301 is designed as a global Phase 3 registrational trial that will evaluate atebimetinib (320 mg QD) in combination with mGnP, compared to standard of care GnP alone, in first-line metastatic PDAC. The primary endpoint of MAPKeeper 301 is OS, and secondary endpoints include PFS, ORR, disease control rate, and quality of life measurements. We plan to enroll a total of approximately 510 patients in MAPKeeper 301, divided equally across the two arms. We expect to dose the first patient in the MAPKeeper 301 trial in mid-2026.

Additionally, we expect the other following near-term milestones related to atebimetinib: presenting further updated circulating tumor DNA data on acquired alterations from cancer patients treated with atebimetinib at a major scientific meeting, in the second quarter of 2026; announcing further updated survival data from over 50 first-line pancreatic cancer patients treated with atebimetinib in combination with mGnP in our ongoing Phase 1/2a clinical trial, in the first half of 2026; and dosing the first patient in a planned clinical trial of atebimetinib in combination with Libtayo in non-small cell lung cancer patients, in the second half of 2026.

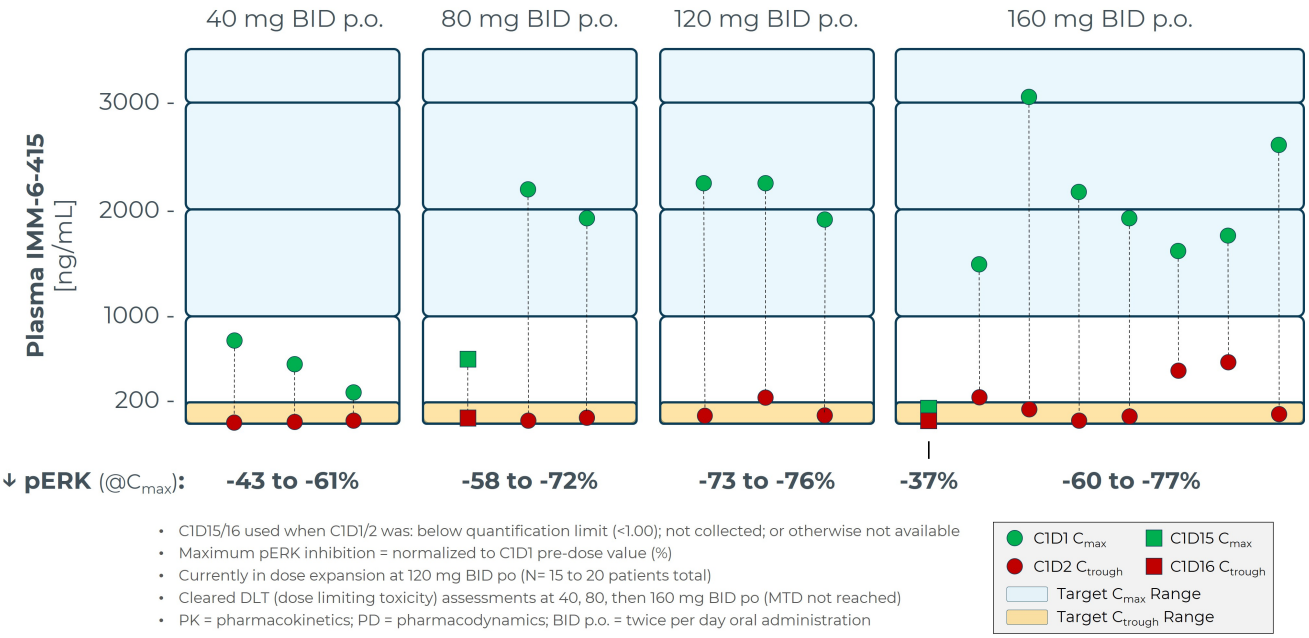
Our Second Clinical Stage Program: Envometinib (IMM-6-415)

Our second program is focused on developing innovative allosteric MEK inhibitors that drive deep cyclic inhibition of the MAPK pathway, designed with unique drug-like properties including a shorter plasma half-life for an accelerated pharmacokinetic cadence dosed twice-daily in humans. Our product candidate for this program is designated as envometinib, and is designed to target MEK in a way that disrupts the MAPK pathway at ERK through reduction of MEK activation. We designed envometinib to have a unique PK and PD profile that may be optimized for distinct solid tumors, potentially including a broad range of MAPK-driven tumors as a monotherapy, as well as for a variety of combination approaches.

In March 2024, we commenced dosing in a Phase 1/2a clinical trial of envometinib for the treatment of patients with advanced solid tumors harboring RAF or RAS mutations. The Phase 1/2a clinical trial was designed to assess the safety, tolerability, PK, PD, and preliminary anti-tumor activity of envometinib. The Phase 1 portion of the clinical trial included dose escalation and dose exploration for envometinib, using a Bayesian modified toxicity probability interval ("mTPI-2") statistical design to establish an optimized recommended Phase 2 dose ("RP2D") in solid tumor patients with evidence of any RAF or RAS mutation. The Phase 2a portion included evaluating envometinib in multiple dose expansion arms at the candidate RP2D.

In January 2025, we announced initial interim PK, PD and safety data from the monotherapy Phase 1 portion of the envometinib clinical trial. As of December 23, 2024, seventeen patients dosed orally with envometinib twice daily were evaluable for PK and PD analyses (as depicted in the image below). Of these patients, the Company dosed three patients at 40 mg (the first dose level), three patients at 80 mg (the second dose level), three patients at 120 mg (the third dose level), and eight patients at 160 mg (the fourth dose level). The majority of patients dosed at the second, third and fourth dose levels achieved significant PK Cmax levels, which is the plasma concentration of therapy in a specific area of the body, with envometinib of over 1,000 ng/mL or approximately 100 nM drug free-fraction. In addition, up to 72%, 76% and 77% PD inhibition of phosphorylated extracellular signal-regulated kinase ("pERK") was observed, as compared to pre-treatment baseline for patients dosed with envometinib at the second, third and fourth dose levels, respectively. The majority of patients dosed at the first, second and third dose levels showed a return to favorably low PK Ctrough levels, with envometinib of less than approximately 200 ng/mL or approximately 20 nM drug free-fraction. We also announced that, as of December 23, 2024, envometinib monotherapy was observed to be generally well tolerated at all tested dose levels, with no dose limiting toxicities or serious adverse events observed.

Envometinib Phase 1: Monotherapy PK/PD Summary Analyses as of December 23, 2024:



In February 2025, we paused further patient enrollment in the envometinib Phase 1/2a clinical trial in order to evaluate the data from patients being treated at the 120 mg dose level and determine next steps for the program. In April 2025, we made the strategic decision to pause further internal advancement of envometinib and focus resources on our lead product candidate atebimetinib. We are pursuing partnership opportunities and considering other potential developmental paths for envometinib.

Additional Deep Cyclic Inhibitor Discovery Research Programs

We are leveraging our platform to continue expanding our Deep Cyclic Inhibitor pipeline by targeting core signaling pathways outside the MAPK pathway, representing critical tumor-addicted pathways in novel ways. We also continue to evaluate and prioritize our pipeline, including our earlier stage discovery pipeline. We currently have multiple additional programs at various stages of drug discovery focused on targeting these pathways through novel pharmacological approaches.

Our Team

We were founded in 2008 by our Chief Executive Officer and President, Benjamin J. Zeskind, Ph.D., and Robert J. Carpenter, a current member of our Board of Directors (the "Board") and its former Chairperson, with the goal of leveraging translational bioinformatics to generate insights into the mechanisms that cause certain patients to respond to specific medicines across multiple therapeutic areas, and then seeking to make responses happen in a much broader population of patients. Our multi-disciplinary research and development ("R&D") team is led by our Chief Scientific Officer, Dr. Brett Hall, who was the translational lead for Sylvant® (siltuximab) and Imbruvica® (ibrutinib) throughout clinical development. Our clinical team is led by our Chief Medical Officer, Igor Matushansky, M.D., Ph.D., who has extensive oncology drug development expertise, including overseeing the completion of NAPOLI-3 leading to the approval of NALIRIFOX for first-line pancreatic cancer, and decades of experience in the clinical treatment of cancer patients. Our leadership team brings together expertise across translational bioinformatics, preclinical and clinical development, and pharmaceutical business operations in oncology and includes individuals with extensive experience at some of the leading pharmaceutical and biotechnology companies, including Johnson & Johnson, Merck, Regeneron, AstraZeneca, Ipsen Pharmaceuticals, Daiichi Sankyo, Novartis and Immunomedics (acquired by Gilead Sciences).

Our History

Our company is built on more than a decade of experience in translational bioinformatics. Since our founding in 2008, we have utilized this experience to generate insights into the mechanisms that cause certain patients to respond to specific medicines across therapeutic areas, and then sought to apply these insights to create medicines aimed at larger groups of patients. Our prior computational biology services business, which we have since ceased, helped us to better understand how translational bioinformatics can contribute to each stage of drug development, from early drug discovery to clinical development and through commercialization. However, we recognized the limitations of applying translational bioinformatics in isolation to specific stages of the drug development process and realized that bioinformatics could be even more helpful if applied continuously throughout the drug development process. Over time, we have developed a proprietary technology platform to facilitate that process and, in early 2018, we began applying the extensive counterintuitive insights from and capabilities of our platform and approach to create a wholly owned pipeline of novel small molecule drug programs, initially focusing on oncology.

Our Strategy

We are a late-stage clinical oncology company focused on keeping cancer patients alive and helping them thrive. We are developing and seeking to commercialize an entirely new category of anti-cancer medicines, Deep Cyclic Inhibitors, which we believe have the potential to be more effective and better tolerated therapies. Our platform is designed to leverage human biological data to generate insights that are not constrained by the inherent limitations of conventional approaches or prevailing scientific views. To achieve our mission, we are executing a near-term strategy with the following key elements:

- ***Apply Our Deep Expertise of the MAPK Pathway to Develop Novel Therapies that Achieve Durable Outcomes and Improve Quality of Life Across a Range of Cancers.*** We believe that our lead product candidate, atebimetinib, has the potential to treat broad populations of solid tumor patients, specifically those with inappropriate activation of the MAPK pathway. Atebimetinib has been specifically designed to provide Deep Cyclic Inhibition of the MAPK pathway at the level of MEK, with a once-daily oral dosing cadence. Atebimetinib was designed to overcome MAPK-feedback loops and to have an intentionally short plasma half-life, with the goal of providing Deep Cyclic Inhibition. Collectively, we believe atebimetinib has potential as both a monotherapy and in combination with other therapeutic agents to provide broader therapeutic activity and an improved tolerability profile relative to known MEK inhibitors, and that atebimetinib has the potential to target patients with solid tumors driven by any mutation in KRAS, NRAS, HRAS, or BRAF.

- ***Advance Atebimetinib Through Late-stage Clinical Development for the Treatment of Pancreatic Cancer.*** We are evaluating atebimetinib in an ongoing Phase 1/2a clinical trial in patients with advanced solid tumors, including those harboring RAS or RAF mutations, and in the process of initiating our MAPKeeper 301 Phase 3 clinical trial to evaluate atebimetinib in combination with mGnP in first-line pancreatic cancer patients. We expect to dose the first patient in the MAPKeeper 301 trial in mid-2026.

- ***Advance Atebimetinib through clinical development for lung cancer and other tumor types.*** In the second half of 2026, we expect to dose the first patient in a planned clinical trial of atebimetinib in combination with Libtayo® in non-small cell lung cancer patients.

- ***Progress Our DCI Pipeline to IND-Enabling Studies*.** Other key programs in our DCI pipeline leverage our deep understanding of core cancer signaling pathways, and are grounded in translational bioinformatics and signaling dynamics. We also actively apply our platform to other relevant pathways as new opportunities arise that may strengthen our pipeline.

- ***Continue to Expand and Advance Our Platform and Portfolio of Product Candidates*.** We have built a late-stage clinical oncology company that fully integrates bioinformatics and translational planning across all aspects of our drug discovery and development activities. We currently utilize our bioinformatics platform for our drug discovery efforts in oncology. These efforts are translationally guided by our proprietary, human-aligned 3D tumor models, and as we advance our product candidates into and through the clinic, we plan to utilize data and insights from our bioinformatics platform and proprietary humanized 3D tumor models to not only guide future clinical development but to also provide key learnings back to our earlier stage programs. Lastly, we continue to iterate on our existing technology and processes, and develop new technologies for our platform, all aimed at creating the most efficient process for the development of product candidates that we believe have the potential to optimize both safety and efficacy in broad patient populations of cancer patients with high unmet medical needs.

Our Bioinformatics Approach

Leveraging our history in translational bioinformatics, we have built a late-stage clinical oncology company that incorporates our expertise into every step of our process to discover and develop novel product candidates. Our goal is to meaningfully improve patient outcomes as compared to drugs developed through traditional drug discovery approaches. Our product candidate atebimetinib is currently being evaluated in an ongoing Phase 1/2a clinical trial, and our planned Phase 3 clinical trial of atebimetinib in combination with mGnP in first-line pancreatic cancer patients is expected to begin dosing in mid-2026. The rest of our programs are in earlier stages of development or discovery. We have expanded our team of experts, including drug discovery and clinical development experts, to develop a pipeline of product candidates by leveraging our translational bioinformatics expertise.

Cancer Overview

Cancer is the second most common cause of death worldwide with approximately 10 million deaths annually and an incidence of approximately 20 million new cases in 2022. Cancer is defined as a collection of diseases in which abnormal cells divide uncontrollably and can invade nearby and distant tissues. The uncontrollable division of abnormal cells typically results in a malignant tumor (i.e., cancerous) or benign tumor (i.e., non-cancerous). There are two main categories of cancer: hematologic (i.e., blood) cancers and solid tumor cancers. Hematologic cancers are cancers of the blood cells, and include leukemia, lymphoma and multiple myeloma. Solid tumor cancers are cancers of any of the body's other organs or tissues, including the pancreas, skin, lung and colon. Core tumor capabilities seen in cancer patients include the ability to indefinitely self-replicate, develop new blood vessels (i.e., angiogenesis), evade cell death (i.e., apoptosis), sustain self-sufficient growth, invade other tissues (i.e., metastasis), alter signaling pathways, evade immune system responses and modify metabolism. Tumor survival is dependent on certain of these capabilities (i.e., tumor addiction).

Pancreatic Ductal Adenocarcinoma (PDAC)

Over 67,000 new cases of PDAC were diagnosed in the U.S., and over 51,000 deaths were reported, per the 2025 cancer census (Siegel 2025). While the 5-year OS for all patients with pancreatic cancer has improved from below 6% in the 20th century to above 10% in the 21st century, the 5-year OS of patients with metastatic pancreatic cancer remains unchanged at just 3%.

Metastatic pancreatic cancer remains one of the most aggressive and highly lethal malignancies. Although it constitutes only about 3% of all cancers in the US, it is the fourth leading cause of cancer deaths in both men and women and is responsible for 8% of all cancer-related deaths for both men and women (Khalaf 2021, Siegel 2025).

MAPK Pathway and Beyond

In all cells, signaling pathways govern how cells regulate themselves as well as direct activities in relation to other cells in the body. One of the most commonly altered signaling pathways in cancer is the MAPK pathway, which consists of the RAS-RAF-MEK-ERK signaling cascade. RAS is a family of related oncogenes found upstream in the MAPK pathway that codes for four highly related protein isoforms, HRAS, NRAS, KRAS4A and KRAS4B. In many solid tumors, the MAPK pathway is inappropriately activated, often through mutations in the key members of the pathway, including RAS. When RAS is switched “on” through the activation of the membrane-bound receptor tyrosine kinase ("RTK"), the MAPK pathway functions to drive cell proliferation, differentiation, survival and a variety of other cellular functions that are critical for the formation of tumors.

Through widespread adaptation of molecular profiling, we now recognize that up to one in two cancer patients harbor tumors which are inappropriately activated through the MAPK pathway. Many of these patients display tumors with activation mutations in RAS or RAF, which lie upstream of MEK and ERK. Because inappropriate activation of the MAPK pathway supports many of the core tumor capabilities described above, efforts to create new therapeutics to target this pathway have been a high priority in cancer drug research. However, to date nearly all therapeutics that target the MAPK pathway have been limited to narrow patient subpopulations and have struggled to balance tolerability, durability of response, and efficacy. Nearly all targeted therapeutics against the MAPK pathway have been designed for sustained pathway suppression, which has resulted in on-target drug-related toxicities that limit clinical durability and potential drug-drug combinations. Furthermore, sustained irreversible covalent inhibition of these pathways may lead to treatment resistance, as highlighted in a study in the *New England Journal of Medicine* (N Engl J Med 2021; 384:2382-2393). The study focused on patients treated with adagrasib, an irreversible covalent inhibitor of $KRAS^{G12C}$, and reported that 45% of patients (17 patients out of 38) in the study receiving adagrasib monotherapy developed resistance. Of these patients, many resistance mechanisms were observed involving non-G12C variations in KRAS, variations in NRAS or BRAF, or other resistance mechanisms related to the MAPK pathway. A second study published in Nature (November 10, 2021) evaluated 43 patients treated with sotorasib, an irreversible covalent inhibitor of $KRAS^{G12C}$, and reported 27 patients with multiple treatment-emergent resistance alterations. Of these, 70% (19 out of 27) patients reported resistance mechanisms involving RAS/RAF mutations (Nature 2021; 599:679-683). A third study in the *New England Journal of Medicine* (N Engl J Med 2023; 389:710-721) also described acquired alterations that may confer resistance to divarasib (another irreversible covalent inhibitor of $KRAS^{G12C}$) including many alterations in KRAS, BRAF, NRAS, and other elements of the MAPK pathway.

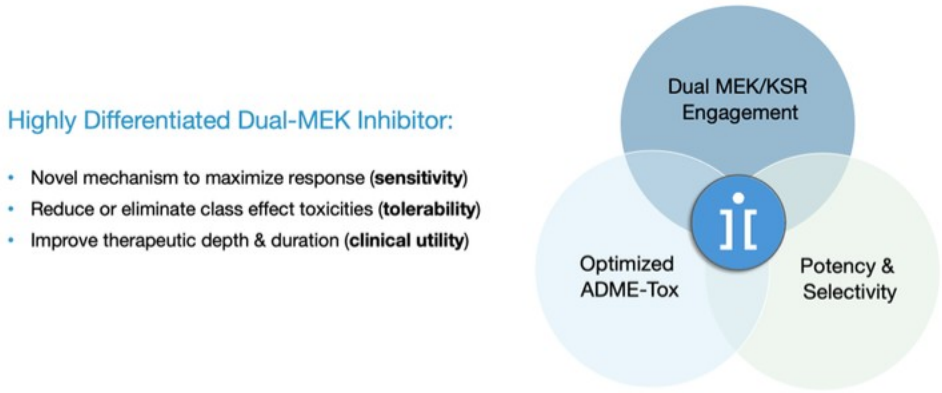
Developing novel therapeutics to effectively, broadly and safely target this pathway may provide clinical benefit in large patient populations with significant unmet needs. In addition, although this pathway represents one of the most active areas in cancer drug discovery and development, targeted therapeutics that more effectively and safely normalize, but not chronically ablate, ERK signaling may uncouple drug activity and tolerability, while optimizing both. Our pipeline is designed to disrupt molecular pathways in a pulsatile way that undermines tumor addiction while limiting drug-related toxicity of normal healthy cells that are less reliant on a sustained high level of signaling along these pathways.

Atebimetinib Design and Preclinical Overview

Background of MEK Inhibitors

Activating mutations of RAS and/or RAF in the MAPK pathway are observed in approximately 30% of all cancer patients, and inappropriate activation of this pathway is observed in up to 50% of all tumors and represents one of the most highly utilized signaling pathways in oncology. In aggressive solid tumors of the pancreas, skin, lungs and colon, mutations in RAS and/or RAF are even more common. For example, approximately 40% of lung cancers and approximately 90% of pancreatic cancers are due to RAS and/or RAF mutations. In turn MEK, which is downstream in the cellular signaling cascade, represents a compelling area for treatment and has previously been validated as a therapeutic target. However, to date, FDA-approved MEK inhibitors have been ineffective at treating RAS mutant tumors when compared to BRAF mutant tumors because of a well-known mechanism of resistance, CRAF-mediated MEK reactivation, also known as CRAF-bypass. In addition, a well-known limitation of current FDA approved MEK inhibitors are high rates of serious drug-related adverse events ("SAE's"), often observed in over 50% of treated patients, which leads to drug intolerability. The longer half-life of these drugs (e.g., up to 2 to 4 days) with once per day or less frequent dosing, or moderate half-life (e.g., 3 to 6 hours) with increased dosing frequency, contributes to high rates of adverse events because typically these drugs chronically and systemically circulate for an extended period of time and harm healthy normal cells, which also rely on the MAPK pathway for functionality and survival. Our goal in developing atebimetinib is to address these shortcomings and potentially provide patients with better outcomes, improved tolerability, durability and expanded drug-drug combination opportunities (as depicted below).

Our Solution: Atebimetinib



We have leveraged our platform to develop our lead product candidate atebimetinib, which is designed to be a highly selective dual-MEK inhibitor and to promote additional scaffold-related disruption of KSR at elevated drug levels. We are currently developing atebimetinib as a potential treatment for patients with cancer, including pancreatic and non-small cell lung cancer ("NSCLC") caused by mutations of RAS or RAF. In order to overcome MAPK-feedback and CRAF-mediated MEK activation, a well-known limitation of some current FDA-approved MEK inhibitors, we developed atebimetinib to allosterically inhibit MEK by targeting the site lying adjacent to the binding pocket of adenosine triphosphate ("ATP"), which would result in downstream inhibition of ERK. In addition, unlike some current FDA-approved MEK inhibitors, atebimetinib is designed to prevent MEK activation through a unique target engagement to prevent RAF or KSR-mediated activation of MEK. We believe that bypassing pathway reactivating drug resistance mechanisms would provide for better patient outcomes by enhancing therapeutic activity throughout the course of treatment. By reducing or eliminating steady state drug trough levels, we also designed atebimetinib to limit or reduce high rates of serious drug-related adverse events that have been observed in current FDA-approved MEK inhibitors (e.g., which can range from 45% to 69%), most often given in combination with a RAF inhibitor, which contributes to discontinuation rates of up to 10% to 15%.

With a goal of improving tolerability, we designed atebimetinib to have a short plasma half-life, to result in a near-zero steady state drug trough concentration to enable deep, cyclic inhibition of the MAPK pathway. We believe this method of drug cadence-driven pathway inhibition has the potential to normalize cancer cell signaling dynamics and prevent further damage to normal healthy cells. Collectively, we believe these dosing attributes may differentiate atebimetinib from known MEK inhibitors by potentially allowing atebimetinib to reduce drug resistance while improving tolerability due to its design to allosterically inhibit MEK, be uniquely resistant to MAPK pathway reactivation and to enable deep, cyclic inhibition stemming from a short plasma half-life.

Preclinical Studies: Overview of Atebimetinib

In multiple preclinical studies, we observed that atebimetinib inhibited activation of MEK (i.e., pMEK) as well as activation of ERK (i.e., pERK) across a wide range of murine and humanized 3D solid tumor models, including those with MAPK pathway activating mutations in KRAS, NRAS, HRAS and BRAF. In addition, in head-to-head preclinical studies, we evaluated atebimetinib in murine-based KRAS, NRAS, and BRAF mutant solid tumor models representing lung (i.e., A549), colon (i.e., Colon-26), pancreas (i.e., MIA PaCa-2. CAPAN-2) and skin cancer (i.e., A375 and SK-MEL-2), and observed superior antitumor activity with insignificant BWL when compared to certain FDA-approved MEK inhibitors and superior or non-inferior antitumor activity when compared to certain FDA-approved KRAS-G12C and BRAF inhibitors, at reported human dose equivalent dose and schedules. Given the data observed in our previously conducted preclinical studies, we believe that atebimetinib has the potential to deliver clinical benefit as monotherapy and in select drug combinations for patients with RAS or RAF mutant solid tumors who currently have limited treatment options.

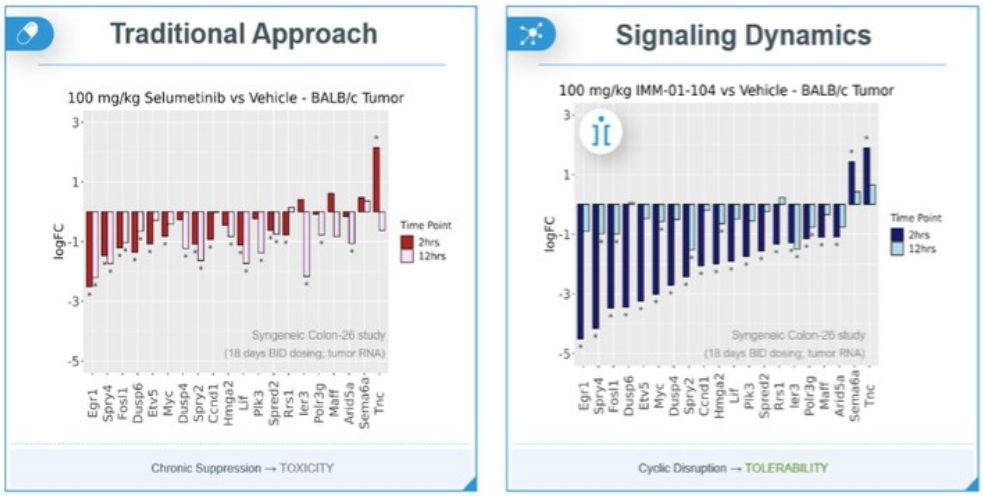
Preclinical Studies: Maximum Tolerated Dose and Therapeutic Effect Data

In our early maximum tolerated dose ("MTD") studies, we observed that oral administration of atebimetinib twice a day of up to 150 mg/kg/dose was well-tolerated in mice. In other preclinical studies, we observed that the maximum therapeutic effect of atebimetinib was reached when administered orally twice a day between 100 and 150 mg/kg/dose. These dosing studies provided the basis of atebimetinib’s dosing schedule in subsequent preclinical studies.

Preclinical Studies: Pharmacogenomics Data

In a pharmacogenomics study utilizing a colorectal $KRAS^{G12D}$ tumor model in BALB/c mice, we evaluated downstream ERK inhibition of the MAPK pathway after atebimetinib treatment. We orally administered vehicle, selumetinib and atebimetinib twice a day at 100 mg/kg/dose, then harvested the tumors after 18 days of chronic treatment at 2 and 12 hours following the last drug dose to evaluate RNAseq changes. The tumors were collected across distinct BALB/c mice and RNAseq changes were evaluated using statistical analysis software. Consistent with atebimetinib's designed short plasma half-life, we observed deep, cyclic inhibition of most of the top genes in the ERK transcriptome, as noted by the differences of the dark and light blue bars in the figure below, which we believe suggests the potential for improved tolerability by allowing healthy normal cells to regenerate before the next dose is administered. For example, *Erg1* and *Spry4* were both downregulated over 16-fold at 2 hours after receiving the first dose on day 18 of the study, and at 12 hours after the first dose, which was prior to the second dose, both genes were approaching their baseline state when compared to vehicle treated tumors (as depicted below). In contrast to atebimetinib, we did not observe deep cyclic inhibition by selumetinib, but rather observed sustained MAPK pathway suppression versus vehicle groups between the two timepoints on day 18 (as depicted below). The top 20 genes were a subset of a 52-gene signature for ERK signaling.

Head-to-Head Comparison of Atebimetinib Against Selumetinib Using a Colon-26 Syngeneic Tumor Model: Deep Cyclic Inhibition of the ERK Transcriptome Observed

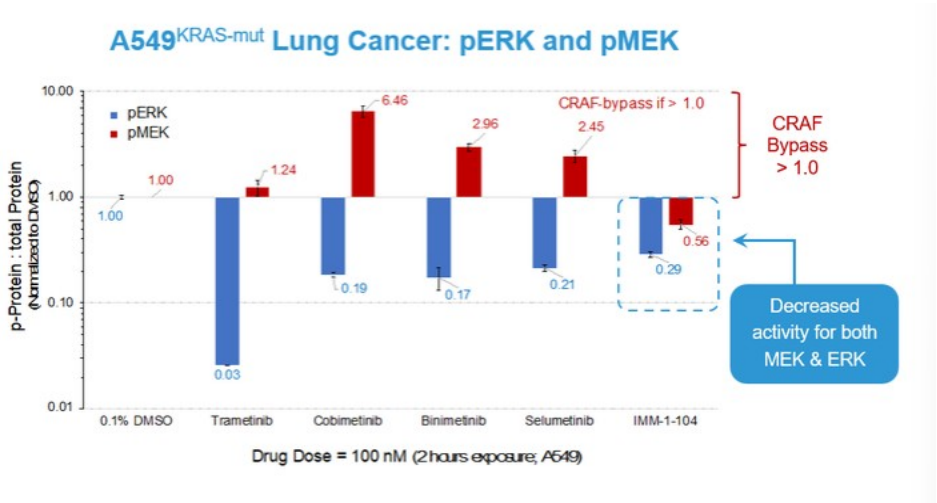


** Adjusted p-value < 0.05, for each treatment versus vehicle (n = 3-4 independent tumors per group)*

Preclinical Studies: Resistance to CRAF-bypass Observed

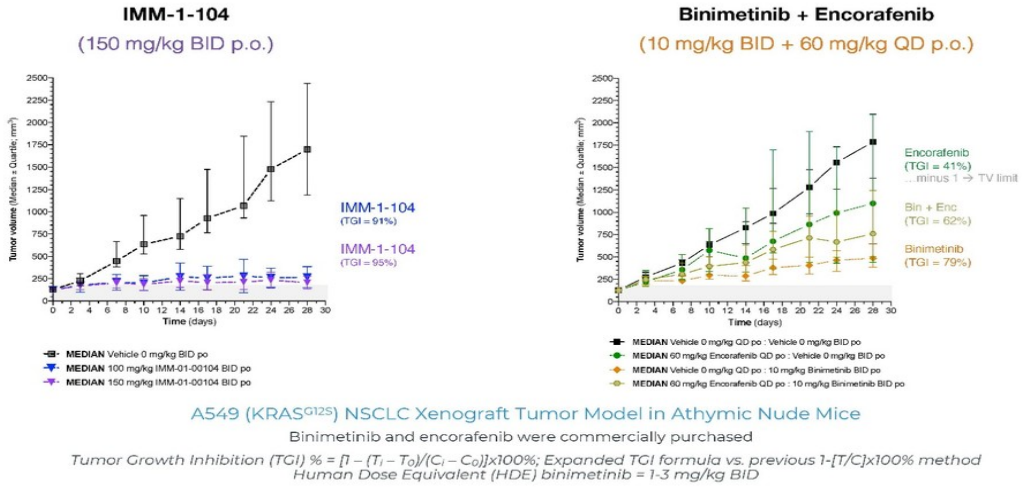
We evaluated atebimetinib head-to-head against four FDA-approved MEK inhibitors for CRAF-bypass resistance in a KRAS mutant NSCLC tumor model. We exposed the tumor cells with 100 nM of each drug for 2 hours and evaluated MEK and ERK activation levels. We observed that atebimetinib reduced overall activity of the MAPK pathway at ERK and pathway reactivation at MEK through a decrease in MEK and ERK activation, resulting in CRAF-bypass resistance. In contrast, we observed that all four FDA-approved MEK inhibitors displayed an increase in activated MEK, resulting in CRAF-bypass (as depicted below).

Head-to-Head Comparison of Atebimetinib against Four FDA-Approved MEK Inhibitors Using a A549 Xenograft Tumor Model: Prevented Downstream Activation of ERK (↓ pERK) and Inhibited Activation of MEK (↓ pMEK)



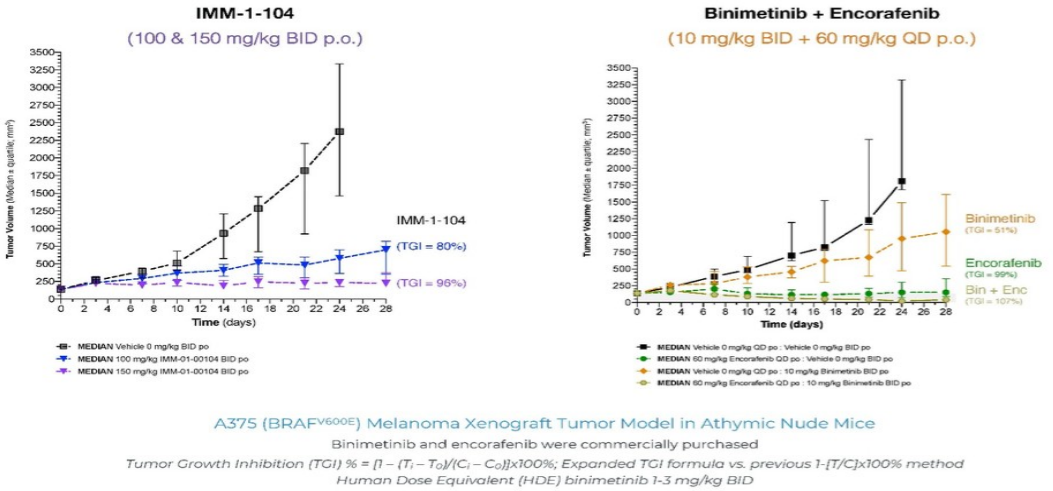
We evaluated atebimetinib head-to-head against binimetinib monotherapy and in combination with encorafenib in the KRAS^{G12S} human NSCLC xenograft tumor model (i.e., A549). When comparing atebimetinib to binimetinib monotherapy, we observed that atebimetinib had greater tumor growth inhibition (as depicted below). The observations of atebimetinib head-to-head against binimetinib alone and in combination with encorafenib, which was not considered relevant for a KRAS mutant, RAF wild-type tumor model, has been included in the figure below for comparison purposes.

Head-to-Head Comparison of Atebimetinib Against Binimetinib +/- Encorafenib Using a A549 Xenograft Tumor Model: Tumor Volume



We also evaluated atebimetinib head-to-head against binimetinib and encorafenib monotherapy and the combination of binimetinib with encorafenib in a $BRAF^{V600E}$ human melanoma xenograft model. It should be noted that the administered combination of binimetinib and encorafenib for BRAF mutant melanoma, such as $BRAF^{V600E/K}$, is an FDA-approved combination. As expected, when comparing atebimetinib alone to binimetinib in combination with encorafenib, we observed that the combination therapy had greater tumor growth inhibition (as depicted below). However, when we compared atebimetinib to binimetinib monotherapy, we observed that atebimetinib had greater tumor growth inhibition (as depicted below). In addition to the monotherapy potential for RAS mutant disease, we believe the greater single agent MEK inhibitor activity observed with our deep cyclic inhibition approach demonstrates the potential of atebimetinib (and/or envometinib, which has an accelerated cadence of deep cyclic inhibition) in drug-drug combinations with other MAPK pathway inhibitors, such as encorafenib, to treat RAF mutant cancers, such as $BRAF^{V600E/K}$, among other MAPK pathway mutations.

Head-to-Head Comparison of Atebimetinib Against Binimetinib +/- Encorafenib Using a A375 Xenograft Tumor Model: Tumor Volume



A375 ($BRAF^{V600E}$) Melanoma Xenograft Tumor Model in Athymic Nude Mice

Binimetinib and encorafenib were commercially purchased

Tumor Growth Inhibition (TGI) % = [1 – (T_i – T_0)/(C_i – C_0)]x100%; Expanded TGI formula vs. previous 1-[T/C]x100% method

Human Dose Equivalent (HDE) binimetinib 1-3 mg/kg BID

In a further *in vivo* study based on humanized 3D tumor model data, we evaluated atebimetinib head-to-head against sotorasib (AMG-510) and gemcitabine alone, and atebimetinib in combination with sotorasib, for 21 days in the $KRAS^{G12C}$ xenograft model (i.e., MIA PaCa-2). In a previous study conducted by a third-party, sotorasib demonstrated sensitivity to this pancreatic tumor model. Comparing atebimetinib alone, against sotorasib and in combination with sotorasib, we observed tumor regressions with insignificant median BWL (i.e., within 3% of baseline), which we believe indicates activity, durability and tolerability of atebimetinib against a $KRAS^{G12C}$ mutant pancreatic cancer model (as depicted below).

Preclinical Studies: 3D Tumor Growth Models

3D tumor growth models mimic the tumor microenvironment ("TME") more closely than 2D culture models, and we believe humanized 3D models more accurately reflect human tumor biology and complexity when translating pharmacological data of MAPK pathway inhibition *in vivo*. We have established and evaluated over 190 humanized 3D tumor models, a majority of which display activating mutations in the RAS isoforms, amongst other altered MAPK pathway targets, including BRAF, CRAF, NF1 and ERK, to evaluate their sensitivities to atebimetinib. In general, we observed that tumor models with KRAS or NRAS mutations and certain molecular profiles were sensitive to atebimetinib, including tumor models displaying BRAF mutations. For example, atebimetinib$_0$ dose-response values in 3D assays as low as 23.7 nM were observed in tumor models that expressed NRAS mutants such as Q61L, Q61R, G12D, Q61K, among others. Similarly, KRAS mutant tumor models were sensitive to atebimetinib treatment, with IC_{50} dose responses as low as 66.7 nM when displaying mutations including Q61H, G12C, G12V, G13D, G12D, G12R, among others. Certain tumor models with BRAF mutations were also found to be sensitive to atebimetinib with IC_{50} dose responses in 3D assays as low as 54.2 nM for V600E (class 1) and G464E (class 2) mutations. A clear driver mutation in RAS or RAF was generally predictive of atebimetinib response, but a smaller number of RAS or RAF mutant models displaying certain oncogenic mutation profiles were found to be insensitive to atebimetinib and displayed IC_{50} dose response values of over 10,000 nM.

We observed that atebimetinib displays broad activity with additional responses in MAPK pathway addicted tumors.

Envometinib (IMM-6-415) Design and Preclinical Overview

Our second program is focused on developing innovative allosteric MEK inhibitors that drive deep cyclic inhibition of the MAPK pathway, designed with unique drug-like properties including a shorter plasma half-life for an accelerated pharmacokinetic cadence dosed twice-daily in humans. Our product candidate for this program is designated as envometinib (IMM-6-415). Envometinib is designed to target MEK in a way that disrupts the MAPK pathway at ERK through reduction of MEK activation. We designed envometinib to have a unique PK and PD profile that may be optimized for distinct solid tumors, potentially including a broad range of MAPK-driven tumors as a monotherapy, as well as for a variety of combination therapy approaches. We evaluated envometinib in a Phase 1/2a clinical trial for the potential treatment of patients with advanced solid tumors. In April 2025, we made the strategic decision to pause further internal advancement of envometinib and focus resources on our lead product candidate atebimetinib. We are pursuing partnership opportunities and considering other potential developmental paths for envometinib.

Preclinical Studies: Overview of Envometinib

In November 2022, in a scientific poster presented at the Society for Immunotherapy of Cancer Annual Meeting, we presented preclinical data demonstrating that envometinib inhibited the growth of RAF and RAS mutant tumors as a monotherapy across multiple human and murine solid tumor models and could be administered in combination with select immune modulators (e.g., checkpoint inhibitors) for the treatment of certain solid tumors, which are often poorly immunologically accessible.

In October 2023, we presented preclinical data at the AACR-NCI-EORTC Conference in which envometinib in combination with encorafenib demonstrated better tumor growth inhibition and improved durability when compared head-to-head with binimetinib plus encorafenib in animal models of RAF mutant melanoma and colorectal cancer, and envometinib as a single agent demonstrated high sensitivity in a wide range of MAPK-driven tumor types, including models of RAS or RAF mutant disease.

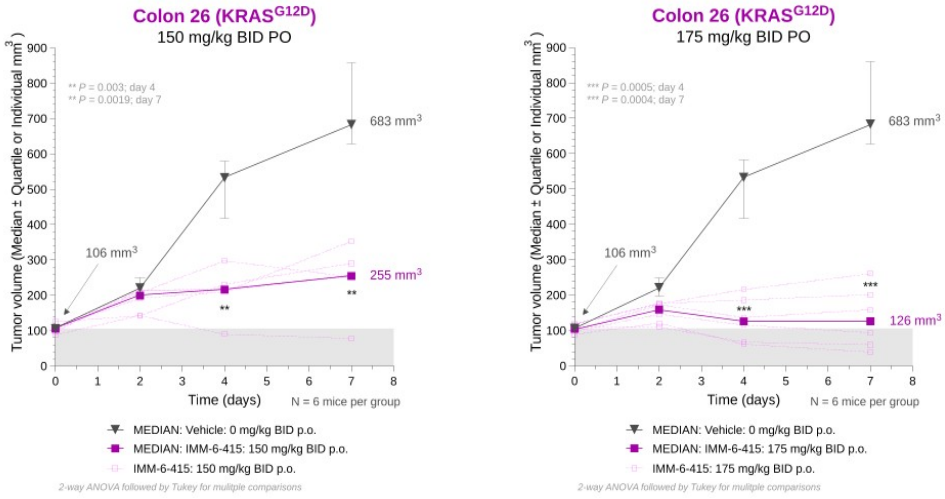
Preclinical Studies: Maximum Tolerated Dose and Therapeutic Effect Data

In our early MTD studies, we observed that oral administration of envometinib twice a day of up to 175 to 180 mg/kg/dose was well-tolerated in mice (middle and right panels in figure above). In other preclinical studies, we observed that the maximum therapeutic effect of envometinib was reached when administered orally twice a day between 150 and 180 mg/kg/dose. These dosing studies provided the basis of envometinib's dosing schedule in subsequent preclinical studies (as depicted in figures below).

Preclinical Studies: Tumor Regression and Body Weight Loss Data

We evaluated envometinib against vehicle and historic responses from atebimetinib in an aggressive murine colorectal tumor model (i.e., Colon-26), which expresses mutant $KRAS^{G12D}$. We observed that envometinib demonstrated robust tumor growth inhibition at top effective doses of 150 and 175 mg/kg BID p.o., with multiple mice experiencing tumor regression during the first 7 days of dosing (as depicted below), with good tolerability, and evidenced limited (-8.61% to +3.34% vs. vehicle group) changes in median BWL at doses in the range of 25 to 175 mg/kg BID p.o. While envometinib displayed a plasma half-life in mice of only a 0.3 to 0.4 hours (0.5 to 0.7 in non-human primates), envometinib led to comparable tumor growth inhibition of that observed with atebimetinib, a molecule that has been observed to have a 1.3 hour half-life in mice (i.e., 3 to 4 times longer than envometinib in the same species), which was previously observed to be superior in a head-to-head comparison against binimetinib and selumetinib in the same model.

Evaluation of Envometinib as Compared to Vehicle Using a Colon 26 Syngeneic Rodent Tumor Model: Tumor Volume



Colon 26 (KRAS^{G12D}) syngeneic colorectal tumor model in immune competent BALB/c mice. Tumor Growth Inhibition (TGI) % = [1 – (Ti – T0)/(Ci – C0)]x100%; Maximum Antitumor Effective Dose Range for Envometinib in mice is 150 mg/kg to 175-180 mg/kg BID p.o.

In a further *in vivo* study based on the positive and negative impact of MAPK pathway activation in antitumor responses, we evaluated envometinib head-to-head against PD1 and CTLA4 checkpoint inhibitors alone, and envometinib in combination with each, for 28 days in the KRAS^{G12D} mutant syngeneic tumor model (i.e., CT-26). Historically, this KRAS mutant colorectal tumor mouse model has demonstrated greater sensitivity to CTLA4 over PD1/PDL1 checkpoint inhibition. Comparing envometinib alone at moderated doses below the maximum cytoreductive levels described above, against anti-PD-1 or anti-CTLA4 treatments and in each combination with envometinib (e.g., QD, BID at multiple dose levels), we observed superior survival through 28 days with insignificant median BWL (i.e., median body weight gain observed in all groups), which we believe indicates the potential for activity, durability and tolerability of envometinib against a KRAS^{G12D} mutant colorectal cancer model in immune competent rodents (as depicted below).

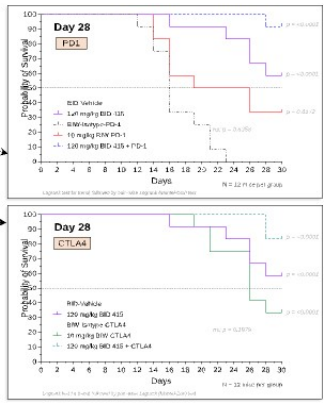
Head-to-Head Comparison of Envometinib +/- anti-PD-1 and anti-CTLA4 Using a CT-26 Syngeneic Tumor Model: Probability of Survival Based on Tumor Volume Limits

IMM-6-415 +/- Checkpoint Inhibitor in **KRAS^{G12D} CT-26**

Schedule	Dose (mg/kg)	Veh	PD-1 (BIW)	CTLA-4 (BIW)	IMM-6-415	IMM-6-415 + PD-1	IMM-6-415 + CTLA-4
BID	120	0/12			7/12	11/12	10/12
BID	60	0/12			0/12	8/12	8/12
BID	30	0/12			0/12	5/12	5/12
QD	120	0/12			0/12	7/12	7/12
QD	60	0/12			1/12	4/12	8/12
QD	30	0/12			0/12	6/12	7/12
BIW	10	0/12	4/12				
BIW	10	0/12		4/12			

• Number of BALB/c mice (out of 12) with tumors through Day 28 with volumes lower than 2,000 mm^3

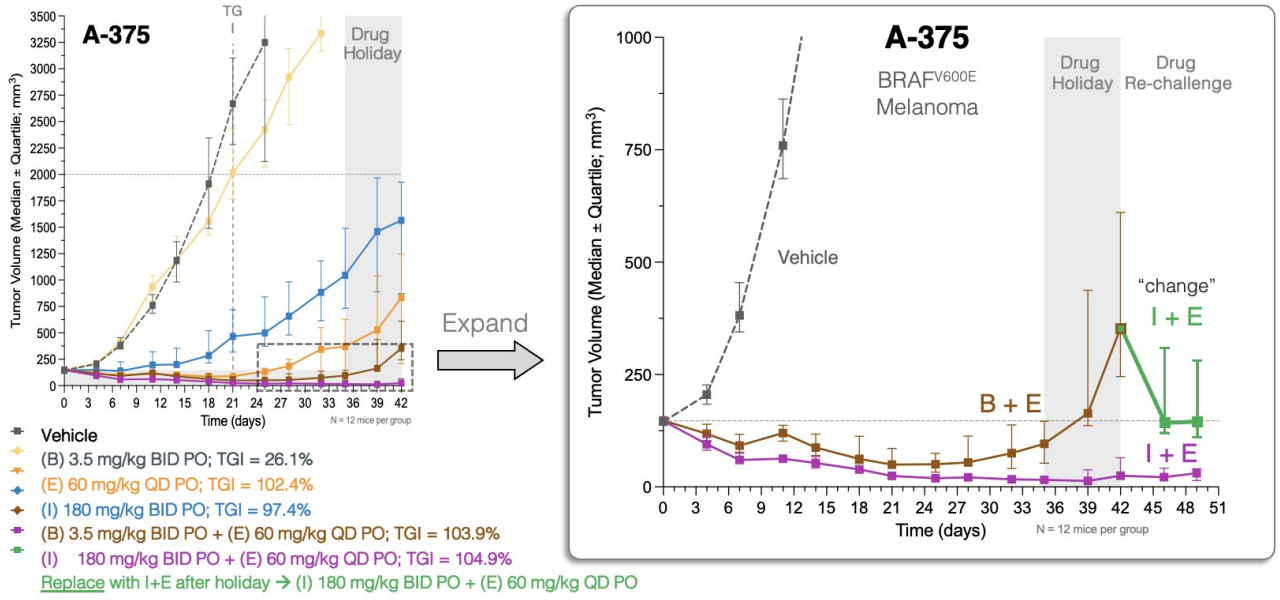
Monotherapy Treated Alive at Day 28
Combination ≥ 3 Advantage



CT-26 (KRAS^{G12D}) syngeneic colorectal tumor model in immune competent BALB/c mice (note: monotherapy and combinations were inactive in athymic nude CT-26 model – data not shown).

We also evaluated envometinib alone and in combination with encorafenib head-to-head against binimetinib and encorafenib monotherapy and the combination of binimetinib with encorafenib in a $BRAF^{V600E}$ human melanoma xenograft model. It should be noted that the administered combination of binimetinib and encorafenib for BRAF mutant melanoma, such as $BRAF^{V600E/K}$, is an FDA-approved combination. As expected, when comparing envometinib alone to binimetinib in combination with encorafenib, we observed that the combination therapy had greater tumor growth inhibition (as depicted below). However, when we compared envometinib to binimetinib monotherapy, we observed that envometinib had greater tumor growth inhibition (as depicted below). When we compared the MEKi plus BRAFi combinations of envometinib plus encorafenib head-to-head versus binimetinib plus encorafenib, the deep cyclic inhibition approach of MEKi with envometinib combinations proved superior to the binimetinib-containing combinations (as depicted below).

Head-to-Head Comparison of Envometinib +/- Encorafenib Against Binimetinib +/- Encorafenib Using a A375 Xenograft Tumor Model: Tumor Volume



A-375 Melanoma $BRAF^{V600E}$ xenograft tumor models in athymic nude mice. Binimetinib (MEK inhibitor) and encorafenib (BRAF inhibitor) were commercially purchased. Tumor Growth Inhibition (TGI) % = [1-(Ti-To)/(Ci-Co)]x100%. No median body weight loss was noted.

Additional Early Discovery Drug Programs

In addition to the discovery programs described above, we are also pursuing drug discovery efforts towards undisclosed but validated oncology targets. We continue to periodically evaluate our drug discovery efforts and are focused on developing and advancing our early pipeline by addressing validated oncology targets in new ways that may better address unmet clinical needs. Our proprietary and we believe, innovative, platforms are central to our discovery and translational efforts, and we continue to prioritize and de-prioritize early discovery drug programs that demonstrate (or fail to demonstrate) clear, targetable patterns of oncogenic addiction that are therapeutically responsive to deep, cyclic target inhibition. This approach ensures that we advance drug programs with potential for broad activity and improved overall tolerability.

Our Platform

Consistent with our approach of weaving bioinformatics and computational biology into every stage of the drug development process, we have developed a proprietary disease-agnostic platform that allows us to leverage human biological data to generate insights that are not constrained by the inherent limitations of conventional approaches or prevailing scientific views. We are developing novel product candidates that aim to optimize both safety and efficacy for diseases with high unmet medical needs and suboptimal treatment options. Key elements of our platform include:

- ***Insights from Human Data.*** Compare distinct groups of individuals who differ in a certain aspect of disease or response to a particular therapy, or identify new patient subsets.

- ***Novel Biology.*** Identify potential novel targets and new ways to drug existing targets including by using our Disease Cancelling Technology ("DCT") and/or our insights into mechanisms of response.

- ***Novel Chemistry.*** Identify small molecules that selectively bind to a target of interest including by using our proprietary technology, and/or engineer PK to achieve optimal signaling dynamics.

- ***Proprietary Translational Planning.*** Use proprietary, humanized 3D preclinical models and bioinformatics to prioritize indications and identify sensitive subpopulations.

- ***Proprietary Clinical Data Analysis.*** We have developed proprietary software and methods to view, analyze, and interpret clinical data to inform decision-making, enhance translational studies, and inform future analyses.

Underlying each of these elements is our rigorous quality control and ability to analyze complex biological datasets. We are one of the few biopharmaceutical companies that has been involved in defining best practices for robustly analyzing bioinformatics data, as evidenced by co-authorship on journal articles together with regulators as well as writing invited reviews to educate the scientific community on this topic. This attention to rigorous quality control pervades all of our analyses, and we believe this enables us to extract meaningful information from a variety of databases of human data, including GENIE and The Cancer Genome Atlas Program ("TCGA").

Our platform is not limited to a single aspect or pathology; rather, it is disease-agnostic, which we believe enables us to identify, develop and evaluate product candidates across multiple disease areas simultaneously, with our current focus in oncology. While we currently have an emphasis on transcriptomic data, our platform is not limited to a single data type and thus we believe it will be able to evolve as new datasets emerge. Our platform enabled the initiation, discovery and development of our product candidates atebimetinib and envometinib, and has led us to identify additional potential product candidates with novel compositions of matter by leveraging our platform and drug discovery process. Moreover, our platform has previously been applied extensively in successful partnerships with large pharmaceutical and biotechnology companies, and through our internal drug discovery and development.

Insights from Human Data

Our analyses often begin by comparing existing transcriptomic data from two groups of patients (e.g., from those whose tumors have metastasized versus those whose tumors have not) to help elucidate the biological mechanisms underlying a particular aspect of disease which we seek to counteract. As another example, we may analyze existing data from patients with differences in response to an existing therapy, in order to better understand what is happening in responders versus non-responders. We may also analyze existing data from patients with a disease to identify novel subsets of patients. Our platform has enabled us to conduct multiple projects that involve stratifying patients into novel subsets. We associate transcriptomic profiles with each subset, which can then be directly inputted into DCT to identify novel targets specific to a given patient subset.

Novel Biology

Disease Cancelling Technology

We have developed DCT to identify targets that reverse a disease signal across multiple relevant genes with the potential to yield product candidates with differentiated mechanisms that are less likely to be discovered by traditional drug discovery methods. Additional biologic context is derived from quantifying the extent to which different time points, concentrations and perturbations (e.g., inhibition and overexpression) may cancel a disease signal more effectively than existing drug targets. DCT ranks target perturbations by the extent to which they generate signals that counteract disease-associated gene expression changes observed in patient data. Thus, we believe DCT enables hypothesis-free, data-driven identification of novel targets and new ways to drug existing targets.

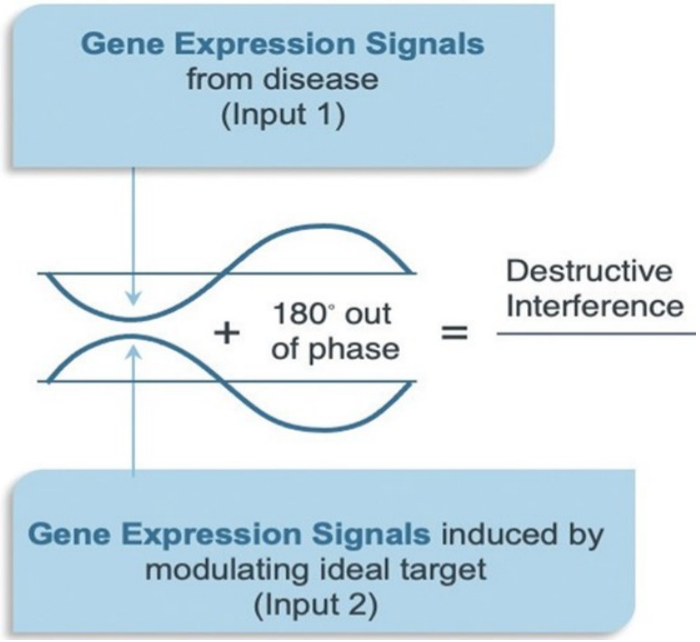
DCT leverages gene expression data derived from human patient samples to identify targets that may rescue abnormal gene expression and restore pathway homeostasis. In addition, DCT identifies biology relevant to attenuating a disease by quantifying the similarity of genome-wide signatures of specific aspects of the disease to signatures of target induced gene expression changes using a mathematical similarity metric. Uniquely, DCT quantifies the per-gene contribution to overall disease amplification or cancellation. An example of a typical analysis begins by running DCT to identify an unwanted, disease-specific gene expression pattern. The ideal input to DCT is focused on a specific aspect of a disease, such as tumors that have metastasized versus those that have not, rather than comparing diseased versus healthy states. DCT identifies target candidates by screening a disease differential expression signature and comparing it to thousands of target gene expression signatures.

DCT is able to rapidly compare disease state signatures against vast numbers of target signatures. DCT ranks signatures resulting from the modulation of specific targets by the extent to which they oppose disease signatures (as depicted below). Unlike some algorithms or artificial intelligence ("AI") approaches, the results originating from DCT are designed to be interpretable from a computational and biological perspective. This platform uses gene expression from patient datasets and does not rely on literature. Together with the target, DCT provides a specific list of testable genes associated with the target of interest, relevant drug concentrations and temporal dynamic information driving the result. Thus, we believe DCT can identify new targets and readily detect dynamic relevant biology relating to modulating a target in a better way.

A summary workflow for DCT's novel target identification can be described as follows:

- Carefully curated and quality-controlled human transcriptomic data representing a specific aspect of disease, or Input 1, is input and vectorized for processing (as depicted below).
- A carefully curated and quality-controlled library of gene expression signals associated with perturbing specific targets at specific time points and concentrations, or Input 2, is input and vectorized for processing (as depicted below). This library can potentially include clustered regularly interspaced short palindromic repeats ("CRISPR"), RNA interference, tool compounds, screening library compounds and existing drugs.
- The strength of disease signal cancellation is measured between Input 1 and every target signature in Input 2.

Disease Cancelling Technology Summary Workflow for Target Identification



A second filtration step selects target candidates for which multiple biological pathways are restored in the proper direction compared to the disease signal. DCT includes a method to compute a per pathway contribution to disease canceling in terms of percent contribution to overall disease reversal for cases when a specific pathway is particularly relevant. DCT is designed to have many capabilities in addition to identifying novel targets or novel ways to drug existing targets. To enable rapid translation to experimental validation, DCT can suggest ideal concentrations, temporal dynamics and marker genes to monitor. DCT is also capable of predicting target combinations for a given disease or an ideal target for combination with an existing therapy. For expanded utility, DCT has a graphical user interface that enables our biologists to interact with, sort, modify, query and run results along with producing visualizations of results.

We believe DCT has several advantages over other target identification technologies. The platform uses patient data as a starting point, rather than artificial 2D *in vitro* models. We have presented data at American Association for Cancer Research and other conferences demonstrating how cell lines fail to capture the heterogeneity of patient tumors, and our discovery team's experience in the 3D tumor modeling field has also highlighted the limitations of 2D *in vitro* data. Moreover, working closely with several FDA-approved drugs, we have found that transcriptomic data was most frequently and dynamically linked to drug activity. Thus, our core insights are derived from transcriptomic data (RNA), while some of our competitor's platforms may focus on sequencing data (DNA), imaging data from phenotypic screens and/or literature.

DCT is focused on identifying novel targets or novel ways to modulate existing targets, with the goal of generating novel therapeutics with improved clinical activity. We have not in-licensed external drugs and we do not focus on "drug repurposing" activities. Our pipeline is composed of programs with potentially novel pharmacological effects.

Biological Mechanisms of Response

We also identify novel biology by applying translational bioinformatics to analyze the biological mechanisms of response of existing therapies. This may include comparing the transcriptional profiles induced by a drug at different timepoints in order to highlight biological feedback loops that we then seek to counteract.

Signaling Dynamics (PK-Driven)

Transcriptomic data has proven critical to these analyses because it provides an understanding of the extent to which specific genes are expressed at any given time, capturing temporal changes in pathway activation. Signaling networks differ between cell types, and we leverage this to modulate targets in such a way that certain cell types will be more impacted than others. Our platform enables us to assess the signaling dynamics of product candidates, which we believe allows us to optimize the chemistry of our product candidate programs to achieve broad therapeutic activity against diseased cells while sparing healthy normal cells. Modulation of these signaling networks impacts cell fate decisions in many cell types, including cancerous cells. Our computational biology expertise enables us to analyze transcriptomic data that closely reflects spatiotemporal dynamics of biological signaling networks.

Proprietary Translational Planning

Humanized 3D Tumor Models.

In oncology, we are deeply experienced in advanced, humanized 3D-based tumor growth models, which based on peer reviewed research by members of our team and others, more accurately predict drug response in animal models, and we believe in patients, compared to standard models. Unlike *in vitro* approaches, the 3D tumor growth models reflect the complexity of tumor biology given their alignment with the TME. Thus, we believe our deep expertise in 3D tumor models enables us to more accurately stratify patients likely to benefit from our potential product candidates.

3D-TGA Background and Utility

Although two-dimensional ("2D") tissue culture has dominated cell-based preclinical oncology research for over 70 years, successful translation and regulatory approval of new oncology drugs are amongst the lowest of all therapeutic areas. Innovations in cell-based platform technologies, such as matrix-based humanized 3D Tumor Growth Assay ("3D-TGA") tumor models, offer the promise to enrich preclinical drug discovery and improve overall clinical translational success. Our company and leadership have a strong history in research and translation of drug response using patient-derived tumor models (e.g., patient-derived xenografts and 3D ex vivo models) and translational bioinformatics using public and internal patient data. Our team has built on previous ex vivo tumor modeling experience and patient-alignment model selection approaches to identify models that better reflect molecular profiles of target patient populations. We believe this effort will help improve translational success of our pipeline and help ensure that established 3D-TGA models perform well as a core platform for innovative oncology drug R&D. By leveraging over two decades of humanized modeling expertise, our translational and discovery teams have built, characterized, and interrogated a large set of 3D-TGA tumor models from commonly used human tumor cell lines (i.e., currently at over 130 tumor models). The cohort of 3D-TGA tumor models span at least 12 major tumor types, including: breast, colorectal, lung, pancreas, melanoma, ovary, liver, stomach, prostate, neuroblastoma, rhabdomyosarcoma, and thyroid. Over time, additional 3D-TGA models may be developed to add new indications or expand existing indications to better test emerging discovery or translational hypotheses. A large, proprietary 3D-TGA collection ensures that new drug candidates, identified as active in one cohort, could be quickly tested for broader tumor activity in additional tumor types. The established collection of 3D-TGA tumor models can also be used to perform novel drug screens and develop novel chemical entities (NCE's) that demonstrate drug activity.

Prioritize Indications and Identify Sensitive Subpopulations

We are able to leverage bioinformatics to analyze genomic data from large patient databases of primary tumor data to identify specific indications where first line patients are likely to have characteristics that align with our more reflective humanized models and identify biological mechanisms and biomarkers that enable us to identify subpopulations that are more likely to be sensitive based on their similarity to our translational approaches.

Analyze Clinical Data

We have developed proprietary software that we believe enables us to view, analyze, and interpret clinical data in new and more robust ways.

Commercialization Plan

We intend to retain significant development and commercialization rights to our product candidates in major markets and, if marketing approval is obtained, to commercialize our product candidates on our own, or potentially in select regions with a partner. We currently have no sales, marketing or commercial product distribution capabilities. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, in connection with the advancement of our product candidates. Clinical data, addressable patient population, commercial infrastructure and manufacturing needs, and the status of our pipeline, may, without limitation, all influence or alter our development and commercialization plans.

Competition

The pharmaceutical and biotechnology industries are characterized by rapid advancement of novel technologies, significant competition and a strong defense of intellectual property rights. While we believe that our proprietary platform and scientific expertise provides us with competitive advantages, we face competition from multiple sources, including larger and better-funded pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and, if approved, commercialize will compete with currently approved therapies and new therapies that may become available in the future. Key factors that would affect our ability to effectively compete with other therapeutics include, without limitation: safety, efficacy, ease of administration, pricing, brand recognition and availability of reimbursement and coverage by third party payors.

Our Oncology Programs

The current FDA-approved treatment options that target MAPK pathway cancers generally are either MEK inhibitors limited by their high rates of serious drug-related adverse events that result in drug intolerability and drug resistance through MAPK-feedback loops, or KRAS inhibitors limited to patients with specific KRAS mutations. We expect that our oncology programs targeting the MAPK pathway may compete with current FDA-approved therapies or clinical programs targeting RAS or RAF mutant tumors that are being advanced by certain pharmaceutical and biotechnology companies.

Intellectual Property

Our ability to obtain and maintain intellectual property protection for our products and technology is fundamental to the long-term success of our business. We rely on a combination of intellectual property protection strategies, including patents, trademarks, copyrights, trade secrets, license agreements, confidentiality policies and procedures, non-disclosure agreements, invention assignment agreements and technical measures designed to protect the intellectual property and confidential information and data used in our business.

As of February 2, 2026, we had: three issued U.S. patents; nine issued patents outside the U.S.; nine pending U.S. patent applications; thirty-seven pending patent applications outside the U.S.; three U.S. provisional applications; and three Patent Cooperation Treaty ("PCT") applications that have not entered national stage. These patents and patent applications relate to various subject matter, including: our product candidate atebimetinib, our product candidate envometinib, and our DCT. Excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable, our owned issued U.S. patent and any patents that may issue from our owned pending U.S. patent applications are expected to expire between February 2039 and January 2046 any patents that may issue from our owned pending foreign patent applications are expected to expire between January 2041 and January 2046.

With respect to atebimetinib, as of February 2, 2026, we had: one issued U.S. patent; ten issued patents outside the U.S.; three pending PCT applications; five pending U.S. patent applications; one U.S. provisional application; and sixteen pending patent applications outside the U.S. The issued claims in our issued U.S. patent are directed to protecting atebimetinib and related compounds. The issued claims in these patents outside the U.S. are directed to protecting atebimetinib, related compounds, pharmaceutical compositions, and methods of use. The pending U.S. patent applications, and these pending patent applications outside the U.S., include claims directed to compounds, pharmaceutical compositions, and methods of use. Any patent that may issue, based upon these pending applications related to atebimetinib, is expected to expire between January 2041 and September 2045, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable.

With respect to envometinib, as of February 2, 2026, we had: two pending PCT applications; three pending U.S. patent applications; and twenty-one pending patent applications outside the U.S. Any patent that may issue based upon the pending PCT applications is expected to expire between November 2043 and January 2046, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable.

With respect to DCT, as of February 2, 2026, we had: two issued U.S. patents. The issued claims of these U.S. patents are directed to methods (processes) and systems. Our issued U.S. patents related to our DCT are expected to expire in April 2039, excluding any possible patent term extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office ("USPTO") in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. We cannot be sure that our pending patent applications that we have filed or may file in the future will result in issued patents, and we can give no assurance that any patents that have issued or might issue in the future will protect our current or future product candidates or (if approved) products, will provide us with any competitive advantage, and will not be challenged, invalidated, or circumvented.

In the United States, the patent term of a patent that claims an FDA-approved drug or biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time that the drug or biologic is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug or biologic may be extended. Similar provisions are available in the EU and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug or biologic. In the future, if product candidates that we may develop receive FDA approval, we expect to apply for patent term extensions where applicable on patents covering those drugs. We plan to seek patent term extensions to any of our future issued patents in any jurisdiction where these are available. However, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether these extensions should be granted, and if granted, the length of these extensions.

We intend to pursue additional intellectual property protection to the extent we believe it would be beneficial and cost-effective. Our ability to stop third parties from making, using or commercializing any of our patented inventions will depend in part on our success in obtaining, defending and enforcing patent claims that cover our technology, inventions, and improvements. With respect to our intellectual property, we cannot provide any assurance that any of our current or future patent applications will result in the issuance of patents in any particular jurisdiction, or that any of our current or future issued patents will effectively protect any of our product candidates, products (if approved) or technology from infringement or prevent others from commercializing infringing products or technology.

In addition to our reliance on patent protection for our inventions, product candidates, products (if approved), and technologies, we also seek to protect our brand through the procurement of trademark rights. As of February 2, 2026, we held certain trademark registrations and pending applications for trademark registration for the marks DEEP CYCLIC INHIBITION, FLUENCY, DISEASE CANCELLING and IMMUNEERING in the United States. Furthermore, we rely on trade secrets, know-how, unpatented technology and other proprietary information, to strengthen our competitive position. We have determined that certain technologies, including some of our software, are better protected as trade secrets. To mitigate the possibility of trade secret misappropriation, we typically enter into non-disclosure and confidentiality agreements with parties who have access to our trade secrets, such as our employees, consultants, advisors and other third parties. We also typically enter into invention assignment agreements with our employees and consultants that obligate them to assign to us any inventions they develop while working for us. We generally control access to our proprietary and confidential information through the use of internal and external controls that are subject to periodic review. Although we take steps to protect our proprietary information and trade secrets, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. As a result, we may not be able to meaningfully protect our trade secrets. For further discussion of the risks relating to intellectual property, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Government Regulation

Among others, the FDA, U.S. Department of Health and Human Services Office of Inspector General, the Centers for Medicare and Medicaid Services and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the preclinical and clinical development, manufacture, marketing and distribution of potential drugs such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, packaging, storage, record keeping, approval, sales, commercialization, marketing, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates. Any product candidates that we develop must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in those foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the European Union ("EU") are addressed in a centralized way, but country-specific regulation remains essential in many respects.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act (the "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 ("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 ("GCP") requirements to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of a NDA after completion of all pivotal trials;
- payment of user fees associated with an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for 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 current good manufacturing practice ("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 GCPs;

- potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA; 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. Some preclinical testing may continue even after the IND is submitted. The IND also includes results of animal and in vitro studies assessing the toxicology, PK, pharmacology, and PD 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 GCPs, which include, among other things, 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 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. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial 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. 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 product candidate has been associated with unexpected serious harm to patients. 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 (depending on its charter) may provide 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, under certain timelines, of ongoing clinical studies and clinical study results to public registries, specifically the clinicaltrials.gov website managed by the National Institutes of Health ("NIH").

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 initial safety, dosage tolerance, absorption, metabolism and distribution of the investigational product candidate in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some product candidates for severe or life-threatening diseases, such as cancer, especially when the product candidate 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, dose tolerance and dosing schedule and to identify possible adverse side effects and safety risks.

- 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 candidate and to provide an adequate basis for regulatory approval.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval (if any). These trials are used to gain additional experience from the treatment of patients in the approved indication. In certain instances, such as with accelerated approval drugs, the FDA may mandate the performance of Phase 4 trials as a condition of approval of an NDA.

A sponsor may choose, but is not required, to conduct a foreign clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical trial is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the trial as support for an IND or application for marketing approval. Specifically, the FDA has promulgated regulations governing the acceptance of foreign clinical trials not conducted under an IND, establishing that such trials will be accepted as support for an IND or application for marketing approval if conducted in accordance with GCP, including review and approval by an independent ethics committee ("IEC") and use of proper procedures for obtaining informed consent from subjects, and the FDA is able to validate the data from the trial through an on-site inspection if the FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical trials. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign trials are conducted in a manner comparable to that required for IND trials. If a marketing application is based solely on foreign clinical data, the FDA requires that the foreign data be applicable to the U.S. population and U.S. medical practice; the trials must have been performed by clinical investigators of recognized competence; and the FDA must be able to validate the data through an on-site inspection or other appropriate means, if the FDA deems such an inspection to be necessary.

During the development process, sponsors are given opportunities to meet with the FDA at certain points. These points are generally prior to submission of an IND, at the end of 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 to obtain the FDA's feedback on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the product candidate.

Concurrently 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 potential 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, 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.

U.S. Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, including results from 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 candidate. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product candidate to the satisfaction of the FDA. 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 product candidates designated as orphan drugs, unless the product application also includes a non-orphan indication.

The FDA reviews an NDA to determine, among other things, whether a product candidate is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product candidate's identity, strength, quality and purity. Under the Prescription Drug User Fee Act (the "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 the FDA because the FDA has approximately two months to make a "filing" decision after it 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 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 GCPs.

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 clinical 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, addressing 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.

If regulatory approval of a product candidate is granted, such approval will be granted for particular indications and may contain limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy ("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 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.

The Pediatric Research Equity Act (the "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 the 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.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition 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 to market the same drug for the same approved indication or use within such rare disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity within the relevant indication (i.e., greater safety, greater efficacy, or a major contribution to patient care) or inability to manufacture the product in sufficient quantities to meet the needs for the indication or use protected by orphan exclusivity. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of different products for the indication or use for which the orphan product has exclusivity or obtain approval for the same product but for a different indication or use for which the orphan product has exclusivity. If an orphan designated product receives marketing approval for a disease or condition broader than what is designated, it may not be entitled to orphan exclusivity. In addition, 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 relating to the approved indication or use of patients with the applicable rare disease or condition.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development and/or review of product candidates that meet certain criteria. Sponsors may request that the FDA allow the use of one or more of these programs. For example, product candidates 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. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the review team during product development, and 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.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, 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 beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any product candidate submitted to the FDA for approval, including a product candidate with a fast track designation or breakthrough therapy designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. An NDA for a product candidate is eligible for priority review if it has the potential to provide significant improvement in treatment, diagnosis or prevention of a serious disease or condition 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, depending on the design of the applicable clinical trials, a product candidate may be eligible for accelerated approval. Drug product candidates intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate 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 generally requires that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials to verify and describe the anticipated clinical benefit. The FDA may withdraw accelerated approval if, among other things, the confirmatory study fails to verify clinical benefit; the applicant fails to perform required confirmatory studies with due diligence; postmarketing use demonstrates that postmarketing restrictions are inadequate to assure safe use; the applicant fails to adhere to agreed-upon postmarketing restrictions; promotional materials are false or misleading; or other evidence demonstrates that the product is not shown to be safe or effective under its conditions of use. In addition, the FDA generally 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 candidate.

Fast track designation, breakthrough therapy designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate 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.

Post-approval Requirements

Drug products manufactured or distributed 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 also are 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, which impose certain 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. 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 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 provisions of 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. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data 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 ("ANDA") or an NDA submitted under Section 505(b)(2) (a "505(b)(2) NDA"), submitted 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 non-patent 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 approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. 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, whether patent or non-patent, 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.

Government Regulation Outside of the United States

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries governing, among other things, pre-clinical studies, clinical trials, marketing authorization, manufacturing, commercial sales and distribution of drugs.

Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product candidates in those countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to comply with applicable foreign regulatory requirements may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-Clinical Studies and Clinical Trials

Similar to the United States, the various phases of non-clinical and clinical research in other jurisdictions, for example in the EU, are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of Good Laboratory Practice ("GLP") as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), Good Clinical Practice ("GCP") guidelines, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy and, in most EU member states, the sponsor is liable to provide “no fault” compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation ("CTR"), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022, with a three-year transition period. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

The CTR provides for a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single clinical trial application ("CTA") submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state’s decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with GMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In order to market our product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. Specifically in the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization ("MA"). To obtain regulatory approval of a product candidate under EU regulatory systems, we must submit a MA application ("MAA"). The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs.

- "Centralized MAs" are issued by the European Commission through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA"), and are valid throughout the EU. The centralized procedure is compulsory for certain types of medicinal products such as (i) medicinal products derived from biotechnological processes, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products ("ATMPs") (such as gene therapy, somatic cell therapy and tissue engineered products) and (iv) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as cancer, HIV/AIDS, diabetes, neurodegenerative diseases or autoimmune diseases and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops.

- "National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure described above. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state. The timeframe to obtain national MAs varies depending on the concerned procedure. In order to grant the MA, the EMA or the competent authorities of the EU member states make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance.

Data and Marketing Exclusivity

In the EU, new products authorized for marketing (i.e., reference products) generally receive eight years of data exclusivity and an additional two years of market exclusivity upon receipt of MA. If granted, the data exclusivity period prevents generic and biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall 10-year market exclusivity period can be extended to a maximum of 11 years if, during the first 8 years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications, which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical or biological entity, and products may not qualify for data exclusivity.

Orphan Medicinal Products

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition; (2) either (a) such condition affects not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from the orphan status, would not generate sufficient return in the EU to justify the necessary investment for its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized for marketing in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition. In the EU, orphan designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Orphan designation must be requested before submitting an MAA. An EU orphan designation entitles a party to incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized procedure. Upon grant of a MA, orphan medicinal products are entitled to ten years of market exclusivity for the approved indication, which means that the competent authorities cannot accept another MAA, or grant a MA, or accept an application to extend a MA for a similar medicinal product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan ("PIP"). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The orphan exclusivity period may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan destination, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, MA may be granted to a similar product for the same indication at any time if: (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

The aforementioned EU rules are generally applicable in the European Economic Area ("EEA"), which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance ("QPPV") who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (“PSURs”).

All new MAA must include a risk management plan (“RMP”) describing the risk management system that we will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

The aforementioned EU rules are generally applicable in the EEA.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Brexit and the Regulatory Framework in the United Kingdom

Since the end of the Brexit transition period on January 1, 2021, and the implementation of the Windsor Framework (described further, below) on January 1, 2025, the United Kingdom ("UK") has not been directly subject to EU laws with respect to medicinal products. The EU laws that have been transposed into UK law through secondary legislation remain applicable in the UK, but new legislation such as the (EU) CTR is not applicable in the UK.

Since January 1, 2021, the Medicines and Healthcare products Regulatory Agency ("MHRA") has been the UK's standalone medicines and medical devices regulator. As a result of the Northern Ireland Protocol, different rules applied in Northern Ireland than in Great Britain (comprising England, Scotland and Wales, "GB"); broadly, Northern Ireland continued to follow the EU regulatory regime. However, on January 1, 2025, a new arrangement called the "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes, and EU labelling and serialization requirements in relation to Northern Ireland, and introduces a UK-wide licensing process for medicinal products.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment and a rolling review procedure. In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain an MA to commercialize products in the UK. Since January 1, 2024, an international recognition procedure has been in place whereby the MHRA has been able to conduct targeted assessments of an MAA by recognizing approvals from trusted partner agencies such as the EMA.

With respect to the framework in relation to clinical trials, on April 28, 2025, the UK government adopted the Medicines for Human Use (Clinical Trials) Amendment Regulations 2024 (becoming fully effective on April 28, 2026), which aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered.

There is no pre-marketing authorization orphan designation in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same as in the EU, but have been tailored for the market; for example, the prevalence of the condition in the UK, rather than the EU, must not be more than five in 10,000. If an orphan designation is granted, the period of market exclusivity will be set from the date of first approval of the product in the UK.

Other Healthcare Laws

Pharmaceutical companies like us are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such regulation may constrain the financial arrangements and relationships through which we research, develop, and ultimately, sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, foreign, federal and state anti-kickback, fraud and abuse, and false claims laws, such as the federal Anti-Kickback Statute and the federal Civil False Claims Act, as well as foreign, federal and state transparency laws and regulations with respect to drug pricing and payments and other transfers of value made by pharmaceutical manufacturers to physicians and other healthcare providers, such as the federal Physician Payment Sunshine Act. In the EU, many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medicinal products, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on pharmaceutical companies. Certain countries also mandate implementation of commercial compliance programs, or require disclosure of marketing expenditures and pricing information. Violations of any of such laws or any other governmental regulations that apply may result in significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations to resolve allegations of noncompliance, exclusion from participation in foreign, federal and state healthcare programs, such as Medicare and Medicaid, 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. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing coverage and reimbursement for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. 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 and also have a material adverse effect on sales.

Moreover, as a condition of participating in, and having products covered under, certain federal healthcare programs, such as Medicare and Medicaid, we may become subject to federal laws and regulations that require pharmaceutical manufacturers to calculate and report certain price reporting metrics to the government, such as Medicaid Average Manufacturer Price ("AMP") and Best Price, Medicare Average Sales Price, the 340B Ceiling Price, and Non-Federal Average Manufacturer Price reported to the Department of Veteran Affairs, and with respect to Medicaid, pay statutory rebates on utilization of manufacturers' products by Medicaid beneficiaries. Compliance with such laws and regulations will require significant resources and may have a material adverse effect on our revenues.

In addition, in many foreign countries the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Member states are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. Member states may approve a specific price or level of reimbursement for the pharmaceutical product, or alternatively adopt a system of direct or indirect controls on the profitability of the company responsible for placing the pharmaceutical product on the market, including volume-based arrangements, caps and reference pricing mechanisms. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates or products, if approved. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

Healthcare Reform

In the United States, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each as amended, collectively known as the "ACA", was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. For example, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- expanded beneficiary eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 138% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expanded the types of entities eligible for the 340B Drug Pricing Program;

- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" and biologic agents apportioned among these entities according to their market share in certain federal government programs;

- established the Center for Medicare and Medicaid Innovation within the Centers for Medicare and Medicaid Services ("CMS") to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;

- created the Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and

- required annual reporting of certain information regarding drug samples that manufacturers and distributors provide to licensed practitioners.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional action is taken by Congress. In addition, the American Rescue Plan, effective January 1, 2024, eliminates the statutory cap on rebate amounts owed by drug manufacturers under the Medicaid Drug Rebate Program (the "MDRP"), which was previously capped at 100% of the AMP for a covered outpatient drug.

Moreover, there has been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. On August 16, 2022, the Inflation Reduction Act of 2022 (the "IRA") was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS published the negotiated prices for the initial ten drugs, which went into effect in 2026, and the subsequent 15 drugs effective in 2027, as well as the next set of 15 drugs that will be subject to negotiation, although the drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated.

In July 2025, the One Big Beautiful Bill Act (the "OBBBA") was enacted, which imposes significant reductions in the funding of the Medicaid program and restrictions for certain groups to access the ACA Marketplace. These changes are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, and may result in an increase in the number of individuals who are unable to access health insurance benefits and medical care, either of which could adversely affect our sales of any product candidate that we potentially commercialize.

Additionally, the Trump administration has pursued a two-fold strategy to reduce drug costs in the U.S. The administration has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. The administration is also pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. While the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry generally and our business specifically.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states.

Similar reform considerations exist outside of the United States. At the EU level for example, in 2011 Directive 2011/24/EU was adopted. This Directive establishes a voluntary network of national authorities or bodies responsible for Health Technology Assessment ("HTA") in the individual EU member states. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, on December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product, for example oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other new medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

We expect that additional state, federal and foreign healthcare reform measures will be adopted in the future, any of which could impact the amounts that federal and state governments and other third-party payors will pay for healthcare products and services.

Data Privacy and Security

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and may apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws, for example the European Union's General Data Protection Regulation ("GDPR"), govern the privacy and security of personal data, including health-related data, in applicable jurisdictions. All such privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Human Capital

As of December 31, 2025, we had 53 full-time employees, 37 of whom were dedicated to research and development, and 20 of whom held doctorate degrees (i.e., Ph.D. or M.D.). 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.

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off.

We believe that much of our success is rooted in our commitment to inclusion. We value skills and experience at all levels and focus on extending our inclusion and belonging initiatives across our entire workforce.

Our Corporate Information

We were incorporated under the laws of the state of Delaware in February 2008. Our principal executive offices are located at 245 Main Street, Second Floor, Cambridge, MA 02142 and our telephone number is (617) 500-8080.

Our corporate website address is *www.immuneering.com*. The information contained in, or accessible through, our website is not incorporated by reference into this Annual Report and you should not consider information on our website to be a part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

Where you can find more information

We are subject to the information requirements of the Securities Exchange Act of 1934, as amended. The United States Securities and Exchange Commission (the "SEC") maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically, such as ourselves, with the SEC at http://www.sec.gov.

Item 1A. Risk Factors

Our future operating results could differ materially from the results described in this Annual Report on Form 10-K due to the risks and uncertainties described below. You should consider carefully the following information about risks below in evaluating our business. If any of the following risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our Class A common stock would likely decline. In addition, we cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. See "Forward-Looking Statements" for a discussion of some of the forward-looking statements that are qualified by these risk factors. Factors that could cause or contribute to such differences include those factors discussed below.

Risks Related to Our Financial Condition and Capital Requirements

We are a late-stage clinical oncology company with a limited operating history in developing pharmaceutical products, have not completed any registrational clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a late-stage clinical oncology company with a limited operating history in developing pharmaceutical products which makes it difficult to evaluate our business and prospects in future product development. We have no products approved for commercial sale and have not generated any revenue from product sales. To date, we have devoted substantially all of our resources and efforts to providing computational biology services to pharmaceutical and biotechnology companies, organizing and staffing our company, business planning, executing partnerships, raising capital, discovering, identifying and developing potential product candidates, securing related intellectual property rights and undertaking research and preclinical studies and clinical trials of our product candidates, including our ongoing Phase 1/2a clinical trial of atebimetinib (also referred to as IMM-1-104) for the treatment of advanced solid tumors. We have not yet demonstrated our ability to successfully complete any registrational 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. As a result, it may be more difficult for you to accurately predict our future success or viability to develop new pharmaceutical products than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by biopharmaceutical companies developing products in rapidly evolving fields. We also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses for the past several years and we expect to continue to incur significant net losses for the foreseeable future and may never obtain profitability.

We have incurred net losses in each reporting period for the past several years, have not generated any revenue from product sales to date and have financed our operations principally through our historical computational biology services to pharmaceutical and biotechnology companies (which have since ceased), the issuance of convertible debt and the sale of our convertible preferred stock, Class A common stock and warrants exercisable for common stock. We have incurred net losses of approximately $56.0 million and $61.0 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of approximately $280.3 million. Our losses have resulted principally from expenses incurred in research and development of our product candidates, from management and administrative costs and from other expenses that we have incurred while building our business infrastructure. We are currently conducting an ongoing Phase 1/2a clinical trial for our product candidate atebimetinib for the treatment of advanced solid tumors and plan to dose the first patient in our MAPKeeper 301 registrational trial in mid-2026. Our other product candidates are in earlier stages of drug development. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses as we discover, develop and market additional potential product candidates.

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

- advance the development of our current and future product candidates, including atebimetinib, through preclinical and clinical development, and, if approved by the FDA or other comparable foreign regulatory authorities, commercialization;
- incur manufacturing costs for our product candidates;
- seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- increase our research and development activities to identify and develop new product candidates;
- hire additional personnel;
- expand our operational, financial and management systems;
- invest in measures to protect and expand our intellectual property;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize;
- incur costs in connection with capital raising activities and potential business restructuring activities, if required;
- expand our manufacturing and develop our commercialization efforts, if any; and
- operate as a public company.

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 indication of our future performance. 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 working capital and our ability to achieve and maintain profitability.

To become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling any products for which we may obtain regulatory approval, achieving market acceptance of any such approved products and receiving reimbursements in amounts above our costs. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical product candidate development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or other regulatory authorities to perform preclinical studies or clinical trials in addition to those currently expected, or if there are any delays in completing our ongoing preclinical studies or clinical trials or the development of any of our product candidates, our expenses could increase and revenue could be further delayed. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations.

We will require substantial additional capital to finance our operations. 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 drug development programs or future commercialization efforts.

Developing pharmaceutical 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 initiate and conduct preclinical studies and clinical trials, including any registrational trials, and seek marketing approval for our current and any 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 commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA or other comparable foreign regulatory authorities to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. Because the design and outcome of our current and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. We also expect to continue to incur the costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations in the future.

As of December 31, 2025, we had $217.0 million in cash, cash equivalents, and marketable securities. Based on our current business plans, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our development activities and other operations into 2029. Our estimate as to how long we expect our existing cash, cash equivalents, and marketable securities to be able to continue to fund our operating expenses and capital expenditures requirements 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.

Our future funding requirements will depend on many factors, including, but not limited to:

- the initiation, progress, timeline, cost and results of our clinical trials for our product candidates, including our planned registrational trial of atebimetinib in combination with mGnP in first-line pancreatic cancer;
- the initiation, progress, timeline, cost and results of additional research and/or preclinical studies related to pipeline development and other research programs we initiate in the future;
- the cost and timing of manufacturing activities as we advance our product candidates through preclinical and clinical development, and possible commercialization;
- the potential expansion of our current development programs to seek new indications;
- the potential negative impact of widespread adverse economic or health events (including due to military conflict or pandemics) on our business;

- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights, in-licensed or otherwise;
- the effect of competing technological and market developments;
- the payment of licensing fees, potential royalty payments and potential milestone payments;
- the cost of general operating expenses;
- the cost and timing of completion of commercial-scale manufacturing activities, if any;
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; and
- the cost of operating as a public company.

Advancing the development of our product candidates will require a significant amount of capital. Our existing cash, cash equivalents, and marketable securities will not be sufficient to fund all of the activities that are necessary to complete the development and potential commercialization of our product candidates.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. For example in the past, due to macroeconomic conditions including inflation and higher interest rates, the stock price of biotech companies, including ours, generally declined, making fundraising in our industry more difficult and on less favorable terms. Furthermore, additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and potentially commercialize our product candidates. 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. In that event, we may have to delay, scale back, or eliminate some or all of our operations, sell assets and/or seek other strategic alternatives.

We maintain the majority of our cash, cash equivalents, and marketable securities in accounts with major U.S. and multi-national financial institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions have in the past impacted and may in the future impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash, cash equivalents, and marketable securities, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

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

We may seek additional capital through a variety of means, including through public or private equity offerings, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, for example as we did in August and September 2025, your ownership interest may be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. In addition to dilution, such financings may result in the imposition of debt covenants, increased fixed payment obligations, other restrictions (including operating restrictions) or other obligations (for example, providing registration or other information rights to certain investors, as we did in connection with private placements of equity securities in 2025) that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our ability to use our net operating losses and other tax attributes may be limited.

As of December 31, 2025, we had approximately $174.8 million of federal and $56.7 million of state net operating loss carryforwards ("NOLs"), available to offset future taxable income. Under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three-year period is subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes such as research tax credits to offset future taxable income. We have not performed an analysis to determine whether our past issuances of stock and other changes in our stock ownership may have resulted in other ownership changes. If it is determined that we have in the past experienced other ownership changes, or if we undergo one or more ownership changes as a result of future transactions in our stock, which may be outside our control, then our ability to utilize NOLs and other pre-change tax attributes could be further limited by Sections 382 and 383 of the Code, and certain of our NOLs and other pre-change tax attributes may expire unused. As a result, if or when we earn net taxable income, our ability to use our pre-change NOLs or other tax attributes to offset such taxable income or otherwise reduce any liability for income taxes may be subject to limitations, which could adversely affect our future cash flows.

Risks Related to Development, Regulatory Approval and Commercialization

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable with respect to outcomes. If we are ultimately unable to obtain regulatory approval for our product candidates, or to obtain regulatory approval to treat the indications we seek to treat with our product candidates, we will be unable to generate product revenue or the level of planned product revenue and our business will be substantially harmed.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. The time required to obtain approval by the FDA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive, or be delayed in receiving, regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials, including without limitation with respect to the appropriate dosing in patients or the use of our product candidates as potential combination therapies;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and/or not effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in a clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other 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 a NDA or other submission or to obtain regulatory approval in the United States, European Union or elsewhere;

- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;

- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. In addition, the FDA, EMA or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates 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 addition, even if we obtain approval of our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a REMS. Regulatory authorities may not approve the price we intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could seriously harm our business.

We may not be able to submit additional INDs or IND amendments or comparable documents in foreign jurisdictions to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We may not be able to submit additional INDs, IND amendments or comparable documents for atebimetinib, for which an IND was previously submitted, or for our other current or potential product candidates on the timelines we expect. We may also experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND or comparable document will result in the FDA or other comparable foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

We have limited experience in designing clinical trials and may experience delays or unexpected difficulties in obtaining regulatory approval for our current and future product candidates.

We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval, including, for example, our planned registrational trial of atebimetinib in combination with mGnP in first-line pancreatic cancer. We cannot be certain that our ongoing or planned clinical trials or any future clinical trials will be successful. For example, in April 2025 we paused further internal advancement of envometinib (IMM-6-415) and the related Phase 1/2a clinical trial. Further, it is possible that the FDA may refuse to accept, or be delayed in accepting, any or all of our planned NDAs for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval for any product candidates. If the FDA does not approve any of our planned NDAs, it may require that we conduct additional costly clinical trials, preclinical studies or manufacturing validation studies before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA or other application that we submit. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for applications in foreign jurisdictions with comparable regulatory agencies, including without limitation the EMA.

We may encounter substantial delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. 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 drugs.

In addition, we are substantially dependent on preclinical, clinical and quality data generated by CROs and other third parties for regulatory submissions for our product candidates. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed, and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase, perhaps substantially.

We do not know whether our future clinical trials will begin on time or enroll patients on time, or whether our future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA, EMA or comparable foreign regulatory authorities disagreeing as to the design, implementation or results of our clinical trials, including without limitation with respect to the appropriate or proper escalation of dosing in patients or the use of our product candidates as potential combination therapies;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- delays in enrollment due to travel or quarantine policies, or other factors related to current or future pandemics or other events outside our control;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidates or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate, with the tumor types, and/or at the stage(s) of disease that we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;

- a facility manufacturing our product candidates or any of their components being ordered by the FDA, EMA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;

- any changes to our manufacturing process that may be necessary or desired;

- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCP, or other regulatory or contractual requirements;

- third-party contractors not performing data collection or analysis in a timely or accurate manner; or

- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA, EMA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

In addition, the occurrence of any public health crisis or similar global events, such as a future pandemic and its variants, could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research and clinical trials, delay, limit or prevent our employees and CROs from continuing research and development activities, impede the ability of patients to enroll or continue in clinical trials, or impede testing, monitoring, data collection and analysis or other related activities, any of which could delay our clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA, EMA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, including with respect to healthcare, cybersecurity and data privacy matters, as well as political and economic risks or military conflicts relevant to such foreign countries.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval, if at all;

- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;

- be subject to additional post-marketing testing requirements;

- be required to perform additional preclinical studies or clinical trials to support approval or be subject to additional post-marketing testing requirements;

- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified REMS;

- be subject to the addition of labeling statements, such as warnings or contraindications;

- be sued; or
- experience damage to our reputation.

Our development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all. Any delay in, or termination of, our clinical trials will delay the submission of an NDA to the FDA or similar applications with comparable foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates, if approved, and generate product revenue. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims for differentiation or the effectiveness or safety of our product candidates. Regulatory agencies such as the FDA and EMA have substantial discretion in the review and approval process and may disagree that our data support the claims we propose.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA, EMA or comparable foreign regulatory authorities. The FDA, EMA or comparable foreign regulatory authorities 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, EMA or comparable foreign regulatory authorities 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, EMA or comparable foreign regulatory authorities, 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 of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

The outcome of preclinical studies 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.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for their intended uses. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies and early-stage clinical trials does not mean that future clinical trials, such as our planned registrational trial of atebimetinib in combination with mGnP in first-line pancreatic cancer, will be successful. We do not know whether any of our product candidates will perform in current or future clinical trials as they have performed in preclinical studies or prior clinical trials. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials.

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 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 candidate. 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 marketing approval to market our product candidates. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could seriously harm our business. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable foreign regulatory authority approval. We cannot guarantee that the FDA, EMA or comparable foreign regulatory authorities will interpret trial results as we do, and more trials could be required before we are able to submit applications seeking approval of our product candidates. To the extent that the results of the trials are not satisfactory to the FDA, EMA or comparable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential. Furthermore, the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA, EMA or comparable foreign regulatory authorities delaying, limiting or denying approval of our product candidates.

Interim, "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 interim, 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. Top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary 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. For example, we disclosed updated interim safety and efficacy data from the Phase 2a portion of our ongoing Phase 1/2a clinical trial of atebimetinib in January 2026. 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 top-line, preliminary and/or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the trading price of our Class A 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 potentially commercialize, our product candidates may be harmed, which could harm our business, results of operations, prospects or financial condition. Moreover, such disclosure could adversely affect the trading price of our Class A common stock.

Our current or future product candidates may cause 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 inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with the use of our product candidates. Results of our preclinical studies and clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or comparable foreign regulatory authorities. The drug-related side effects could 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 harm our business, financial condition and prospects significantly.

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 approved or other investigational products, 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 subjects 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 harm our business, financial condition and prospects significantly.

Patients in our clinical trials may in the future suffer significant drug-related adverse events or other side effects, including those not observed in our preclinical studies or previous clinical trials. Some of our product candidates may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, our product candidates, when used in combination with other therapies, may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing surgical, radiation, chemotherapy or other aggressive treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still negatively impact the success of our clinical trials. Similarly, already critically ill patients that we enroll in our clinical trials have in the past and may in the future experience adverse medical events due to the general gravity or advanced stage of such patients' illnesses, in each case which could adversely affect our clinical trials even though such outcomes are not related or attributable to our product candidates.

If significant drug-related 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, EMA, 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 harm our business, financial condition and prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and costlier than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. Other potentially significant negative consequences include that:

- we may be forced to suspend marketing of that product, or be forced to or decide to remove the product form the marketplace;

- regulatory authorities may withdraw or change their approvals of that product in one or more countries;

- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of the product for patients, or to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or to be sued and held liable for harm caused to subjects or patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Additionally, our clinical trials will compete with other clinical trials for product candidates that focus on the same therapeutic targets as our current and potential future product candidates, which may further limit enrollment of eligible patients or may result in slower enrollment than we anticipate. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Patient enrollment may also be affected if our competitors have ongoing clinical trials for product candidates 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' product candidates. Patient enrollment for any of our 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 other developmental or 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 for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- 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;
- continued enrollment of prospective patients by clinical trial sites;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or will not survive the full terms of the clinical trials (including without limitation because they may be late-stage cancer patients); and

- delays or difficulties in enrollment and completion of studies due to ongoing and future pandemics, or other widespread adverse health events.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

Even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of our product candidates, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement, as well as pricing, by third-party payors, including government authorities;
- the availability of the approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our products or product candidates or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

If any of our product candidates is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

We may be unable to obtain U.S. or foreign regulatory approvals and, as a result, may be unable to commercialize our product candidates.

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. We cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not conducted, managed or completed large-scale or pivotal clinical trials nor completed the regulatory approval process with the FDA, EMA or any other regulatory authority. The time required to obtain approvals from the FDA, EMA and other regulatory authorities is unpredictable, and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can and often changes during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA, EMA or other applicable regulatory authority policy during the period of drug development, clinical trials and regulatory review.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are developing and seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of approving a NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA and EMA approval processes described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA or EMA approval.

Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to use and expand our DCT platform and capabilities to build a pipeline of product candidates with commercial value.

A key element of our strategy is to use and expand our DCT platform to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of various cancers. Although our research and development efforts to date have resulted in our discovery, preclinical and clinical development of atebimetinib and other product candidates, it and other product candidates may not be safe or effective for the indications for which we study them in clinical trials, and we may not be able to develop any other product candidates. Our DCT platform is evolving and may not reach a state at which building a pipeline of product candidates is possible.

The scientific research that forms the basis of our efforts to develop product candidates with our platforms is still ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our DCT platform is both preliminary and limited. As a result, we are exposed to a number of unforeseen risks and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates. For example, we have only generated interim data from the ongoing Phase 1/2a trial of atebimetinib, and otherwise our data for this product candidate is limited to animal models and preclinical cell lines, the results of which may not translate into humans. As a result, it is possible that safety or other adverse events or concerns could negatively affect the development of atebimetinib or our other current or future product candidates, including adversely affecting patient enrollment among the patient populations that we intend to treat.

Given the novelty of our technologies, we intend to work closely with the FDA, EMA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates; however, due to a lack of comparable experiences, the regulatory pathway with the FDA, EMA and comparable regulatory authorities may be more complex and time-consuming relative to other more well-known therapeutics. Even if we obtain human data to support our product candidates, the FDA, EMA or comparable foreign regulatory agencies may lack experience in evaluating the safety and efficacy of our product candidates developed using our platforms, which could result in a longer than expected regulatory review process, increase our expected development costs, and delay or prevent commercialization of our product candidates. The validation process takes time and resources, may require independent third-party analyses, and may not be accepted or approved by the FDA, EMA and other comparable foreign regulatory authorities. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies.

Additionally, a key element of our strategy is to use and expand our platforms to build a pipeline of product candidates and progress those product candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have been focused on identifying a pipeline of product candidates directed at various disease types, we may not be able to develop product candidates that are safe and effective. Even if we are successful in building our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be approvable or marketable products that will receive marketing approval and achieve market acceptance.

Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA, EMA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which likely would result in significant harm to our financial position and adversely affect our stock price.

We intend to develop certain of our current product candidates in combination with other therapies, and may develop our future product candidates in combination with other therapies, which exposes us to additional risks.

We intend to develop atebimetinib as a potential biologic/drug combination product, and we may also develop other current or future product candidates as biologic/drug combination products. Additional time may be required to obtain regulatory approval for any of our current or future product candidates if or when they are developed as potential combination products. Any of our product candidates that may be biologic/drug combination products will require coordination within the FDA, EMA and other comparable foreign regulatory authorities for review of their biologic and drug components. Although the FDA, EMA and other comparable foreign regulatory authorities have systems in place for the review and approval of combination products, we may experience delays in the development and commercialization of our product candidates that may be combination products due to regulatory timing constraints and uncertainties in the product development and approval process.

In addition, even if any product candidate we develop 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, EMA or comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA, EMA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate our current product candidates or any other future product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell our product candidates we develop in combination with an unapproved therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA, EMA or other regulatory approval.

If the FDA, EMA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy.

If we successfully develop our product candidates, we may seek approval from the FDA through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we initially contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We may seek an accelerated approval for one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Similar considerations exist with respect to the potential use of accelerated approval pathways in other jurisdictions outside of the United States.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success than our product candidates. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products.

Third parties with product candidates or products targeting the MAPK pathway may produce negative preclinical or clinical data which may adversely affect public perception of our product candidates, and may negatively impact regulatory approval of, or demand for, our potential products.

Certain of our product candidates, including atebimetinib, are based on the DCI of the MAPK pathway as a model of therapeutic intervention. Our DCI approach may not be viewed as distinct from other existing therapies targeting the MAPK pathway, and negative third party data from preclinical studies and/or clinical trials using other MAPK-targeted therapies could negatively impact the perception of the therapeutic use of such product candidates or products on the whole. This could, among other things, negatively impact our ability to enroll patients in clinical trials. The clinical and commercial success of our product candidates will depend in part on the public's and clinical community's acceptance of the use of DCI therapies. Moreover, our success depends upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available. Adverse events in our clinical trials, or those of our competitors or of academic researchers utilizing MAPK-targeted therapies, even if not ultimately similar or attributable to our DCI product candidates, and the resulting publicity, could result in increased governmental regulation, unfavorable public perception, increased volatility in our stock price, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for our product candidates that are approved, if any, and a decrease in demand for any such products, if approved.

Risks Related to Our Business

We are early in our development efforts. Our business is substantially dependent on the successful development of our current and future product candidates. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval to treat the indications that we seek to treat with our product candidates, and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts and we have not yet completed our Phase 1/2a clinical trial for our lead product candidate atebimetinib. Further, we have only disclosed interim data for atebimetinib, and in April 2025 we paused further internal advancement of envometinib and the related Phase 1/2a clinical trial. Our other product candidates are in earlier stages of drug development. We have invested substantially all of our efforts and financial resources in the identification of targets, preclinical and clinical development of small molecules targeting the MAPK and other pathways in cancer therapy.

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 effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from product sales.

The success of our current and future product candidates will depend on several factors, including without limitation the following:

- the successful and timely completion of additional preclinical studies;
- the successful initiation, patient enrollment and completion on a timely basis of our ongoing and any future clinical trials (including our planned registrational trial of atebimetinib in combination with mGnP in pancreatic cancer), despite any delays including those arising out of ongoing or future pandemics, or other widespread adverse health events;
- maintaining and establishing relationships with CROs and clinical sites for clinical development, both in the United States and internationally;
- the frequency and severity of adverse events in the clinical trials;
- the efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- the timely receipt of marketing approvals from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;

- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for clinical development;
- the maintenance of existing, or the establishment of new, scaled production arrangements with third-party manufacturers to obtain finished products that are appropriate for commercial sale of our product candidates, if approved;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- the protection of our rights in our intellectual property portfolio;
- the successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for atebimetinib or any other product candidate we develop, we may not be able to continue our operations.

We are substantially dependent on our platform, including our proprietary technologies, which are supported by our information technology systems. Any failure of these or other elements of our platform will materially harm our business.

We are substantially dependent on our platform, including our proprietary technologies, which are supported by our information technology systems, for significant elements of our drug discovery process, bioinformatics and computational biology software systems, database of information relating to our product candidates and their role in the targeted disease process, amongst others. Although we invest substantially in the backup/restore, high-availability architecture, monitoring and reporting, documentation and preventive security controls of our systems and proprietary technologies, these elements of our platform are still vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious or inadvertent human acts, and natural disasters. Our information technology systems and proprietary technologies are potentially also vulnerable to physical or electronic break-ins, employee errors, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology systems and proprietary technologies, failures or significant downtime of these systems could prevent us from conducting research and development activities for our current and future product candidates, and ultimately delay our drug discovery process. Any failure of our information technology systems and proprietary technologies will materially harm our business.

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

Our future results of operations are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates beyond those we currently have in preclinical studies and early stage clinical trial 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 studies or earlier 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 the product candidates we have or may develop will depend on many factors, including without limitation the following:

- the success of our research methodology in identifying potential indications or product candidates;
- 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;
- adverse events in the clinical trials; and
- any potential interruptions or delays resulting from factors related to ongoing or future pandemics, or other widespread adverse health events.

Even if we successfully advance any other 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 other product candidates.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. We will have to develop our own sales, marketing and supply organization or outsource some or all of these activities to a third party to commercialize our products. If we decide to license our product candidates to others, we may need to rely on the marketing assistance and guidance of those collaborators.

Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization, if at all. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates, technologies or processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In addition, our products may need to compete with off-label drugs used by physicians to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

In particular, there is intense competition in the fields of oncology we are pursuing. We have competitors both in the United States and internationally, including major multinational biopharmaceutical companies, established biotechnology companies, specialty biopharmaceutical companies, emerging and start-up companies, universities and other research institutions. Our product candidates and programs for oncology will compete with products or programs being advanced by certain of these pharmaceutical and biotechnology companies, organizations and institutions. We also compete with these organizations to recruit management, scientists and clinical development and other personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates.

We have chosen to initially address well-validated biochemical targets, and therefore expect to face competition from existing products and products in development for each of our product candidates. There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities and experience than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing products in our field before we do.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

If the market opportunity for any product candidate that we develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.

We intend to initially focus our product candidate development on treatments for various oncology indications. Our projections of addressable patient populations that may benefit from treatment with our product candidates are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we develop could be significantly diminished and have an adverse material impact on our business.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any product candidate.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our data that our applications are insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs for our product candidates, it may require that we conduct additional clinical trials, preclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, even if performed and completed, may not be considered sufficient by the FDA to approve our NDAs. Similar considerations exist with respect to potentially obtaining marketing approvals in other jurisdictions outside of the United States.

Any delay in obtaining, or an inability to obtain, marketing approvals, whether in the United States or internationally, would prevent us from commercializing our product candidates, generating revenues, and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

Unfavorable global and regional economic, political and health conditions could adversely affect our business, financial condition or results of operations.

Our business could be adversely affected by global or regional economic, political and / or health conditions. For example, various macroeconomic factors could adversely affect our business, financial condition and results of operations, including changes in inflation, interest rates and overall economic conditions and uncertainties, such as those resulting from political instability (such as workforce uncertainty), trade disputes between nations, and the current and future conditions in the global financial markets. For example, the imposition of tariffs by the U.S. government and any retaliatory tariffs imposed in response have created significant uncertainty, including in the amount, applicability and duration of such tariffs. Tariffs impacting the availability or price of resources used to manufacture our current or future product candidates could adversely affect our preclinical studies and clinical trials and, if in the future any of our product candidates are approved, tariffs may also adversely impact the price and / or demand for such approved products. Moreover third-party vendors, including CROs and CMOs upon which we rely, may suffer disruptions in their businesses or experience significant increases in the cost of their goods or services sold (which they may pass through, in part or in whole, to us) due to factors beyond their control, including tariffs. Additionally, if sustained high rates of inflation or other factors were to significantly increase our business costs, we may be unable to manage such increased expenses or pass through price increases. A global financial crisis or global or regional political and economic instability, wars, terrorism, civil unrest, outbreaks of disease, and other unexpected events, such as supply chain constraints or disruptions, could cause extreme volatility in the capital and credit markets and disrupt our business. Business disruptions could include, among others, disruptions to our research or clinical activities, including due to supply chain or distribution constraints or challenges, clinical enrollment, clinical site availability, patient accessibility, and conduct of our clinical trials, as well as temporary closures of the facilities of suppliers or contract manufacturers in the biotechnology supply chain. In addition, during certain crises and events, patients may prioritize other items over certain or all of their treatments and/or medications, which could have a negative impact on our clinical trials A severe or prolonged economic downturn, political disruption and / or adverse health conditions could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which political, economic, health and / or financial market conditions could adversely impact our business.

Ongoing and potential future pandemics could adversely impact our business, including our current and future clinical trials, supply chain and business development activities.

The effects of government actions, our own policies or those of third parties to address ongoing pandemics and any future pandemic may negatively impact productivity and slow down or delay our future clinical trials, preclinical studies and research and development activities, and may cause disruptions to our supply chain and impair our ability to execute our business development strategy. We may also experience delays in receiving approval from regulatory authorities to initiate or conduct our ongoing or planned clinical trials and delays in regulatory review or approval of any NDA or similar foreign filing we may submit following positive results, if any, in a pivotal study for any of our drug candidates. We may also experience operational delays such as delays or difficulties in enrolling patients in our clinical trials; interruption of key clinical trial activities, such as clinical trial site 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, the occurrence of which could affect the integrity of clinical trial data; and changes in local regulations as part of a response to ongoing or future pandemics, which may require us to change the ways in which our clinical trials are conducted and result in unexpected costs, or to discontinue such clinical trials altogether..

While the potential economic impact brought by, and the duration of, ongoing or future pandemics is difficult to assess or predict, there has in the past been (for example, because of COVID-19 and its variants) and could further be a significant disruption of global financial markets due to a pandemic, that may reduce our ability to access capital and negatively affect our liquidity and financial position. In addition, the trading prices for our Company and other biopharmaceutical companies have in the past been volatile due in part to pandemic, and the same may occur in the future.

These and other disruptions in our operations and the global economy, due to ongoing or future pandemics or any other widespread public health crisis, could negatively impact our business, results of operations and financial condition.

Risks Relating to Our Dependence on Third Parties

We substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our preclinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We, our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, 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 by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with investigational drug substance produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected 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.

Further, there is no guarantee that any such CROs, investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. These risks are heightened as a result of the efforts of government agencies and the CROs themselves may take to limit the spread of disease from ongoing or future pandemics, including quarantines and shelter-in-place orders. 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 independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if CROs 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, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely.

Our CROs generally have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs may also have an ability to terminate their respective agreements with us for other reasons, including without limitation if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on, and in the future may rely on, third-party datasets and collaborations with third parties to inform patient selection, drug target identification and other bioinformatic and computational biology analyses for our existing product candidates and any future product candidates and for the supply of biomarker companion diagnostics.

We are using bioinformatics, including data analytics, biostatistics and computational biology, throughout our drug discovery and development process, including to identify new target and biomarker opportunities. As part of this approach, we interrogate public and proprietary datasets, including, but not limited to, human tumor genetic information and specific cancer-target dependency networks. We rely on these datasets and data analytics for multiple analyses, including identifying or validating some of our biomarker-target relationships and access to these databases may not continue to be available publicly or through a proprietary subscription on acceptable terms. Our past, present and future use of such datasets could also create potential liabilities for us if the data provided to us contains inherent errors, inaccuracies or artifacts, or if we improperly analyze, handle, store or utilize the data.

Many of our product candidates also rely on the availability and use of commercially available tumor diagnostics panels or data on the prevalence of our target patient population to inform the patient selection and drug target identification for our product candidates. In cases where such biomarker diagnostic is not already commercially available, we expect to establish strategic collaborations for the clinical supply and development of companion diagnostics. If these diagnostics are not able to be developed at a commercially reasonable cost or at all, or if commercial tumor profiling panels are not able to be updated to include additional tumor-associated genes, or if clinical oncologists do not incorporate molecular or genetic sequencing into their clinical practice, we may not be successful in developing our existing product candidates or any future product candidates.

If we decide to establish new collaborations in the future, but are not able to establish those collaborations on a timely basis, on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to, among other things, expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. 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.

We may face significant competition in seeking appropriate collaborators and the related negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for future 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 them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We may enter into collaborations in the future with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may seek third-party collaborators in the future for the development and commercialization of one or more of our product candidates. Our likely collaborators for any future collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates could pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may de-emphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or 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 if, for example, the collaborators believe that such competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in 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;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

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 may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA, EMA or other comparable regulatory authority regulations, provide accurate information to such regulators, comply with international, federal and state health care fraud and abuse and compliance laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, submission of false claims, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting/rebating, marketing and promotion, consulting, 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 serious harm to our reputation. 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, individual 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.

Risks Related to Manufacturing

The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency.

Manufacturing drugs requires facilities specifically designed for and validated for this purpose, as well as sophisticated quality assurance and quality control procedures. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization (if applicable) as a result of these challenges, or otherwise, 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.

We contract with third parties, including contract manufacturing organizations and consultants, for the manufacture of our product candidates for preclinical studies and clinical trials, and expect to continue to do so for commercialization of any approved product candidate. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or be able to acquire such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements. Furthermore, the raw materials for our product candidates may be sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we may obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or non-renewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, including due to the impact of ongoing or future pandemics, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to or voluntarily change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines and that the product produced is equivalent to that produced in a prior facility. The delays associated with the verification of a new manufacturer and equivalent product could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our, or a third-party's, failure to execute on our manufacturing requirements, to do so on commercially reasonable terms and timelines, or to comply with cGMP requirements could adversely affect our business in a number of ways, including without limitation:

- inability to meet our product specifications and quality requirements consistently;
- inability to initiate or continue clinical trials of our product candidates under development;
- delays in submitting regulatory applications, or receiving marketing approvals, for our product candidates, if at all;
- inability to commercialize any product candidates that receive marketing approval on a timely basis;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities or our manufacturing facilities, if any, to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates;
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates; and
- our future profit margins.

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

As product candidates progress through preclinical studies and clinical trials to potential marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

Risks Related to Legal and Regulatory Compliance Matters

Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to international, federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, and government price reporting, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable international, federal and state healthcare laws and regulations include, among others, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;

- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per claim penalties per false claim or statement. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Criminal Statute on False Statements Relating to Healthcare Matters, which makes it a crime to knowingly and willfully falsify, conceal, or cover up a material fact, make any materially false, fictitious, or fraudulent statements or representations, or make or use any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services;

- the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity, such as a pharmaceutical manufacturer, that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal healthcare programs to provide items or services reimbursable by a federal healthcare program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicare and Medicaid Services ("CMS") information regarding payments and other transfers of value to physicians (as defined by statute), certain non-physician providers including physician assistants and nurse practitioners, and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information reported is publicly available on a searchable website, with disclosure required annually;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and

- some state laws require biotechnology companies to report information to state agencies and/or commercial purchasers on the pricing of certain drug products that exceed a certain level as identified in the relevant statute. Some of these laws and regulations contain ambiguous requirements that government officials have not yet clarified. Given the lack of clarity in the laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians, some of whom have had, have or may have ownership interests in us, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid (or analagous programs in jurisdictions outside the United States), integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. For instance, in the U.S., most healthcare providers, including research institutions from which we may 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, and the regulations promulgated thereunder, or collectively, HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners.

We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, the EU GDPR governs certain collection and other processing activities involving personal data about individuals in the EEA. The GDPR imposes substantial fines for breaches and violations. 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. Further, since January 1, 2021, companies have to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR.

The GDPR and UK GDPR regulate cross-border transfers of personal data out of the EEA and the UK respectively. Recent legal developments in Europe have created complexity and uncertainty regarding such transfers, including in relation to transfers to the United States. On July 16, 2020, the Court of Justice of the European Union or the CJEU invalidated the EU-US Privacy Shield Framework ("Privacy Shield") under which personal information could be transferred from the EEA (and the UK) to relevant self-certified U.S. entities. The CJEU further noted that reliance on the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism and potential alternative to the Privacy Shield) alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. Successor legislation and regulation to the Privacy Shield have not been, and may never be, widely adopted in practice for data transfers in the biotechnology field. As the enforcement landscape further develops, and supervisory authorities issue further guidance on international data transfers, we could suffer additional costs, complaints and/or regulatory investigations or fines; we may have to stop using certain tools and vendors and make other operational changes; and/or it could otherwise affect the manner in which we provide our services, and could also adversely affect our business, operations and financial condition.

If we or third-party CMOs, CROs or other contractors, consultants or agents fail to comply with applicable federal, state, local or foreign regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any such third party's ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could also give rise to liability, breaches of data security or reputational damage.

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, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA, EMA or other 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 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, if at all, to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be covered and reimbursed by third-party payors. If 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 an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, 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. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

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. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product candidate that we may be able to commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, 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, including without limitation the EEA, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 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 materials. Our operations may also produce hazardous waste products. We may 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 will maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the potential use of hazardous materials in the future, 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 hazardous and flammable materials, including chemicals and biological 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.

The FDA or other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We intend to conduct international clinical trials in the future. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any other comparable foreign regulatory authority does not accept such data, it could result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our current or future product candidates not receiving approval for commercialization in the applicable jurisdiction.

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.

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 product candidates will be harmed.

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and 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, EMA or foreign regulatory authorities approve 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 on-going compliance with cGMPs and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, EMA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory authority requirements may subject our company to administrative or judicially imposed sanctions, including without limitation:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

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

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We currently have a limited set of compliance policies and personnel, and intend to further develop our compliance infrastructure in the future, as our clinical development programs progress. Developing a compliance infrastructure is costly and time-consuming, and even a well-designed and implemented compliance program cannot necessarily prevent all violations of relevant laws. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our product candidates, if approved. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

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, EMA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA, EMA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. For example, the U.S. 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 U.S. government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is 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.

Disruptions at the FDA, the SEC and other government agencies including those caused by funding shortages, mandated personnel reductions, policy changes or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA (as well as other U.S. agencies and analogous bodies outside the United States) to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the FDA, 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.

Disruptions at the FDA and other agencies, whether domestic or in jurisdictions outside of the United States, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government shut down several times (including for an extended period beginning in October 2025) and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Similarly, incoming administrations have taken and may in the future take measures to reduce personnel at, and funding for, regulatory agencies including the FDA and the SEC. For example, the current administration has issued executive orders that may significantly reduce the federal workforce and could adversely affect the FDA's ability to attract and retain qualified scientific reviewers, which could result in longer review times for our applications. If a prolonged government shut down, funding or personnel reduction, policy change, or other disruption at the FDA occurs, continues to occur and/or worsens, 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, as a public company, future government shutdowns could impact our ability to further access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, initially in response to the global COVID-19 pandemic, the FDA implemented changes to its inspection activities to ensure the safety of its employees and those of the firms it regulates, and any resurgence or emergence of any pandemic or other widespread adverse health event may lead to further inspection delays. Regulatory authorities outside the United States have in the past and may in the future adopt similar restrictions or other policy measures in response to such events. If a prolonged government shutdown occurs or continues, or if global health concerns prevent the FDA, EMA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, EMA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

A fast track designation from the FDA (or similar designation from a comparable foreign regulatory authority), even when granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive regulatory approval.

In February 2024, July 2024 and December 2024, respectively, we announced that the FDA granted fast track designation for atebimetinib for the treatment of patients: with PDAC who have failed one line of treatment; with PDAC in the first-line setting; and with unresectable or metastatic NRAS-mutant melanoma who have progressed on or are intolerant to PD-1/PD-L1 based immune checkpoint inhibitors. Depending on the data from our preclinical studies and clinical trials, we may decide to seek additional fast track designations for atebimetinib or for other product candidates. The fast track program is intended to expedite or facilitate the process for reviewing product candidates that meet certain criteria. Specifically, potential drugs are eligible for fast track designation if they are intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate may have opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. An NDA submitted for a fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even where we have received fast track designation for our product candidates, such product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw fast track designation if it believes that the designation is no longer supported by data from our related clinical development program. Furthermore, such a designation does not increase the likelihood that atebimetinib or any other product candidate that may be granted fast track designation will receive regulatory approval in the U.S. Many product candidates that have received fast track designation have ultimately failed to obtain approval.

Similar considerations as the foregoing exist with respect to any foreign regulatory authority that may grant a comparable designation to any product candidate.

We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjected biologic products to potential competition by lower-cost biosimilars; increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price; required collection of rebates for drugs paid by Medicaid managed care organizations; 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; expanded the types of entities eligible for the 340B Drug Pricing Program; created 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 & Medicaid Innovation at CMS 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, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included the American Rescue Plan Act of 2021, which eliminated the statutory Medicaid drug rebate cap, which was set at 100% of a drug's average manufacturer price as of January 1, 2024. Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. On August 16, 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS published the negotiated prices for the initial ten drugs, which went into effect in 2026, and the subsequent 15 drugs effective in 2027, as well as the next set of 15 drugs that will be subject to negotiation, although the drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In July 2025, the OBBBA was enacted, which imposes significant reductions in the funding of the Medicaid program and restrictions for certain groups to access the ACA Marketplace. These changes are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, and may result in an increase in the number of individuals who are unable to access health insurance benefits and medical care, either of which could adversely affect our sales of any product candidate that we potentially commercialize.

Additionally, the Trump administration has pursued a two-fold strategy to reduce drug costs in the U.S. The administration threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. The administration is also pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. While the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry generally and our business specifically.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. 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. Further, it is possible that additional governmental action is taken in response to ongoing or new pandemics or to other widespread adverse health events.

We may be subject to the UK Bribery Act 2010 (the "Bribery Act"), the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations, including our research and development, clinical trial, and (if any of our product candidates receives approval) commercial activities, whether conducted in the United States or internationally, may be subject to anti-corruption laws, including the Bribery Act, the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act and other anti-corruption laws that apply in countries where we currently or may in the future do business. The Bribery Act, the FCPA and these other (or similar) laws generally prohibit us, our employees and our intermediaries from authorizing, promising, offering or providing, directly or indirectly, improper or prohibited payments or anything else of value to government officials or other persons to obtain or retain business or gain some other business advantage. Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. We and our partners may operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. We may also be subject to other laws and regulations from time to time governing our international operations, including regulations administered by the governments of the United States, the United Kingdom or elsewhere and authorities in the European Union or elsewhere, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by the United Kingdom, United States or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

We may be subject to various laws relating to foreign investment and the export of certain technologies, and our failure to comply with these laws or adequately monitor the compliance of our suppliers and others with which we do business with could subject us to substantial fines, penalties and injunctions, the imposition of which on us could have a material adverse effect on the success of our business.

We may be subject to U.S. laws that regulate foreign investments in U.S. businesses and access by foreign persons to technology developed and produced in the United States. These laws include section 721 of the Defense Production Act of 1950, as amended by the Foreign Investment Risk Review Modernization Act of 2018, and the regulations at 31 C.F.R. Parts 800 and 801, as amended, administered by the Committee on Foreign Investment in the United States, and the Export Control Reform Act of 2018, which is being implemented in part through Commerce Department rule-making to impose new export control restrictions on “emerging and foundational technologies” yet to be fully identified. Application of these laws, including as they are implemented through regulations being developed, may negatively impact our business in various ways, including without limitation by: restricting our access to capital and markets; limiting the collaborations we may pursue; regulating the export of our products, services, and technology from the United States and abroad; increasing our costs and the time necessary to obtain required authorizations and to ensure compliance; and threat of monetary fines and other penalties for non-compliance.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and/or other intellectual property protection for our product candidates and technologies or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully develop and commercialize our product candidates, products (if any) and technology may be impaired, and we may not be able to compete effectively in our market.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. Our commercial success depends in part on our ability to obtain and maintain patent, trade secret or other intellectual property protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing the proprietary rights of others. If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology or our product candidates, our competitive position could be harmed. We generally seek to protect our proprietary position by filing patent applications in the United States and, in some cases, abroad related to our product candidates, technology platforms and their uses that are important to our business.

As of February 2, 2026, we had granted and pending patent filings directed to our product candidates and platforms. With respect to atebimetinib, we had global patent filings providing patent protection for the compound expected into at least 2041 and in the United States until 2042, as well as other pending Patent Cooperation Treaty ("PCT") applications that have not yet entered the national phase providing the basis for additional national phase potential patent claims directed to methods of treatment and pharmaceutical compositions expected into at least 2045, if granted (excluding any possible patent term adjustments, extensions, or terminal disclaimers, and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable). Further, patent prosecution with respect to our pending patent applications related to our product candidates is in many cases in the early stages. With respect to our platform technology, we have granted U.S. patents expiring in 2039 directed to our Disease Cancelling Technology platform (excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable). We filed patent applications related to our platform technology only in the U.S., so it is possible that a competitor may practice outside the U.S. the aspects of our platform technology disclosed in those patent applications. We maintain other aspects of our platform technology as trade secrets, which were not disclosed in those patent applications. There can be no assurance that any of our current and future issued patents and patent applications, if any, owned by us or our future in-licensed patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents if issued will not be infringed, designed around, invalidated or rendered unenforceable by third parties, or would effectively prevent others from commercializing competitive products or technologies. In addition, our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology and such third parties practice the technology in countries where such patents have issued. Composition of matter patents for pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents may provide protection for any method of use. We cannot be certain that the claims in our pending patent applications related to composition of matter of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents can protect the claimed uses of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the existence, issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain.

Although we may obtain licenses to issued patents in the United States and foreign countries in the future, we cannot be certain that the claims in future in-licensed U.S. pending patent applications, if any, corresponding international patent applications and patent applications in certain foreign countries will be considered patentable by the USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in future in-licensed issued patents will not be found invalid or unenforceable if challenged.

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

- USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- patent applications may not result in any patents being issued;

- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than we or our potential licensors do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell our product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than the patent law typically applied by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also 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 or in all jurisdictions where protection may be commercially advantageous. In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product or technology. For example, certain jurisdictions do not allow for patent protection with respect to method of treatment. Moreover, the scope of claims in a patent application can be significantly reduced before any claims in a patent are issued, and claim scope can be reinterpreted after issuance. Even if our current or future patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner, which could materially adversely affect our business, financial condition, results of operations and prospects.

It is also possible that we may not identify, or that we may not timely file on identified, patentable aspects of our research and development output before it is too late to obtain patent protection. 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 USPTO might require that the term of a patent issuing from a pending patent application to be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license, including those from our licensors, if any, and from third parties. We also may require the cooperation of our potential future licensors in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our potential future licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we may in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

Even if our current or future 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 potential future in-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 any future in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review ("PGR"), and/or inter partes review ("IPR"), or other similar proceedings in the USPTO or foreign patent offices challenging our patent rights. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity of our patents, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. There is also no assurance that there is no prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us. Such loss of patent rights, loss of exclusivity or our patent claims being narrowed, invalidated or held unenforceable could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, although we seek to enter into non-disclosure and confidentiality agreements with parties who have access to patentable or trade secret aspects of our technology platforms and research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, licensors, and other third parties, any of these parties may breach such agreements and disclose such aspects or output before a patent application is filed, thereby jeopardizing our ability to seek patent protection or maintain the trade secret status of our technology platforms or research and development output. Moreover, it is possible that we may not enter into non-disclosure and confidentiality agreements with such parties, thereby potentially compromising our confidential information or otherwise subjecting it to potential loss or misuse.

As referenced above, we have filed patent applications directed to our platform technologies that involve certain of our proprietary software modules. Moreover, while software and other of our proprietary works may be protected under copyright law, we have chosen not to register any copyrights in these works, and instead, rely on the above-referenced patent applications for protection of certain modules and trade secret protection for other of our software modules. In order to bring a copyright infringement lawsuit in the United States, the copyright must be registered. Accordingly, the remedies and damages available to us for unauthorized use of our software may be limited.

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

In the future, we may enter into license agreements under which we are granted rights to intellectual property that may be important to our business. We expect that any future license agreements where we in-license intellectual property would 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 use the licensed intellectual property in an unauthorized manner or are subject to bankruptcy-related proceedings, the licensors may have the right to materially modify the terms of the licenses, such as by rendering currently exclusive licenses non-exclusive, or terminate the licenses, in which event we would not be able to market products covered by the licenses. 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 from third parties to advance our research or allow commercialization of our product candidates or platform, and we cannot provide any assurances that third-party patents do not exist that might be enforced against our product candidates or platform in the absence of such a license. 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 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 on commercially reasonable terms, if at all. 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 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, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. 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.

In addition, disputes may arise between us and any future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted and obligations imposed under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense 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;
- the amounts, if any, we owe to a potential licensor in respect of sublicense fees or income or in respect of backup product;
- 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 its affiliates and sublicensees and by us and our partners and sublicensees.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our future 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 agreements 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.

The patent protection and patent prosecution for some of our product candidates may be dependent on our future licensors and third parties.

We or our future potential licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects as to form in the preparation or filing of our potential future in-licensed patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our future potential licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our future potential licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our future potential in-licensed patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

As a future potential licensee of third parties, we would rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our future license agreements. We would not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Future potential licensors may have the right to control enforcement of our future potential licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our future licensors. We cannot be certain that our future licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If any of our future potential licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents directed to any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties in the future, we may still be adversely affected or prejudiced by actions or inactions of our potential licensors and their counsel that took place prior to us assuming control over patent prosecution.

Technology we may acquire or license from various third parties in the future may be subject to retained rights. Our future licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for use in fields other than the fields licensed to us or for use in noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It may be difficult to monitor whether our future licensors may limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe or misappropriate their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement or misappropriation of the patents and other proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Because the intellectual property landscape in the industry in which we participate is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our ability to freely make, use, and sell our products without infringing third party rights. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates, as well as related to our platform.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates or platform may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that others have not filed patent applications for a product candidate or technology covered by our pending patent applications, or that we were the first to file a patent application related to a product candidate or technology. Our competitors may have filed, and may in the future file, patent applications covering our product candidates, products (if approved) 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 relating to such technologies. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe.

In addition, identification of third-party patent rights that may be relevant to our product candidates or platform is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

Further, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time-consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or unenforceable or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or

- require us to enter into royalty or licensing agreements, that may not be available on commercially reasonable terms, or at all, or that might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us to date, others may hold proprietary rights that could prevent our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin activities relating to our product candidates or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or develop our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates or processes to avoid infringement, if necessary.

Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and results of operations.

Parties making claims against us may be able to sustain the costs of complex patent or trade secret litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Moreover, if our product candidates or platform are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of these claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of such licensees and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

We may be involved in lawsuits to protect or enforce our patents or the patents of our future licensors, which could be expensive, time-consuming and unsuccessful. Further, our future in-licensed issued patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe or otherwise violate our, or our future licensors', patents, trademarks or other intellectual property. To prevent infringement or other violations, we and/or our future licensors may be required to file claims, which can be expensive and time-consuming. Further, our future licensors may need to file such claims, but elect not to file them. In addition, in a patent infringement proceeding, a court may decide that a patent we own or license is not valid, is unenforceable and/or is not infringed. If we or any of our future licensors or potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty or written description, non-patentable subject matter (laws of nature, natural phenomena, or abstract idea), obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent intentionally 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 to the USPTO 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 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 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 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.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights, particularly those in a foreign jurisdiction, 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. 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). 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.

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

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our Class A common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Derivation or interference proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation or interference proceedings provoked by third parties or brought by us or our future licensors, or declared by the USPTO or similar proceedings in foreign patent offices, may be necessary to determine the priority of inventions with respect to our or our potential future licensors' patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our, or our licensors', defense of such proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application.

Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in our patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

The Leahy-Smith Act also includes a number of significant changes that (i) affect the way patent applications are prosecuted, (ii) redefine prior art, and (iii) provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, 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 have been insufficient to invalidate the claim if presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation increase the uncertainties and costs surrounding the prosecution of our or our future licensors' patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and 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 many other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves 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. Further, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. 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. 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 or our future licensors' 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 or our licensors' ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

We or our future licensors may be subject to claims challenging the inventorship or ownership of our or our future in-licensed patents and other intellectual property.

We may also be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we or our future licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we or our future licensors are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

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

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

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 term of a patent, and the protection it affords, is limited. Even if patents directed to our product candidates are obtained, once the patent term has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of product candidates, patents directed to our product 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.

Depending upon the timing, duration and specifics of FDA marketing approval, if any, of our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA-approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we or our licensors may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we or our licensors are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. 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 the case.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents 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 foreign countries do not protect intellectual property rights to the same extent as federal and state 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 jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we or our licensors have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our, or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our, or our potential future licensors', patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our or our potential future licensors' patents at risk of being invalidated or interpreted narrowly and our or our potential future licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us. We, or our licensors, may not prevail in any lawsuits that we or our potential future licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our, or our potential future licensors', efforts to 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 in-license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we, or our licensors, are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on third parties to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. While an inadvertent lapse, including due to the effect of a widespread adverse health event, our patent maintenance vendors or law firms, 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. If we fail to maintain the patents and patent applications relating to our product candidates, our competitive position would be adversely affected.

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

In addition to seeking patent protection for some of our technology and product candidates, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position, especially with respect to our technology platform. Any disclosure, either intentional or unintentional, by our employees or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a security breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We have taken steps to protect our trade secrets and unpatented know-how, including entering into non-disclosure and confidentiality agreements with third parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Further, we cannot provide any assurances that all such agreements have been duly executed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. In addition, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we or our licensors do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach, in each case which could materially harm our business.

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 pharmaceutical and biotechnology 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 we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information, 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, which could adversely affect 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 team and other employees.

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, prescribers 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.

Moreover, any name we have proposed to use with a product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe and other jurisdictions outside of the United States. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We use third-party open source software, which could negatively affect our ability to offer our solutions and subject us to litigation or other actions.

We use open source software licensed to us by third-party authors under "open source" licenses in our platform and solutions and expect to continue to use such open source software in the future. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide support, warranties, indemnification or other contractual protections regarding infringement claims or the quality of the code. To the extent that our platform depends upon the successful operation of open source software, any undetected errors or defects in this open source software could prevent the deployment or impair the functionality of our platform, delay introductions of new solutions, result in a failure of our platform, and injure our reputation. For example, undetected errors or defects in open source software could render it vulnerable to breaches or security attacks, and, as a result, possibly make our systems more vulnerable to data breaches. In addition, the public availability of such software may make it easier for others to compromise our platform.

Further, there are uncertainties regarding the proper interpretation of and compliance with open source licenses, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to use such open source software, and consequently to provide or distribute our platform and solutions. Some open source licenses contain express requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use, or grant other licenses to our intellectual property. If we combine our proprietary software with open source software in a certain manner, we could, under certain open source licenses, be required to release the source code of our proprietary software to the public. This would allow our competitors to create similar offerings with lower development cost, effort and time and ultimately could result in a loss of our competitive advantages. Alternatively, to avoid the public release of the affected portions of our source code, we could be required to expend substantial time and resources to re-engineer some or all of our software.

Despite our efforts to monitor our use of open source software to avoid subjecting our platform to conditions we do not intend, there is a risk that open source licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to provide or distribute our platform. Additionally, we may from time to time face claims from third parties claiming ownership of, or seeking to enforce the terms of, an open source license, including by demanding release of source code for the open source software, derivative works or our proprietary source code that was developed using, or that is distributed with, such open source software. These claims could also result in litigation and could require us to make our proprietary software source code freely available, devote additional research and development resources to re-engineer our platform, seek costly licenses from third parties, pay monetary damages to the owner of the copyright in the relevant open source software or otherwise incur additional costs and expenses, any of which could result in reputational harm and would have a negative effect on our business and results of operations. In addition, if the license terms for the open source software we utilize change, we may be forced to re-engineer our platform, incur additional costs to comply with the changed license terms or replace the affected open source software. Although we have implemented policies to regulate the use and incorporation of open source software into our platform and solutions, we cannot be certain that such policies will be effective and that we have not incorporated open source software in our platform and solutions in a manner that is inconsistent with such policies.

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

The degree of future protection afforded by intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example and without limitation:

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we may own or license;
- we or our potential future licensors might not have been the first to make the inventions covered by the issued patents or patent application that we may own or license;
- we or our potential future licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our, or our future licensors', pending patent applications will not lead to issued patents;
- future issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

Risks Related to Employee Matters and Managing our Growth

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

We currently do not have and have never had a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we may obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that may receive regulatory approval or any such commercialization may experience delays or limitations. Moreover, even if we do successfully enter such arrangements with third parties, any of those third parties may fail to perform in a satisfactory or timely manner, if at all. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical, administrative and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our results of operations. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary, including bioinformatics and computational biologist specialists, for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. We currently do not maintain "key person" insurance for any of our executive officers (other than our chief executive officer) or other employees, and such insurance, even if in place, may not be adequate.

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 a wide range of 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 (if approved) our product candidates will be limited and the potential for successfully growing our business will be harmed.

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 December 31, 2025, we had 53 full-time employees, including 37 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, including operating as a public company, 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 without limitation:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA, EMA and other comparable foreign regulatory agencies' review process of atebimetinib and any other product candidates that we develop, 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 atebimetinib and any other product candidates will depend, in part, on our ability to effectively manage any future growth, and 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 any current or 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 atebimetinib and any other current or future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

A variety of risks associated with operating internationally could materially adversely affect our business.

We currently have limited international operations, but our business plans incorporate potential international expansion, including the planned addition of international clinical trial sites, potential engagement with a collaborator based internationally, or if any of our product candidates receives regulatory approval. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our product candidates in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining intellectual property protection and enforcing our intellectual property rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability including wars, terrorism and political unrest (for example, the ongoing conflict between Russia and Ukraine, as well as in the Middle East), outbreak of disease (for example, COVID-19 and other pandemics), boycotts, curtailment of trade and other business restrictions;
- increased susceptibility to trade disputes between nations, including from the imposition of tariffs, which may adversely impact operations (such as conducting ex-U.S. clinical trials or sourcing materials internationally);
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales (if any) and activities that may fall within the purview of the FCPA, its books and records provisions, its anti-bribery provisions or other anti-bribery and anti-corruption laws.

Any of these factors, among others, could significantly limit or harm our future international expansion and operations and, consequently, our results of operations.

Acquisitions, joint ventures or other transactions involving third parties could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We have in the past and may in the future acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, licensing arrangements, supply agreements or investments in complementary businesses. We have limited or in some cases no experience in completing such transactions. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including without limitation:

- disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- diversion of management time and focus from operating our business to acquisition integration or other collaboration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- possible write-offs or impairment charges relating to acquired businesses;
- disputes regarding intellectual property and/or the scope and interpretation of licensing terms; and
- inability to develop a sales force for any additional product candidates.

Potential foreign transactions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Additionally, the anticipated benefit of any such transaction may not materialize. For example, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of additional debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

We have broad discretion in the use of our cash reserves and may not use them effectively.

Our management has broad discretion to use our cash reserves and could use them in ways that do not improve our results of operations or enhance value, for example by prioritizing the development of certain product candidates and / or medical indications over others that could have been more successful. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business and/or delay the development of our product candidates. Additionally, pending their use, we may invest our cash reserves in a manner that does not produce income or that loses value.

Risks Related to Ownership of Our Class A Common Stock

We may be unable to maintain an active, liquid and orderly trading market for our Class A common stock and, as a result, it may be difficult for you to sell your shares of our Class A common stock.

The market value of our Class A common stock has in the past decreased from time to time, and may in the future decrease from time to time, and you may not be able to resell your shares of our Class A common stock at or above the price you purchased them. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our Class A common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of Class A common stock as consideration.

The price of our stock has been and may in the future be volatile, and you could lose all or part of your investment.

The trading price of our Class A common stock has in the past been, and in the future is likely to be, highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors may negatively affect the market price of our Class A common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section, elsewhere in this filing, and in our other SEC filings, these factors include:

- the timing and results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our Class A common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions, including the effects of recession or slow economic growth in the U.S. and abroad, interest rates, tariffs, inflation, fuel prices, international currency fluctuations, corruption, political instability, acts of war, acts of terrorism, ongoing or future military conflicts, and ongoing or future pandemics or other public health crises.

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 Class A common stock.

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 Class A common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. 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 results of operations 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 (as has happened in the past), we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant percentage of our voting stock and these stockholders will be able to influence us through this ownership position. These stockholders, if they were to vote their shares in the same or a similar manner as one another, may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our Class A common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their Class A common stock, and might affect the prevailing market price for our Class A common stock.

Sales of a substantial number of shares of our Class A and/or Class B common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our Class A and/or Class B common stock, or the perception that these sales might occur, could depress the market price of our Class A common stock and could impair our ability to raise capital through the sale of additional equity securities. The shares of Class A common stock that were sold in the initial public offering and shares of Class A common stock that have been or will be sold under any registration statement declared effective by the SEC are, or will be, as applicable, freely transferable without restrictions or further registration under the Securities Act, except for any shares acquired by our affiliates, as defined in Rule 144 under the Securities Act. The remaining shares of our Class A common stock that are outstanding are either unrestricted or restricted as a result of securities laws. In addition, there are shares of Class A common stock that are either subject to outstanding options or reserved for future issuance under our existing equity incentive plans and may become eligible for future sale subject to vesting, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of Class A common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our Class A common stock could decline.

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

We do not currently intend to pay dividends on our Class A common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our Class A common stock.

We have never declared or paid any cash dividends on our equity securities. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future, if ever. Any return to stockholders will therefore be limited to any appreciation in the value of our Class A common stock, which is not certain.

Provisions in our certificate of incorporation and 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 Class A common stock.

Our certificate of incorporation and bylaws contain provisions that could depress the market price of our Class A common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified Board so that not all members of our Board are elected at one time;
- permit only the Board 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 to unilaterally amend the bylaws (as, for example, the Board did in February 2024);
- 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 (the "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 certificate of incorporation, our bylaws or Delaware or other applicable 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 Class A common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws provides for an exclusive forum in the Court of Chancery of the State of Delaware for certain 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 certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for 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 pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that a federal district court of the United States of America is the exclusive forum for the resolution of any complaint asserting a cause or causes of action against any defendant arising under the Securities Act. Such provision is intended to benefit and may be enforced by us, our officers, directors, employees and agents, including the underwriters and any other professional or entity who has prepared or certified any part of this filing or our other SEC filings. Nothing in our amended and restated certificate of incorporation or amended and restated bylaws preclude stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees, agents or stockholders, which may discourage lawsuits with respect to such claims or make such lawsuits more costly for stockholders, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. 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 the choice of forum provision contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General Risks

Our information technology systems or use of artificial intelligence, or those of any of our CROs, manufacturers, other contractors, consultants, collaborators or potential future collaborators, may fail or suffer security 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.

Our information technology systems and those of our current and any future CROs, CMOs and other contractors, consultants, collaborators, agents and third-party service providers, are vulnerable to attack, interruption and damage from computer viruses (e.g. ransomware), cybersecurity threats, malicious code, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information.

The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased and evolved. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. If we or our third-party vendors were to experience a significant security breach of our or their information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

We and our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to our trade secrets, health-related or other personal information or other proprietary or sensitive information, it could result in a material disruption of our drug discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions, and it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to data privacy and security laws. Notifications and follow-up actions related to a security breach 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 past, present 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 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 breach were to result in a loss 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 potential commercialization of our product candidates could be delayed or halted, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal, local and/or international privacy and security laws.

In addition, we (and likely many of our third-party vendors, agents and other collaborators) are adopting and exploring the use of Artificial Intelligence ("AI") in our business. As an emerging and rapidly evolving technology, our (and, to the extent applicable, our third-party vendors', agents' and other collaborators') use of AI presents risks that could adversely affect our operations, information security and reputation. For example, AI systems may produce inaccurate or flawed outputs due to improper algorithms, or insufficient and/or erroneous training data. Reliance on flawed outputs could result in lower quality decision-making or prevent us from effectively utilizing AI in our business. We may also become vulnerable to operational disruptions if any AI technologies that we use experience downtimes or are compromised by cyberattacks. Moreover, if any of our confidential or proprietary information is integrated into public AI systems, whether purposefully or accidentally, it could result in the loss of confidentiality (including with respect to intellectual property) or other premature disclosure issues that negatively impact our business operations. If we (or our third-party agents and other collaborators) do not effectively implement guardrails and train staff on the safe and proper use of AI, or if staff fail to effectively adhere to established guardrails and training on the use of AI, we may experience adverse effects on our business, including without limitation data breaches, the loss of confidential information (including our intellectual property), unintentional disclosure of personal data, reputational harm, or other misuse of our proprietary information.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. 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 or ultimate disposition, could be costly and divert management attention.

Additionally, there can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information. See Part I. Item 1C. "Cybersecurity" contained in this Annual Report on Form 10-K for additional information.

Our operations are vulnerable to interruption by fire, severe weather conditions, power loss, telecommunications failure, terrorist activity, military conflict, future pandemics and other events beyond our control, which could harm our business.

Our facilities are located in regions which experience severe weather from time to time. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major tornado, flood, fire, earthquake, power loss, terrorist activity, geopolitical conflicts, military conflict, future pandemics, public health crises or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our Class A common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this and other periodic reports;

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act");

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our Class A common stock less attractive because we may rely on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We intend to take advantage of the extended transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

The requirements of being a public company may strain our resources, result in more litigation and divert management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), the listing requirements of Nasdaq and other applicable securities laws, rules and regulations. Complying with these laws, rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and results of operations. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight will be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and results of operations. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, rules, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, rules, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, rules, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, rules, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory or other governmental authorities may initiate legal proceedings against us and our business may be adversely affected.

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our Board, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in this filing and in future filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm 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 harm our business and the trading price of our Class A common stock.

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. 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, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, 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. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company or a non-accelerated filer (as defined under applicable SEC rules), our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. 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.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our Class A common stock has been and may in the future 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. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

New tax legislation may impact our results of operations and financial condition.

The U.S. government has enacted, and may in the future enact further, significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate, an increase in the tax rate applicable to the global intangible low-taxed income and elimination of certain exemptions, and the imposition of minimum taxes or surtaxes on certain types of income. For example, the recently enacted Inflation Reduction Act, among other changes, introduced a 15% corporate minimum tax on certain United States corporations and a 1% excise tax on certain stock redemptions by United States corporations. Additionally, in July 2025, the Act to Provide for Reconciliation Pursuant to Title II of H. Con. Res. 14 was enacted, which for example (and among other things) extends certain tax cuts while eliminating certain others. The likelihood and / or potential impact of these or other further changes being enacted or implemented is unclear. We are currently unable to predict whether such changes will occur, and if they do occur, what their scope will be. If such changes were to be enacted or implemented, we are currently unable to predict the ultimate impact on our business.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a cybersecurity incident response plan. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information.

We design and assess our cybersecurity risk management program based in part on the National Institute of Standards and Technology Cybersecurity Framework ("NIST CSF"). This does not, nor is it in any way intended to, imply that we currently or may in the future meet any particular technical standards, specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and/or financial risk areas.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, potential products, services, and our broader enterprise IT environment;
- a cyber security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, as we believe appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training of our employees, incident response personnel, and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- risk management processes with respect to third party service providers, suppliers, and vendors.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition.

Cybersecurity Governance

Our Board of Directors considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee oversight of cybersecurity and other information technology risks. The Audit Committee oversees management’s implementation of our cybersecurity risk management program.

The Audit Committee receives periodic reports from management on our cybersecurity risks. In addition, management is tasked with updating the Audit Committee, if and as necessary, regarding any material cybersecurity incidents, as well as other incidents with lesser impact potential.

The Audit Committee periodically reports to the full Board of Directors regarding its activities, which may include those related to cybersecurity. The full Board of Directors may also from time to time receive briefings from management related to our cyber risk management program. Directors may receive presentations on cybersecurity topics from our management, internal cyber security / information technology staff, or external experts as part of continuing education on topics that impact public companies.

Our management team, including our Executive Director of IT with supervision by our Chief Legal Officer, is responsible for assessing and managing our material risks from cybersecurity threats. The management team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and external cybersecurity consultants. Our Executive Director of IT has previous experience managing information technology infrastructure and cybersecurity, as well as responding to cybersecurity incidents, at other biopharmaceutical companies.

Our management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the information technology environment.

Item 2. Properties

Our principal office is located at 245 Main Street, Second Floor, Cambridge, Massachusetts 02142, where we lease approximately 100 square feet of office space under a service agreement that we last renewed to have a lease term commencing on December 1, 2025 and ending on November 30, 2026.

We also lease a property in San Diego, California, with approximately 38,613 square feet of office and laboratory space under a lease that terminates on April 30, 2032.

Additionally, we lease approximately 150 square feet of office space in New York, New York under a service agreement that currently runs through September 30, 2026.

We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings

From time to time we may be involved in claims and proceedings arising in the course of our business. The outcome of any such claims or proceedings, regardless of the merits, is inherently uncertain. We are not currently party to any material legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information for Common Stock

Our common stock trades under the symbol "IMRX" on the Nasdaq Global Market.

Holders of Our Common Stock

As of March 1, 2026, there were approximately 60 registered holders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in "street name" by brokers or held by other "nominees". The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain all available funds and 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, if ever.

Securities Authorized for Issuance Under Equity Compensation Plans

See Item 12, Part III of this Form 10-K.

Unregistered Sales of Equity Securities

Other than sales previously reported in the Company's Current Reports on Form 8-K filed with the SEC, the Company did not sell any unregistered securities during the period covered by this Annual Report on Form 10-K.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the quarterly period ended December 31, 2025.

Item 6. [Reserved]

Item 7.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing in Part II, Item 8 of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part I, Item IA. ''Risk Factors'' of this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a late-stage clinical oncology company focused on keeping cancer patients alive and helping them thrive. We are developing and seeking to commercialize an entirely new category of anti-cancer medicines, Deep Cyclic Inhibitors, which we believe have the potential to be more effective and better tolerated targeted therapies.

Deep Cyclic Inhibition® ("DCI") is a novel mechanism that aims to deprive tumor cells of the sustained proliferative signaling required for rapid growth, while sparing healthy cells through a cadenced, normalized level of signaling. Our Deep Cyclic Inhibitors inhibit clinically-validated core signaling pathways, such as the MAPK pathway. Our novel approach is designed to improve durability and tolerability, and differentiates us from chronically targeted precision therapies, which are generally limited by toxicity, resistance and/or application to specific mutations only.

Our lead product candidate, atebimetinib (IMM-1-104), is an oral, once-daily Deep Cyclic Inhibitor of MEK, designed to improve durability and tolerability across many cancer indications, including MAPK pathway-driven tumors such as pancreatic cancer. We are currently in the process of initiating a Phase 3 clinical trial of atebimetinib, which we call the MAPKeeper 301 trial, to evaluate atebimetinib in combination with mGnP in first-line pancreatic cancer patients. We expect to dose the first patient in the MAPKeeper 301 trial in mid-2026.

MAPKeeper 301 is designed as a global Phase 3 registrational trial that will evaluate atebimetinib (320 mg QD) in combination with mGnP, compared to standard of care GnP alone, in first-line metastatic PDAC. The primary endpoint of MAPKeeper 301 is overall survival, and secondary endpoints include progression-free survival, overall response rate, disease control rate, and quality of life measurements. We plan to enroll a total of approximately 510 patients in MAPKeeper 301, divided equally across the two arms.

In January 2026, we announced positive interim response and safety data from our ongoing Phase 2a clinical trial arm evaluating atebimetinib in combination with mGnP in first-line pancreatic cancer patients, which is part of our ongoing Phase 1/2a clinical trial of atebimetinib in patients with advanced solid tumors. We also announced that we expect the following near-term milestones related to atebimetinib: presenting further updated circulating tumor DNA data on acquired alterations from cancer patients treated with atebimetinib at a major scientific meeting, in the second quarter of 2026; announcing further updated survival data from over 50 first-line pancreatic cancer patients treated with atebimetinib in combination with mGnP in our ongoing Phase 1/2a clinical trial, in the first half of 2026; and dosing the first patient in a planned clinical trial of atebimetinib in combination with Libtayo® in non-small cell lung cancer patients, in the second half of 2026.

Our development pipeline also includes our additional clinical-stage product candidate envometinib (IMM-6-415) and other early-stage research programs, including research focused on validated core cancer-signaling pathways outside of the MAPK pathway.

For the period from inception through 2017, we devoted substantially all of our efforts to business planning, service revenue generation, developing tools to aid in drug discovery, and recruiting management and technical staff. Since 2018, we have focused significant effort on our own internal research and development programs, and since December 2022 have exclusively focused our efforts on such programs. We have financed our operations through service revenues (which have since ceased), the issuance of convertible debt and the sale of convertible preferred stock, common stock and warrants exercisable for common stock.

On December 22, 2021, we completed the acquisition of all outstanding shares of capital stock of BioArkive, Inc., a California corporation ("BioArkive"), for a market value of $8.75 million. BioArkive was a San Diego based contract research organization that previously provided preclinical research services and biosample storage to us and other biotechnology companies. BioArkive was fully integrated into our operations following the acquisition and now exclusively supports our internal preclinical research activities for our oncology pipeline. In connection with the acquisition, we assumed BioArkive's lease agreement obligations.

We sold 5,164,159 shares of common stock under our 2022 ATM Program (as defined below), at a weighted average price per share of $3.03, for aggregate gross proceeds of $15.6 million ($15.0 million net of offering expenses) during the year ended December 31, 2025. We did not sell any shares of common stock under our 2022 ATM Program during the three months ended December 31, 2025. We also did not sell any shares of common stock under our 2025 ATM Program (as defined below) during the three months or year ended December 31, 2025.

On August 21, 2025, we entered into a Securities Purchase Agreement (the "August 2025 Purchase Agreement") with the purchasers party thereto, pursuant to which we agreed to sell securities to such purchasers in a private placement (the "August 2025 Private Placement"). The August 2025 Purchase Agreement provided for the sale and issuance by us to the purchasers of: (i) an aggregate of 5,251,349 shares of our common stock at a purchase price of $3.95 per share, (ii) for certain purchasers, in lieu of common stock, an aggregate of 1,077,764 pre-funded warrants (the "Pre-Funded Warrants") to purchase up to the same number of shares of our common stock, and (iii) an aggregate of 2,848,096 warrants (the "Purchase Warrants") to purchase up to the same number of shares of our common stock. The Pre-Funded Warrants were issued for a purchase price equating to $3.949 per Pre-Funded Warrant (which was the per share purchase price for the common stock issued in the August 2025 Private Placement, less the $0.001 per share unfunded exercise price for each Pre-Funded Warrant); following the October 2025 Cashless Exercise (as defined below), no Pre-Funded Warrants remained issued and outstanding. The Purchase Warrants were issued with an exercise price of $5.50 per share; as of December 31, 2025, no Purchase Warrants had been exercised. As of December 31, 2025, we had received aggregate net proceeds of $23.4 million from the August 2025 Private Placement, after deducting placement expenses of $1.6 million. The August 2025 Private Placement closed on August 26, 2025.

On September 24, 2025, we entered into a Securities Purchase Agreement (the "September 2025 Purchase Agreement") with Aventis Inc. ("Aventis"), a wholly owned subsidiary of Sanofi, a French société anonyme ("Sanofi"), pursuant to which we agreed to sell securities to Aventis in a private placement (the "September 2025 Private Placement"). The September 2025 Purchase Agreement provided for the sale and issuance by us to Aventis of an aggregate of 2,708,559 shares of our common stock at a purchase price of $9.23 per share. We received aggregate net proceeds of $23.4 million from the September 2025 Private Placement, after deducting placement agent discounts and commissions of $1.5 million and placement costs of $0.1 million. The September 2025 Private Placement closed on September 26, 2025.

On September 26, 2025, we completed an underwritten follow-on equity offering, pursuant to which we issued and sold 18,959,914 shares of our common stock at an offering price of $9.23 per share (the "September 2025 Offering"), with Leerink Partners LLC and Oppenheimer & Co. Inc. acting as underwriters. The aggregate net proceeds received by us from the September 2025 Offering were $164.1 million, after deducting underwriting discounts and commissions, as well as offering costs of $0.4 million.

Since our inception, we have had significant annual operating losses. Our net loss was approximately $56.0 million and $61.0 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of approximately $280.3 million and approximately $217.0 million in cash, cash equivalents, and marketable securities.

We have not had any internally developed products approved for sale. We do not expect to generate any product sales unless and until we successfully complete development of, obtain regulatory approval for, and successfully bring to market one or more of our internally developed product candidates. If we obtain regulatory approval for any of our internally developed product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources including, without limitation, potential collaborations, licenses or similar arrangements.

Based on our current business plans, we believe that our existing cash, cash equivalents, and marketable securities as of December 31, 2025 will enable us to fund our development activities and other operations into 2029. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. We may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate some or all planned activities to reduce costs.

As of March 6, 2026, the issuance date of the consolidated financial statements for the year ended December 31, 2025 in this Annual Report on Form 10-K, based on our recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future and the need to raise additional capital to finance future operations, we believe that our existing cash, cash equivalents, and marketable securities will enable us to fund our development activities and other operations into 2029. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured.

Components of Our Results of Operations

Operating Expenses

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

Research and Development

Research and development expenses account for a significant portion of our total operating expenses. Our research and development expenses consist primarily of direct and indirect costs incurred in connection with the development of our research platform, product candidates, discovery efforts and preclinical and clinical activities related to our program pipeline.

Our direct costs include:

- program specific expenses incurred under agreements with third-party CROs and other vendors that conduct our preclinical and clinical activities on our behalf, including clinical trial sites that conduct research and development activities on our behalf;
- laboratory expenses related to the execution of discovery programs, preclinical studies and clinical trials; and
- costs related to production of clinical and preclinical materials, including fees paid to contract manufacturers.

Our indirect costs include:

- personnel-related expenses, consisting of employee salaries, bonuses, benefits and stock-based compensation expense, and recruiting costs for personnel engaged in research and development activities;
- contractor and consulting fees related to the preparation and ongoing support of clinical trials; and
- facility and equipment related expenses, consisting of indirect and allocated expenses for rent, depreciation and amortization, maintenance of facilities, insurance, and other supplies.

We expense research and development costs in the periods in which they are incurred.

Our direct research and development expenses consist of external costs and fees paid to consultants, contractors, CMOs and CROs in connection with our preclinical and clinical development and manufacturing activities. Such program costs also include the external costs of laboratory and consumable materials and costs of raw materials that are directly attributable to and incurred for any single program. We do not allocate employee costs, contractor/consultant fees, costs associated with our platform development and discovery efforts, payments made under third-party licensing agreements, costs of laboratory supplies and consumable materials that are not directly attributable to any single program, and facilities expenses, including rent, depreciation/amortization, and other indirect costs, to specific product development programs because these costs are deployed across multiple programs and our platform technology and, as such, are not separately classified.

Due to the inherently unpredictable nature and numerous risks and uncertainties associated with product development and the current stage of development of our product candidates and programs, we cannot reasonably estimate or know the nature, timing and estimated costs necessary to complete the remainder of the development of our product candidates or programs. We are also unable to predict if, when, or to what extent we will obtain approval and generate revenues from the commercialization and sale of any of our product candidates.

The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, such as, without limitation:

- successful completion of preclinical studies and initiation of clinical trials for future product candidates;
- successful enrollment and completion of clinical trials for our current product candidates;
- data from our clinical programs that support an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- acceptance by the FDA or other applicable regulatory agencies of IND applications and amendments, clinical trial applications and/or other regulatory filings for our product candidates;
- expansion and maintenance of a workforce of experienced scientists and others to continue to develop our product candidates;
- successful application for and receipt of marketing approvals from applicable regulatory authorities;
- obtainment and maintenance of intellectual property protection and regulatory exclusivity for our product candidates;
- making of arrangements with contract manufacturing organizations for, or establishment of, commercial manufacturing capabilities;
- establishment of sales, marketing and distribution capabilities and successful launch of commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effective competition with other therapies;
- obtainment and maintenance of coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- maintenance, enforcement, defense and protection of our rights in our intellectual property portfolio;
- avoidance of infringement, misappropriation or other violations with respect to others' intellectual property or proprietary rights; and
- maintenance of a continued acceptable safety profile of our product candidates following receipt of marketing approvals, if any.

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

The process of conducting the necessary preclinical and 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.

We may never succeed in achieving regulatory approval for any of our product candidates. Further, a number of factors, including those outside of our control, could adversely impact the timing and duration of our product candidates' development, which could increase our research and development expenses. We may obtain unexpected results from our preclinical studies and clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA, EMA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the advancement of preclinical and clinical development.

We expect that our research and development expenses will substantially increase for the foreseeable future as we continue to implement our business strategy, which includes: advancing our product candidates through clinical development (including atebimetinib in our MAPKeeper 301 Phase 3 clinical trial), expanding our research and development efforts, including hiring additional personnel to support our research and development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development. As of the date of this Annual Report on Form 10-K, we cannot reasonably determine or accurately project total program-specific expenses through commercialization, if such was to occur. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related expenses, including employee salaries, bonuses, benefits, stock-based compensation, and recruiting costs for personnel in executive, finance, and other administrative functions. Other significant general and administrative expenses include legal fees relating to intellectual property and corporate matters, professional fees for accounting, tax and consulting services, insurance costs, travel expenses and facility related expenses not otherwise included in research and development expenses.

We expect our general and administrative expenses will increase for the foreseeable future if and as we continue to increase our general and administrative headcount to support our continued research and development activities and, if any product candidates receive marketing approval, commercialization activities, as well as to support our operations generally. We also expect to continue to incur increased expenses associated with operating as a public company, including costs related to accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and rules and regulations of the Securities and Exchange Commission ("SEC"), Sarbanes-Oxley Act, director and officer insurance costs, and investor and public relations costs.

Amortization of intangible asset

Amortization of intangible asset relates to the technology acquired in the BioArkive acquisition.

Other Income (Expense)

Interest income

Interest income consists of interest earned on our cash, cash equivalents, and marketable securities balances. The primary objective of our investment policy is capital preservation.

Other income, net

Other income consists of the accretion of discounts related to our marketable securities.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the periods indicated:

	Year Ended December 31,		Change	
	2025	2024	$	%
	(in thousands, except percentages)			
Operating expenses				
Research and development	$ 42,048	$ 47,964	$ (5,916)	(12.3)%
General and administrative	17,298	16,078	1,220	7.6 %
Amortization of intangible asset	29	29	—	— %
Total operating expenses	59,375	64,071	(4,696)	(7.3)%
Loss from operations	(59,375)	(64,071)	4,696	(7.3)%
Other income (expense)				
Interest income	3,039	2,593	446	17.2 %
Other income, net	312	441	(129)	(29.3)%
Net loss	**$ (56,024)**	**$ (61,037)**	**$ 5,013**	(8.2)%

Research and Development

The following table summarizes the components of our research and development expenses for the periods indicated:

	Year Ended December 31,		Change	
	2025	2024	$	%
	(in thousands, except percentages)			
Direct research and development expenses by program:				
Atebimetinib (IMM-1-104)	$ 17,639	$ 18,099	$ (460)	(2.5)%
Envometinib (IMM-6-415)	2,204	6,521	(4,317)	(66.2)%
Other programs	5,857	6,031	(174)	(2.9)%
Indirect research and development expenses:				
Employee-related costs	11,988	12,912	(924)	(7.2)%
Stock-based compensation expense	2,801	2,755	46	1.7 %
Facilities and other expenses	1,316	1,401	(85)	(6.1)%
Depreciation/amortization	243	245	(2)	(0.8)%
Total research and development	$ 42,048	$ 47,964	$ (5,916)	(12.3)%

Research and development expenses decreased by approximately $5.9 million, or 12.3%, to approximately $42.0 million for the year ended December 31, 2025 as compared to approximately $48.0 million for the year ended December 31, 2024. The decrease of approximately $5.9 million was primarily due to a decrease of approximately $5.0 million related to direct research and development expenses, consisting of: an approximately $0.5 million decrease in expenses related to the atebimetinib program, primarily driven by a decrease in certain chemistry, tablet and safety study costs, offset by increased costs related to Phase 3 clinical trial initiation; an approximately $4.3 million decrease in expenses related to the paused envometinib program; and an approximately $0.2 million decrease in expenses for earlier stage programs, as compared to the same prior year period. The overall decrease in research and development expenses was additionally driven by a decrease in indirect research and development costs of approximately $1.0 million, primarily driven by decreased employee-related costs of approximately $0.9 million, and decreased facilities and other allocated expenses of approximately $0.1 million.

General and Administrative

The following table summarizes the components of our general and administrative expenses for the periods indicated:

	Year Ended December 31,		Change	
	2025	2024	$	%
	(in thousands, except percentages)			
Employee-related costs	$ 8,925	$ 8,253	$ 672	8.1 %
Stock-based compensation expense	3,510	3,746	(236)	(6.3)%
Professional fees	3,125	2,584	541	20.9 %
Facilities and other allocated expenses	256	297	(41)	(13.8)%
Other	1,482	1,198	284	23.7 %
Total general and administrative	$ 17,298	$ 16,078	$ 1,220	7.6 %

General and administrative expenses increased by approximately $1.2 million, or 7.6%, to approximately $17.3 million for the year ended December 31, 2025 compared to approximately $16.1 million for the year ended December 31, 2024. The increase of approximately $1.2 million was primarily due to: increased employee-related costs of approximately $0.7 million; increased professional fees incurred for accounting, auditing, legal, public relations and tax services of approximately $0.5 million; and increased other expenses (primarily consisting of offering costs associated with various financing efforts) of approximately $0.3 million, offset by a decrease in stock-based compensation of approximately $0.2 million.

Amortization of Intangible Asset

Amortization of intangible asset was $29 thousand for the years ended December 31, 2025 and 2024. This amortization is related to the technology acquired from the BioArkive acquisition completed in December 2021.

Other Income, net

Interest income from the interest earned on our cash, cash equivalents and marketable securities balances increased by approximately $0.4 million, driven by a higher total cash balance resulting from various financing events, in the year ended December 31, 2025 as compared to the year ended December 31, 2024.

Other income, net was approximately $0.3 million in the year ended December 31, 2025, compared to $0.4 million in the year ended December 31, 2024. These amounts were primarily a result of the accretion of premiums related to our marketable securities.

Liquidity and Capital Resources

Sources of Liquidity

We finance our operations through the issuance of convertible notes payable, convertible preferred stock, common stock, warrants exercisable for common stock and the exercise of stock options. As of December 31, 2025, we had an accumulated deficit of $280.3 million and $217.0 million in cash, cash equivalents and marketable securities. Cash, cash equivalents and marketable securities are comprised of deposits at major financial banking institutions and highly liquid investments with an original maturity of three months or less at the date of purchase. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, reflected in the change in our outstanding accounts payable and accrued expenses.

Since our inception, we have incurred significant operating losses. Our net loss was approximately $56.0 million and $61.0 million for the years ended December 31, 2025 and 2024, respectively. 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 the next several years, if at all. To date, our operations have been financed primarily by service revenues (which have since ceased) and proceeds from sales of our debt and equity securities.

On August 10, 2022, we filed a Registration Statement on Form S-3 (File No. 333-266738) (the “2022 Shelf Registration Statement”) with the SEC in relation to the registration of our common stock, preferred stock, debt securities, warrants and/or units or any combination thereof in the aggregate amount of up to $200 million for a period of up to three years from the date of its effectiveness on August 19, 2022.

Also on August 10, 2022, we entered into an Equity Distribution Agreement (the "2022 Sales Agreement") with Piper Sandler & Co (the "Sales Agent"), to sell shares of our common stock with aggregate gross proceeds of up to $50 million, from time to time, through an "at the market" equity offering program (the "2022 ATM Program") under the 2022 Shelf Registration Statement. We sold 5,164,159 shares of common stock under the 2022 ATM Program, at an weighted average price per share of $3.03, for aggregate gross proceeds of $15.6 million ($15.0 million net of offering expenses) during the year ended December 31, 2025. We sold 1,318,752 shares of common stock under the 2022 ATM program, at a weighted average price per share of $3.38, for aggregate gross proceeds of $4.5 million ($4.2 million net of offering expenses) during the year ended December 31, 2024. We did not sell any shares of common stock under the 2022 ATM Program during the three months ended December 31, 2025 or December 31, 2024, respectively. In August 2025, the 2022 Shelf Registration Statement and the 2022 ATM Program expired, and the 2022 Sales Agreement was terminated.

On August 13, 2025, we filed a Registration Statement on Form S-3 (File No. 333-289589) (the “2025 Shelf Registration Statement”) with the SEC in relation to the registration of our common stock, preferred stock, debt securities, warrants and/or units or any combination thereof in the aggregate amount of up to $300 million for a period of up to three years from the date of its effectiveness on August 20, 2025.

Also on August 13, 2025, we entered into an Equity Distribution Agreement (the "2025 Sales Agreement") with the Sales Agent, to sell shares of our common stock with aggregate gross proceeds of up to $100 million, from time to time, through an "at the market" equity offering program (the "2025 ATM Program") under the 2025 Shelf Registration Statement. In connection with the September 2025 Offering, we: (i) reduced the maximum aggregate offering price for sales of shares of common stock pursuant to at-the-market transactions under the 2025 ATM Program by $1,250,007 (the "Reduced Amount"), resulting in a new maximum aggregate offering price of up to $98,749,993 under the 2025 ATM Program, and (ii) suspended the 2025 ATM Program and terminated the continuous offering under the 2025 ATM Program, in each case, as to the Reduced Amount. We did not sell any shares of common stock under the 2025 ATM Program during the three and twelve months ended December 31, 2025 or December 31, 2024, respectively.

On August 21, 2025, we entered into the August 2025 Purchase Agreement with the purchasers party thereto, pursuant to which we agreed to sell securities to such purchasers in the August 2025 Private Placement. The August 2025 Purchase Agreement provided for the sale and issuance by us to the purchasers of: (i) an aggregate of 5,251,349 shares of our common stock at a purchase price of $3.95 per share, (ii) for certain purchasers, in lieu of common stock, an aggregate of 1,077,764 Pre-Funded Warrants to purchase up to the same number of shares of our common stock, and (iii) an aggregate of 2,848,096 Purchase Warrants to purchase up to the same number of shares of our common stock. The Pre-Funded Warrants were issued for a purchase price equating to $3.949 per Pre-Funded Warrant (which was the per share purchase price for the common stock issued in the August 2025 Private Placement, less the $0.001 per share unfunded exercise price for each Pre-Funded Warrant). On October 6, 2025, certain purchasers from the August 2025 Private Placement exercised an aggregate of 1,077,764 Pre-Funded Warrants previously issued to them pursuant to the August 2025 Purchase Agreement. Each such exercise was made pursuant to the cashless exercise provision of the applicable Pre-Funded Warrant, such that an aggregate of 166 shares of common stock were withheld in lieu of cash payment of the $0.001 exercise price for each Pre-Funded Warrant share, and the exercising purchasers were issued an aggregate of 1,077,598 shares of common stock (the "October 2025 Cashless Exercise"). Following the October 2025 Cashless Exercise, no Pre-Funded Warrants remained issued and outstanding. The Purchase Warrants were issued with an exercise price of $5.50 per share; as of December 31, 2025, no Purchase Warrants had been exercised. As of December 31, 2025, we had received aggregate net proceeds of $23.4 million from the August 2025 Private Placement, after deducting placement expenses of $1.6 million. The August 2025 Private Placement closed on August 26, 2025.

Also on August 21, 2025, in connection with the August 2025 Purchase Agreement, we entered into a Registration Rights Agreement (the “Registration Rights Agreement”) with the purchasers in the August 2025 Private Placement. Pursuant to the Registration Rights Agreement, we agreed to prepare and file a registration statement with the SEC for purposes of registering the resale of the common stock and the shares of common stock issuable upon exercise of the Pre-Funded Warrants and Purchase Warrants (collectively, the “Warrant Shares”) purchased by the purchasers in the August 2025 Private Placement, and any shares of common stock issued as a dividend or other distribution with respect to, in exchange for or in replacement of such common stock or Warrant Shares. On September 3, 2025, we filed a Registration Statement on Form S-3 (File No. 333-289997) (the “2025 Resale Registration Statement”) with the SEC in relation to the registration for re-sale of the common stock and Warrant Shares from the August 2025 Private Placement. The SEC declared the 2025 Resale Registration Statement effective on September 8, 2025.

The foregoing and other related summaries contained herein do not purport to be complete and are qualified in their entirety by reference to the August 2025 Purchase Agreement, the Registration Rights Agreement, the Pre-Funded Warrants and the Purchase Warrants, which are filed as Exhibits 10.18, 10.19, 4.4 and 4.5, respectively, to this Annual Report on Form 10-K.

On September 24, 2025, we entered into the September 2025 Purchase Agreement with Aventis, a wholly owned subsidiary of Sanofi, pursuant to which we agreed to sell securities to Aventis in the September 2025 Private Placement. The September 2025 Purchase Agreement provided for the sale and issuance by us to Aventis of an aggregate of 2,708,559 shares of our common stock at a purchase price of $9.23 per share. We received aggregate net proceeds $23.4 million from the September 2025 Private Placement, after deducting placement agent discounts and commissions of $1.5 million and placement costs of $0.1 million. The September 2025 Private Placement closed on September 26, 2025.

Pursuant to the September 2025 Purchase Agreement, we also agreed to (i) notify Aventis within three business days of us engaging in discussions with any third party regarding, or the board of directors authorizing us to pursue or initiate a process to pursue, any transaction that would be reasonably expected to result in a change of control of the Company or an affiliate of the Company (a "Change of Control") or any other license, sale, assignment, transfer, grant or other disposition of the Company's or an affiliate of the Company's rights to research, develop, manufacture, commercialize, or otherwise exploit atebimetinib (a "Covered Transaction" and, collectively, a "Strategic Transaction Process"), (ii) provide Aventis the opportunity to participate in such Strategic Transaction Process subject to customary confidentiality and other undertakings on substantially the same procedural terms and timeframe as other participants, and (iii) for a period of 120 days following the date of the September 2025 Purchase Agreement, not enter into any Covered Transaction or commence, continue, or otherwise engage in any discussions, or negotiate with any third party, to enter into any Covered Transaction (provided that this provision shall not limit the entry by us into, or any engagement in discussion or negotiations with any third party regarding, a Change of Control transaction). These provisions contain customary confidentiality restrictions and limitations on disclosure obligations, and will terminate upon the earlier of: (a) such time as Aventis and its affiliates no longer hold at least 50% of the securities purchased from the Company pursuant to the September 2025 Purchase Agreement, (b) 90 days after the public release of the topline results of the overall survival of the Phase 3 clinical trial of atebimetinib in pancreatic cancer, (c) the liquidation, dissolution or winding-up of the affairs of the Company, or the consummation of any Change of Control or any other deemed liquidation event of the Company and (d) such time as all development activities with respect to atebimetinib have been terminated.

In addition, pursuant to the September 2025 Purchase Agreement, Aventis agreed (i) until the date that is six months after the closing date of the September 2025 Private Placement, to be subject to customary lock-up restrictions with respect to sales of shares of our common stock (or similar transactions with the same economic effect), subject to certain customary exceptions, (ii) until the first anniversary of the closing date of the September 2025 Private Placement, to be subject to stand-still restrictions with respect to acquisitions of shares of the our common stock and similar activities, subject to certain customary exceptions and fall-away provisions, and (iii) until the first anniversary of the closing date of the September 2025 Private Placement or such earlier time as the stand-still restrictions shall have fallen away, vote with respect to all voting securities of the Company as to which it is entitled to vote in accordance with the recommendation of a majority of our board of directors.

The foregoing and other related summaries contained herein do not purport to be complete and are qualified in their entirety by reference to the September 2025 Purchase Agreement, which is filed as Exhibit 10.20 to this Annual Report on Form 10-K.

On September 26, 2025, we completed the September 2025 Offering, pursuant to which we issued and sold 18,959,914 shares of our Class A common stock at an offering price of $9.23 per share, with Leerink Partners LLC and Oppenheimer & Co. Inc. acting as underwriters. The aggregate net proceeds received by us from the September 2025 Offering $164.1 million, after deducting underwriting discounts and commissions, as well as offering costs of $0.4 million.

As of December 31, 2025, we had contractual obligations related to various leases of $0.8 million for 2026, $0.8 million for 2027, $0.8 million for 2028, $0.8 million for 2029, $0.9 million for 2030 and $1.2 million for the periods thereafter.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. In particular, we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our internally developed product candidates as well as add operational, financial and management informational systems and personnel to support our product development. In addition, if and when we seek and obtain regulatory approval to commercialize any product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product candidate. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

Based on our current business plans, we believe that our existing cash, cash equivalents, and marketable securities as of December 31, 2025 will enable us to fund our development activities and other operations into 2029. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. We may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate some or all planned activities to reduce costs.

We have no off-balance sheet arrangements that have a material current effect or that are reasonably likely to have a material future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Going Concern Assessment

Management considered whether or not there are conditions or events, in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern, and concluded that there are none as it estimates that the entity's cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least one year from the date of issuance of the financial statements appearing within this Annual Report on Form 10-K.

Cash Flows

The following table summarizes our sources and uses of cash for the periods indicated:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (45,345)	$ (55,000)
Investing activities	(88,738)	26,435
Financing activities	226,583	5,304
Net increase (decrease) in cash and cash equivalents	$ 92,500	$ (23,261)

Net Cash Used in Operating Activities

During the year ended December 31, 2025, operating activities used approximately $45.3 million of cash, primarily resulting from our net loss of approximately $56.0 million and net amortization of premium (accretion of discount) on marketable securities of $0.2 million, partially offset by stock-based compensation expense of approximately $6.3 million, changes in our operating assets and liabilities of $3.8 million, and $0.7 million for the reduction in carrying amount of right-of-use assets and depreciation and amortization.

During the year ended December 31, 2024, operating activities used approximately $55.0 million of cash, primarily resulting from our net loss of approximately $61.0 million, changes in our operating assets and liabilities of $0.9 million, and net amortization of premium (accretion of discount) on marketable securities of $0.3 million, partially offset by stock-based compensation expense of approximately $6.5 million and $0.7 million for the reduction in carrying amount of right-of-use assets and depreciation and amortization.

Net Cash Used in Investing Activities

During the year ended December 31, 2025, cash used from investing activities was approximately $88.7 million, primarily related to purchases of marketable securities of $88.6 million and $0.1 million for purchases of property and equipment.

During the year end December 31, 2024, cash provided from investing activities was approximately $26.4 million, primarily related to maturities of marketable securities of $31.9 million, offset by purchases of marketable securities of $5.4 million and $0.1 million for purchases of property and equipment.

Net Cash Provided by Financing Activities

During the year ended December 31, 2025, net cash provided by financing activities was approximately $226.6 million, primarily driven by proceeds of approximately: $15.0 million from the sale of common stock under our 2022 ATM program, net of commissions; $0.4 million from the sale of common stock pursuant to our employee stock purchase plan; $0.4 million from the exercise of stock options; $25.0 million from the sale of common stock, Pre-Funded Warrants and Purchase Warrants in the August 2025 Private Placement; $25.0 million from the sale of common stock in the September 2025 Private Placement; and $164.5 million from the sale of common stock in the September 2025 Offering, net of underwriting commissions. The above were partially offset by aggregate payments of offering and placement expenses, as applicable, of $3.7 million.

During the year ended December 31, 2024, net cash provided by financing activities was approximately $5.3 million, primarily driven by proceeds of approximately $4.2 million from the sale of common stock under our 2022 ATM program, net of offering expenses, in addition to $0.7 million from the exercise of stock options and approximately $0.4 million from our employee stock purchase plan.

Future Funding Requirements

We expect that our expenses will increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for our product candidates in development. The timing and amount of our operating and capital expenditures will depend largely on:

- the costs and results of our ongoing clinical trial for atebimetinib, our planned registrational trial of atebimetinib in combination with mGnP in first-line pancreatic cancer, and potential future clinical trials for atebimetinib and our other product candidates;
- the scope, progress, results and costs of discovery research, preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient ("API"), and manufacture of our product candidates and the terms of such arrangements;
- the payment or receipt of milestones and receipt of other collaboration-based revenues, if any;
- the costs and timing of future commercialization activities, if any, including product manufacturing, sales, marketing and distribution, for any of our product candidates for which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property related claims;
- the extent to which we acquire or in-license other products, product candidates, technologies or data referencing rights;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- our ability to access the private and public capital markets or to obtain financing at commercially reasonable rate;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the costs of operating as a public company; and
- the impacts of ongoing or future pandemics, or other widespread adverse health events.

Based on our currently forecasted operating plan, we believe that our existing cash, cash equivalents, and marketable securities as of December 31, 2025 will enable us to fund our operating expenses and capital expenditure requirements into 2029. Therefore, based on our recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future and the need to raise additional capital to finance future operations, as of March 6, 2026, the issuance date of the consolidated financial statements for the year ended December 31, 2025 included elsewhere in this Annual Report on Form 10-K, management considered whether or not there are conditions or events, in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern, and concluded that there are none as it estimates that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these consolidated financial statements.

Critical Accounting Policies and Use of Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of our consolidated financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development Costs

We incur substantial expenses associated with manufacturing and clinical trials. Accounting for clinical trials relating to activities performed by CROs and other external vendors requires management to exercise significant estimates in regard to the timing and accounting for these expenses. We estimate costs of research and development activities conducted by service providers, which include the conduct of sponsored research, preclinical studies and contract manufacturing activities. The diverse nature of services being provided under CRO and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain clinical activities complicates the estimation of accruals for services rendered by CROs and other vendors in connection with clinical trials. Because payments of research and development activities do not always line up with the provision of such services, the balance sheet may reflect either an accrued or prepaid position. In estimating the duration of a clinical trial, we evaluate the start-up, treatment and wrap up periods, compensation arrangements and services rendered attributable to each clinical trial and fluctuations are regularly tested against payment plans and trial completion assumptions.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. We make significant judgments and estimates in determining the accrued liabilities and prepaid expense balances in each reporting period. As actual costs become known, we adjust our accrued liabilities or prepaid expenses. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that are used to conduct and manage clinical trials on our behalf. We accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

Stock-Based Compensation

We measure stock-based awards granted to employees, non-employees and directors based on their fair value on the date of the grant using the Black-Scholes option-pricing model for options or the difference between the purchase price per share of the award, if any, and the fair value of our common stock on the date of grant for restricted stock awards. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the award for employees and directors and the period during which services are performed for non-employees. We use the straight-line method to record the expense of awards with service-based vesting conditions.

The Black-Scholes option-pricing model uses as inputs: the fair value of our common stock, the assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options, and our expected dividend yield.

Off-balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our consolidated financial statements appearing in this Annual Report on Form 10-K.

Emerging Growth Company Status

As an emerging growth company ("EGC") under the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include presentation of only two years of audited consolidated financial statements, an exemption from the requirement to provide an auditor’s report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board, and less extensive disclosure about our executive compensation arrangements.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an EGC to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we: (i) are no longer an emerging growth company, or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We may qualify as an EGC until December 31, 2026, which is the end of the fiscal year following the fifth anniversary of our IPO, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30 of any year before that time, or if we have annual gross revenues of $1.235 billion or more in any fiscal year, we will cease to be an EGC as of December 31 of the applicable year. We also will cease to be an EGC if we issue more than $1.0 billion of non-convertible debt over a three-year period.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

As a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, we are not required to provide this information.

Item 8. Financial Statements and Supplementary Data

Immuneering Corporation
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Immuneering Corporation

Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of Immuneering Corporation and its subsidiaries (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion
These 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 U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ RSM US LLP

We have served as the Company's auditor since 2020.

Boston, Massachusetts
March 6, 2026

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

IMMUNEERING CORPORATION

CONSOLIDATED BALANCE SHEETS

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 128,645,025	$ 36,144,720
Marketable securities, current	44,186,244	—
Prepaids and other current assets	3,414,685	3,442,849
Total current assets	176,245,954	39,587,569
Marketable securities, non-current	44,183,186	—
Property and equipment, net	938,481	1,122,865
Goodwill	6,690,431	6,690,431
Intangible asset, net	321,147	350,413
Right-of-use assets, net	3,322,249	3,667,352
Other assets	283,562	1,295,783
Total assets	**$ 231,985,010**	**$ 52,714,413**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,542,737	$ 1,958,536
Accrued expenses	7,842,367	4,973,129
Other liabilities	291,513	233,665
Lease liabilities	397,104	338,438
Total current liabilities	10,073,721	7,503,768
Long-term liabilities:		
Lease liabilities, net of current portion	3,427,321	3,824,419
Total liabilities	13,501,042	11,328,187
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2025 and December 31, 2024; 0 shares issued or outstanding at December 31, 2025 and December 31, 2024	—	—
Class A common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2025 and December 31, 2024; 64,648,230 and 31,050,448 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	64,648	31,050
Class B common stock, $0.001 par value, 20,000,000 shares authorized at December 31, 2025 and December 31, 2024; 0 shares issued and outstanding at December 31, 2025 and December 31, 2024	—	—
Additional paid-in capital	498,658,072	265,650,362
Accumulated other comprehensive income	81,332	—
Accumulated deficit	(280,320,084)	(224,295,186)
Total stockholders' equity	218,483,968	41,386,226
Total liabilities and stockholders' equity	**$ 231,985,010**	**$ 52,714,413**

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

IMMUNEERING CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
FOR THE YEARS ENDED DECEMBER 31, 2025 AND 2024

	Year Ended December 31,	
	2025	**2024**
Operating expenses		
Research and development	$ 42,048,461	$ 47,964,388
General and administrative	17,298,241	16,077,746
Amortization of intangible asset	29,267	29,267
Total operating expenses	59,375,969	64,071,401
Loss from operations	(59,375,969)	(64,071,401)
Other income (expense)		
Interest income	3,039,406	2,593,300
Other income, net	311,665	441,493
Net loss	**$ (56,024,898)**	**$ (61,036,608)**
Net loss per share attributable to common stockholders, basic and diluted	(1.27)	(2.04)
Weighted-average common shares outstanding, basic and diluted	44,011,830	29,981,565
Other comprehensive income:		
Unrealized gain from marketable securities	81,332	778
Comprehensive Loss	**$ (55,943,566)**	**$ (61,035,830)**

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

IMMUNEERING CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEAR ENDED DECEMBER 31, 2025 AND 2024

	Class A Common Stock		Class B Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value	Shares	Par Value				
Balance at December 31, 2023	29,271,629	$ 29,272	—	$ —	$ 253,806,267	$ (778)	$ (163,258,578)	$ 90,576,183
Issuance of common stock upon exercise of stock options	229,299	229	—	—	732,229	—	—	732,458
Issuance of common stock under at-the-market offering, net of commissions, underwriting discounts and $0.1 million issuance costs	1,318,752	1,319	—	—	4,236,078	—	—	4,237,397
Issuance of common stock through employee stock purchase plan	230,768	230	—	—	374,422	—	—	374,652
Stock-based compensation expense	—	—	—	—	6,501,366	—	—	6,501,366
Net loss	—	—	—	—	—	—	(61,036,608)	(61,036,608)
Other comprehensive income	—	—	—	—	—	778	—	778
Balance at December 31, 2024	31,050,448	$ 31,050	—	$ —	$ 265,650,362	$ —	$ (224,295,186)	$ 41,386,226
Issuance of common stock upon exercise of stock options	136,060	136	—	—	368,396	—	—	368,532
Issuance of common stock under at-the-market offering, net of commissions, underwriting discounts and $0.2 million issuance costs	5,164,159	5,164	—	—	15,014,882	—	—	15,020,046
Issuance of common stock through employee stock purchase plan	300,143	300	—	—	421,610	—	—	421,910
Issuance of common stock, pre-funded warrants, and common stock warrants through private placement, net of $1.6 million in placement costs	5,251,349	5,251	—	—	23,388,923	—	—	23,394,174
Cashless exercise of prefunded warrants	1,077,598	1,078	—	—	(1,078)	—	—	—
Issuance of common stock through public offering, net of underwriting discounts and $0.4 million in offering costs	18,959,914	18,960	—	—	164,119,551	—	—	164,138,511
Issuance of common stock through private placement with Aventis Inc., net of $1.6 million in placement agent discounts and placement costs	2,708,559	2,709	—	—	23,384,291	—	—	23,387,000
Stock-based compensation expense	—	—	—	—	6,311,135	—	—	6,311,135
Net loss	—	—	—	—	—	—	(56,024,898)	(56,024,898)
Other comprehensive income	—	—	—	—	—	81,332	—	81,332
Balance at December 31, 2025	64,648,230	$ 64,648	—	$ —	$ 498,658,072	$ 81,332	$ (280,320,084)	$ 218,483,968

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

IMMUNEERING CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEAR ENDED DECEMBER 31, 2025 and 2024

	2025	2024
Cash flows from operating activities:		
Net loss	$ (56,024,898)	$ (61,036,608)
Adjustment to reconcile to net loss to net cash used in operating activities:		
Depreciation and amortization expense	324,517	355,807
Reduction in carrying amount of right-of-use assets	345,103	328,377
Amortization of intangibles	29,267	29,267
Stock-based compensation expense	6,311,135	6,501,366
Net accretion of discount on marketable securities	(155,748)	(259,181)
Loss on disposal of fixed assets	2,093	6,784
Change in assets and liabilities:		
(Increase) decrease in:		
Prepaid expenses and other current assets	491,837	(24,865)
Other assets	1,114,245	(261,337)
Increase (decrease) in:		
Accounts payable	(400,799)	(112,143)
Accrued expenses	2,899,237	(200,831)
Lease liabilities	(338,432)	(300,102)
Other liabilities	57,848	(26,105)
Net cash used in operating activities	(45,344,595)	(54,999,571)
Cash flows from investing activities:		
Purchases of property and equipment	(142,226)	(84,875)
Purchases of marketable securities	(88,596,021)	(5,410,170)
Maturities of marketable securities	—	31,930,000
Net cash (used in) provided by investing activities	(88,738,247)	26,434,955
Cash flows from financing activities:		
Payment of offering costs	(3,726,266)	(40,988)
Proceeds from exercise of stock options	368,532	732,458
Proceeds from issuance of common stock under ATM, net of offering expenses	15,020,046	4,237,397
Proceeds from employee stock purchase plan	421,910	374,652
Issuance of common stock through public offering, net of commissions and underwriting discounts	164,500,006	—
Issuance of common stock through private placement with Aventis Inc.	25,000,000	—
Proceeds from sale of common stock, prefunded warrants and common stock warrants	24,998,919	—
Net cash provided by financing activities	226,583,147	5,303,519
Net increase (decrease) in cash and cash equivalents	92,500,305	(23,261,097)
Cash and cash equivalents at beginning of period	36,144,720	59,405,817
Cash and cash equivalents at end of period	$ 128,645,025	$ 36,144,720
Supplemental disclosures of noncash investing and financing information:		
Deferred offering costs in accounts payable/accrued expenses	$ 45,000	$ —
Cashless exercise of prefunded warrants	$ 1,078	$ —

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

IMMUNEERING CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – Organization and Nature of Business

Immuneering Corporation, a Delaware corporation (“Immuneering” or the “Company”), was incorporated in 2008. Immuneering is a late-stage clinical oncology company developing medicines for broad populations of cancer patients, with an initial aim to therapeutically address patients harboring RAS and/or RAF mutations. The Company aims to achieve broad activity through Deep Cyclic Inhibition® ("DCI") of the mitogen-activated protein kinase ("MAPK") pathway, impacting cancer cells while sparing healthy cells. Immuneering’s lead product candidate, atebimetinib (IMM-1-104), is currently in a Phase 1/2a clinical trial in patients with advanced solid tumors harboring RAS/RAF mutations. The Company is developing atebimetinib as a once-daily oral therapy, aiming for activity through DCI of the MAPK pathway at the level of mitogen-activated protein kinase kinase ("MEK"). The Company’s development pipeline also includes several early-stage programs.

On October 30, 2019, Immuneering formed a wholly owned subsidiary, Immuneering Securities Corporation (“ISC”), a Massachusetts securities corporation, for the sole purpose of buying, selling and holding securities on the Company’s behalf.

On December 22, 2021, the Company acquired all outstanding shares of capital stock of BioArkive, Inc. (“BioArkive”), a California corporation, which as a result became a wholly owned subsidiary.

Immuneering, ISC and BioArkive are collectively referred to as the “Company” throughout these consolidated financial statements.

The Company is subject to a number of inherent risks associated with any biotechnology company that has substantial expenditures for research and development. These risks include, but are not limited to, the need to obtain adequate additional funding, possible failure of clinical trials or other events demonstrating lack of clinical safety or efficacy of its product candidates, dependence on key personnel, reliance on third-party service providers for manufacturing drug product and conducting clinical trials, the ability to successfully secure its proprietary technology, and risks related to the regulatory approval and commercialization of a product candidate. There can be no assurance that the Company’s research and development programs will be successful. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees, advisors, and consultants.

On August 10, 2022, the Company entered into an Equity Distribution Agreement (the "2022 Sales Agreement") with Piper Sandler & Co (the "Sales Agent"), to sell shares of its common stock with aggregate gross proceeds of up to $50 million, from time to time, through an “at the market” equity offering program (the "2022 ATM Program"). The Company sold 5,164,159 shares of common stock under the 2022 ATM Program, at a weighted average price per share of $3.03, for aggregate gross proceeds of $15.6 million ($15.0 million net of offering expenses) during the year ended December, 2025. The Company sold 1,318,752 shares of common stock under the 2022 ATM Program, at a weighted average price per share of $3.38, for aggregate gross proceeds of $4.5 million ($4.2 million net of offering expenses) during the year ended December 31, 2024. The Company did not sell any shares of common stock under the 2022 ATM Program during the three months ended December 31, 2025 or December 31, 2024, respectively.

On April 20, 2023, the Company completed an underwritten follow-on equity offering, pursuant to which it issued and sold 2,727,273 shares of its Class A common stock $0.001 par value per share at an offering price of $11.00 per share. The aggregate net proceeds received by the Company from the offering were $28,200,003, after deducting underwriting discounts and commissions, but before deducting offering costs payable by the Company of $203,768.

On August 13, 2025, the Company entered into an Equity Distribution Agreement (the "2025 Sales Agreement") with the Sales Agent, to sell shares of its common stock with aggregate gross proceeds of up to $100 million, from time to time, through an “at the market” equity offering program (the "2025 ATM Program"). In connection with the September 2025 Offering (as defined below), the Company: (i) reduced the maximum aggregate offering price for sales of shares of common stock pursuant to at-the-market transactions under the 2025 ATM Program by $1,250,007 (the "Reduced Amount"), resulting in a new maximum aggregate offering price of up to $98,749,993 under the 2025 ATM Program, and (ii) suspended the 2025 ATM Program and terminated the continuous offering under the 2025 ATM Program, in each case, as to the Reduced Amount. The Company did not sell any shares of common stock under the 2025 ATM Program during the three months or year ended December 31, 2025 or December 31, 2024, respectively.

On August 21, 2025, the Company entered into a Securities Purchase Agreement (the "August 2025 Purchase Agreement") with the purchasers party thereto, pursuant to which the Company agreed to sell securities to such purchasers in a private placement (the “August 2025 Private Placement”). The August 2025 Purchase Agreement provided for the sale and issuance by the Company to the purchasers of: (i) an aggregate of 5,251,349 shares of its common stock at a purchase price of $3.95 per share, (ii) for certain purchasers, in lieu of common stock, an aggregate of 1,077,764 pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to the same number of shares of its common stock, and (iii) an aggregate of 2,848,096 warrants (the “Purchase Warrants”) to purchase up to the same number of shares of its common stock. The Pre-Funded Warrants were issued for a purchase price equating to $3.949 per Pre-Funded Warrant (which was the per share purchase price for the common stock issued in the August 2025 Private Placement, less the $0.001 per share unfunded exercise price for each Pre-Funded Warrant). On October 6, 2025, certain purchasers from the August 2025 Private Placement exercised an aggregate of 1,077,764 Pre-Funded Warrants previously issued to them pursuant to the August 2025 Purchase Agreement. Each such exercise was made pursuant to the cashless exercise provision of the applicable Pre-Funded Warrant, such that an aggregate of 166 shares of common stock were withheld in lieu of cash payment of the $0.001 exercise price for each Pre-Funded Warrant share, and the exercising purchasers were issued an aggregate of 1,077,598 shares of common stock (the "October 2025 Cashless Exercise"). Following the October 2025 Cashless Exercise, no Pre-Funded Warrants remained issued and outstanding. The Purchase Warrants were issued with an exercise price of $5.50 per share; as of December 31, 2025, no Purchase Warrants had been exercised. As of December 31, 2025, the Company had received aggregate net proceeds of $23.4 million from the August 2025 Private Placement, after deducting placement expenses of $1.6 million. The August 2025 Private Placement closed on August 26, 2025.

On September 24, 2025, the Company entered into a Securities Purchase Agreement (the "September 2025 Purchase Agreement") with Aventis Inc. ("Aventis"), a wholly owned subsidiary of Sanofi, a French société anonyme ("Sanofi"), pursuant to which the Company agreed to sell securities to Aventis in a private placement (the “September 2025 Private Placement”). The September 2025 Purchase Agreement provided for the sale and issuance by the Company to Aventis of an aggregate of 2,708,559 shares of its common stock at a purchase price of $9.23 per share. The Company received aggregate net proceeds of $23.4 million from the September 2025 Private Placement, after deducting placement agent discounts and commissions of $1.5 million and placement costs of $0.1 million. The September 2025 Private Placement closed on September 26, 2025.

On September 26, 2025, the Company completed an underwritten follow-on equity offering, pursuant to which it issued and sold 18,959,914 shares of its Class A common stock at an offering price of $9.23 per share (the "September 2025 Offering"), with Leerink Partners LLC and Oppenheimer & Co. Inc. acting as underwriters. The aggregate net proceeds received by the Company from the September 2025 Offering were $164.1 million, after deducting underwriting discounts and commissions, as well as offering costs of $0.4 million.

To date, the Company has primarily funded its operations with proceeds from the sale of its capital stock, warrants to purchase stock, and convertible notes. The Company has incurred recurring losses over the past several years and as of December 31, 2025, the Company had an accumulated deficit of $280.3 million. The Company expects to continue to generate operating losses for the foreseeable future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company’s inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurances that additional funding will be available on terms acceptable to the Company, or at all. If the Company is unable to raise additional funds when needed, it may be required to delay, reduce the scope of, or eliminate development programs, which may adversely affect its business and operations. Management considered whether or not there are conditions or events, in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern, and concluded that there are none as it estimates that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these consolidated financial statements.

Note 2 - Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting standards set by the Financial Accounting Standards Board ("FASB"). The FASB sets generally accepted accounting principles ("GAAP") to ensure the consolidated financial statements are consistently reported. References to GAAP issued by the FASB in these footnotes are to the FASB Accounting Standards Codification ("ASC"). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses during the reporting periods. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities and the recording of expenses that are not readily apparent from other sources. Significant estimates reflected in these consolidated financial statements include but are not limited to: the accrued research and development expenses, the determination of fair value of stock-based awards, and the impairment of goodwill and intangible assets. Actual results may differ materially and adversely from these estimates.

Cash and Cash Equivalents

Cash and cash equivalents are comprised of deposits at major financial banking institutions and highly liquid investments with an original maturity of three months or less at the date of purchase.

Marketable Securities

Our marketable securities are classified as available-for-sale pursuant to ASC 320, Investments – Debt and Equity Securities and are recorded at fair value. Unrealized gains/(losses) are included as a component of accumulated other comprehensive loss in the consolidated balance sheets and statements of stockholders' equity and a component of total comprehensive loss in the consolidated statements of comprehensive loss, until realized.

We review marketable securities for impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable. Unrealized losses are evaluated for impairment under ASC 326, Financial Instruments - Credit Losses, to determine if the impairment is credit-related or noncredit-related. Credit-related impairment is recognized as an allowance on the balance sheet with a corresponding adjustment to earnings, and noncredit-related impairment is recognized in other comprehensive (loss) income, net of taxes. Evidence considered in this assessment includes reasons for the impairment, compliance with our investment policy, the severity of the impairment, collectability of the security, and any adverse conditions specifically related to the security, an industry, or geographic area.

There were no impairments of the Company's available-for-sale marketable securities measured and carried at fair value during the year ended December 31, 2025. Realized gains and losses are included in other income, net on a specific-identification basis. There were no realized gains or losses on marketable securities for the years ended December 31, 2025 and 2024, respectively.

Fair Value Measurements

We record cash equivalents and marketable securities at fair value. ASC 820, Fair Value Measurements and Disclosures, establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and our own assumptions (unobservable inputs). The hierarchy consists of three levels:

Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 – Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, directly or indirectly, for substantially the full term of the asset or liability.

Level 3 – Unobservable inputs that reflect our own assumptions about the assumptions market participants would use in pricing the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

Our financial assets, which include cash equivalents and marketable securities, have been initially valued at the transaction price, and subsequently revalued at the end of each reporting period, utilizing third-party pricing services or other observable market data. The pricing services utilize industry standard valuation models, including both income and market based approaches, and observable market inputs to determine value. After completing our validation procedures, we did not adjust or override any fair value measurements provided by the pricing services as of December 31, 2025. Fair value information for these assets, including their classification in the fair value hierarchy is included in Note 4 Fair Value Measurements**.**

There have been no changes to the valuation methods during the year ended December 31, 2025. We evaluate transfers between levels at the end of each reporting period.

The carrying amounts reflected in the consolidated balance sheets for cash, accounts receivable, accounts payable and accrued expenses approximate their respective fair values because of the short-term maturity of those financial instruments.

Concentration of Credit Risk

Financial instruments which potentially subject us to credit risk consist primarily of cash, cash equivalents, and marketable securities. We hold these investments in highly rated financial institutions, and, by policy, limit the amount of credit exposure at any one financial institution. These investments at times exceed federally insured limits. We have not experienced any credit losses in such accounts and do not believe we are exposed to any significant credit risk on the funds. We have no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts, or other hedging arrangements.

Property and Equipment

Property and equipment are recorded at cost, net of accumulated depreciation and amortization. Expenditures for major replacements and improvements are capitalized, while expenditures for general repairs and maintenance are expensed as incurred. Upon retirements or disposition of property and equipment, the related cost and accumulated depreciation and amortization are removed from the consolidated balance sheet and any resulting gain or loss is recorded in the consolidated statement of operations. Depreciation and amortization are calculated using the straight-line method once assets are placed in service.

Asset Class	Estimated Useful Lives
Computer equipment	3 years
Furniture and fixtures	5 years
Lab equipment	7 years
Leasehold improvements	1-10 years

Impairment of Long-lived Assets

Periodically, the Company evaluates its long-lived assets, which consist primarily of property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. To date, no impairments have occurred.

Leases

The Company provides for leases in accordance with ASC Topic 842, Leases. The Company determines if an arrangement is a lease at contract inception. Right-of-use assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at the commencement date of the lease based upon the present value of future lease payments over the expected lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. As most of the Company’s leases do not provide an implicit interest rate, the Company uses its incremental borrowing rate, which is based on rates that would be incurred to borrow on a collateralized basis over a term equal to the lease payments in a similar economic environment, in determining the present value of lease payments.

The Company has elected not to separate lease and non-lease components as a single lease component. The Company's leases are reflected in right-of-use assets and lease liabilities (current and non-current) in the consolidated balance sheets.

Income Taxes

The Company provides for income taxes in accordance with ASC Topic 740, Income Taxes. The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The Company measures deferred tax assets and liabilities using the enacted tax rates for the years and jurisdictions in which the temporary differences are expected to be recovered. A change to the tax rates used to measure the Company's deferred taxes is recognized in income during the period in which the new rate(s) were enacted.

The Company recognizes deferred tax assets to the extent the Company's assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including the future reversals of existing taxable temporary differences, projected future taxable income exclusive of reversing temporary differences and carryforwards, tax-planning strategies, taxable income in prior carryback years if permitted under tax law, and the results from prior years. If the Company determines it is more likely than not, that all or a portion of a deferred tax asset will not be realized a valuation allowance is recorded with a charge to income tax expense. Alternatively, if the Company determines that all or a portion of a deferred tax asset previously not meeting the more likely than not threshold will be realized, the Company reduces its valuation allowance and recognizes a benefit in income tax expense.

The Company recognizes and measure uncertain tax benefits in accordance with ASC 740 based on a two-step process in which (1) the Company determines whether it is more likely than not that the tax position will be sustained based on the technical merits of the position, and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than fifty percent likely to be realized upon ultimate settlement with the related tax authority. The Company's policy is to recognize interest and penalties related to uncertain tax positions, if any, in income tax expense.

As of December 31, 2025 and 2024, the Company had uncertain tax positions of $1,493,736 and $1,136,528, respectively. The Company has classified the unrecognized tax benefits as reductions of its tax credit carryforwards.

Research and Development

Research and development costs are expensed as incurred. Research and development costs consist of expenses incurred in performing research and development activities, including salaries and benefits, materials and supplies, preclinical expenses, stock-based compensation expense, depreciation of equipment, contract services, and other outside expenses. The Company also incurs costs to develop software programs for internal use in identifying potential human drug targets which may then lead to the development of human drug candidates. To date the software programs have primarily been used for internal research and development activities and the costs incurred have been expensed as research and development.

Research and Manufacturing Contract Costs and Accruals

The Company has entered into various research, development and manufacturing contracts with research institutions and other companies inside and outside of the United States. These agreements are generally cancellable, and related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research, development and manufacturing costs. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding obligations to those third parties as of period end. Any accrual estimates are based on a number of factors, including the Company's knowledge of the progress towards completion of the research, development and manufacturing activities, invoicing to date under the contracts, communication from the research institutions and other companies of any actual costs incurred during the period that have not yet been invoiced and the costs included in the contracts. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company. The historical accrual estimates made by the Company have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Comprehensive Income (Loss)

Comprehensive income (loss) includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders.

Deferred Offering Costs

The Company capitalizes certain legal, professional, and other third-party charges related to ongoing equity financings as deferred offering costs until fully consummated. These costs are to be recorded as a reduction of the offering's proceeds which are recorded to additional paid-in capital within stockholders' equity. Should the Company choose not to initiate such financing, the deferred offering costs would be immediately expensed as operating expenses.

Common Stock Warrants

The Company accounts for warrants issued as a separable unit in connection with sale of common stock as either liability or equity in accordance with ASC 480-10, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity ("ASC 480-10") or ASC 815-40, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock ("ASC 815-40"). Under ASC 480-10, warrants are considered liabilities if they are mandatorily redeemable and they require settlement in cash or other assets, or a variable number of shares. If warrants do not meet liability classification under ASC 480-10, the Company considers the requirements of ASC 815-40 to determine whether the warrants should be classified as liability or equity. If warrants do not require liability classification under ASC 815-40 or other applicable generally accepted accounting principles in the United States of America, the warrants should be classified as equity.

Net Income (Loss) per Share

The Company only has one class of shares outstanding and basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted average number of shares of common stock and pre-funded warrants outstanding for the period. Diluted net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of shares of common stock and pre-funded warrants outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock awards. The pre-funded warrants are included as outstanding shares in the computation as the exercise price is negligible and the pre-funded warrants are fully vested and exercisable. For periods in which the Company reports a net loss, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for each of the years ended December 31, 2025 and 2024.

Stock-based Compensation

The Company issues stock-based awards to employees and nonemployees in the form of stock options. The Company accounts for stock-based awards in accordance with ASC 718, Compensation — Stock Compensation ("ASC 718"), which requires all stock-based payments to employees and non-employees, including grants of employee stock options and modifications to existing stock options, to be recognized in the consolidated statement of operations based on their fair values.

The fair value of options is estimated on the grant date using the Black-Scholes option-pricing model ("Black-Scholes"). Black-Scholes requires the Company to make assumptions and judgments about the variables used in the calculation including the expected term of its stock option, the volatility of the Company's common stock, and an assumed risk-free interest rate. The Company uses the simplified calculation of expected life and volatility, which is based on an average of the historical volatility of a group of publicly traded companies in a similar industry that the Company believes would be considered a peer group had it been a publicly held company for the duration of the expected life of the award. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. Forfeitures are recognized as they occur. No dividend yield was assumed as the Company does not pay, and does not expect to pay, dividends on its common stock. The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management's judgment.

The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if the Company had used different assumptions or estimates, the fair value of its common stock and its stock-based compensation expense could be materially different.

Goodwill

Goodwill represents the excess of the fair value of the acquiree over the recognized bases of the net identifiable assets acquired and includes the future economic benefits from other assets that could not be individually identified and separately recognized. Goodwill is not amortized, but instead is periodically reviewed for impairment and an impairment charge is recorded in the periods in which the recorded carrying value of goodwill exceeds its fair value.

On a quarterly basis, the Company performs a review of its business to determine if events or changes in circumstances have occurred which could have a material adverse effect on the fair value of the Company and its goodwill. If such events or changes in circumstances were deemed to have occurred, the Company would perform an impairment test of goodwill as of the end of the quarter and record any noted impairment loss.

The goodwill test is performed at least annually, or more frequently if events or changes in circumstances indicate that the asset might be impaired.

The Company performs its annual impairment test during the fourth quarter of each fiscal year. There were no impairments during the years ended December 31, 2025 or 2024.

Intangible Assets

Intangible assets are recognized at fair value, as an asset apart from goodwill if the asset (i) arises from contractual or other legal rights, or (ii) is separable. Intangible assets, principally representing technology acquired, are capitalized and amortized on the straight-line method over their expected useful lives.

The Company reviews the recoverability of its long-lived assets (including amortizable intangible assets), other than goodwill, when events or changes in circumstances occur that indicate that the carrying value of the asset may not be recoverable.

Recently Issued But Not Yet Adopted Accounting Pronouncements and Legislation

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company is an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company elected to avail itself of this extended transition period and, as a result, the Company will not be required to adopt certain new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

In November 2024, the FASB issued Accounting Standards Update ("ASU") No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40) (“ASU 2024-03”). The guidance in ASU 2024-03 aims to improve disclosures around an entity's expenses. Upon adoption, companies will be required to disclose in the notes to the financial statements a disaggregation of certain expense categories included within the expense captions on the face of the income statement. The standard is effective for fiscal years beginning after December 15, 2026 and interim periods in fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating this standard's potential impact on its consolidated financial statements and related disclosures.

The One Big Beautiful Bill Act ("OBBBA") was enacted on July 4, 2025. The Company has evaluated whether OBBBA has a material impact on its 2025 financial statements. The only provision of OBBBA that impacts the Company’s income tax accounting under ASC740 is the new IRC. Sec. 174A, which permanently allows taxpayers to fully expense domestic research or experimental ("R&E") expenditures paid or incurred in taxable years beginning after Dec. 31, 2024. The requirement to capitalize foreign Sec. 174 expenses over 15 years has not changed. On August 28, 2025, the IRS released procedural guidance (Rev. Proc. 2025-28) for implementing Section 174A and related elections for domestic research or experimental. Transition rules provide taxpayers with options to account for any remaining unamortized domestic R&E expenditures paid or incurred in taxable years beginning after December 31, 2021, and before January 1, 2025. Taxpayers may continue to amortize such unamortized amounts over the remaining five-year period; alternatively, they may elect to deduct any remaining unamortized domestic R&E expenditures either entirely in the first tax year beginning after December 31, 2024, or ratably over two taxable years (e.g., 2025 or ratably in 2025 and 2026). The Company has decided it will elect to continue to amortize previously capitalized and unamortized domestic R&E expenditures over the remaining five-year period. As of December 31, 2024, the company had approximately $77.8 million of remaining unamortized domestic R&E expenditures, representing approximately $17.1 million of its gross deferred tax asset. As of December 31, 2025, the company had approximately $54.7 million of remaining unamortized domestic R&E expenditures, representing approximately $12.0 million of its gross deferred tax asset.

In December 2025, the FASB issued Update ASU 2025-11, "Interim Reporting (Topic 270): Narrow-Scope Improvements". This ASU clarifies and improves existing interim reporting guidance by consolidating disclosure requirements within Topic 270 and introducing a disclosure principle requiring entities to disclose events and changes occurring after the most recent annual reporting period that are expected to have a material effect on the entity's financial condition or results of operations. The ASU does not introduce significant changes to recognition or measurement guidance. The amendments in this Update are effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. We are currently evaluating the effect of adopting this pronouncement on our financial statements and disclosures.

Note 3 – Marketable Securities

Marketable securities consisted of the following as of December 31, 2025:

	December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Assets:				
Current:				
U.S. Treasuries	$ 6,495,181	$ 5,504	$ —	$ 6,500,685
Government securities	7,943,758	4,742	—	7,948,500
Debt securities	7,628,117	496	(59)	7,628,554
Commercial Paper	22,102,080	6,425	—	22,108,505
Total Current	44,169,136	17,167	(59)	44,186,244
Non-current:				
U.S. Treasuries	37,717,598	58,682	—	37,776,280
Government securities	3,998,584	—	(1,544)	3,997,040
Debt securities	2,406,640	3,226	—	2,409,866
Total Non-current	44,122,822	61,908	(1,544)	44,183,186
Total marketable securities	$ 88,291,958	$ 79,075	$ (1,603)	$ 88,369,430

There were no marketable securities as of December 31, 2024.

The Company's marketable securities are classified as available-for-sale pursuant to ASC 320, Investments – Debt and Equity Securities and are recorded at fair value. Unrealized gains (losses) are included as a component of accumulated other comprehensive loss in the consolidated balance sheets and statements of stockholders' equity and a component of total comprehensive loss in the consolidated statements of comprehensive loss, until realized. The Company assesses its available-for-sale marketable securities for impairment on a quarterly basis. There were no impairments of the Company's available-for-sale marketable securities measured and carried at fair value during the years ended December 31, 2025 and 2024. Realized gains and losses are included in other income (expense).

The Company's marketable securities portfolio contains investments in U.S. Treasury, other U.S. government-backed securities, and commercial paper. The Company reviews its portfolio based on the underlying risk profile of the securities and does not expect there to be a loss on these investments. The Company also regularly reviews the securities in an unrealized loss position and evaluates the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions.

During the years ended December 31, 2025 and 2024, the Company recognized no year-to-date credit loss related to its short-term investments, and had no allowance for credit loss recorded as of December 31, 2025 and 2024.

Note 4 – Fair Value Measurements

The following table summarizes our cash equivalents and marketable securities measured at fair value on a recurring basis as of December 31, 2025 and 2024, respectively:

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market	$ 105,330,208	$ —	$ —	$ 105,330,208
U.S. Treasuries	1,992,340	—	—	1,992,340
Government securities	—	9,222,990	—	9,222,990
Commercial paper	—	11,827,667	—	11,827,667
Total cash equivalents	107,322,548	21,050,657	—	128,373,205
Marketable securities:				
U.S. Treasuries	$ 44,276,965	$ —	$ —	$ 44,276,965
Government securities	—	11,945,540	—	11,945,540
Debt securities	—	10,038,420	—	10,038,420
Commercial paper	—	22,108,505	—	22,108,505
Total marketable securities	44,276,965	44,092,465	—	88,369,430
Total cash equivalents and marketable securities	$ 151,599,513	$ 65,143,122	$ —	$ 216,742,635

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market	$ 35,865,754	$ —	$ —	$ 35,865,754
Total cash equivalents	$ 35,865,754	$ —	$ —	$ 35,865,754

There were no transfers between Level 1 and Level 2 and the Company had no financial assets or liabilities that were classified as Level 3 at any point during the years ended December 31, 2025 and 2024.

Note 5 – Property and Equipment, net

Property and equipment, net consisted of the following:

	December 31, 2025	December 31, 2024
Computer equipment	$ 596,917	$ 570,778
Furniture and fixtures	98,628	98,628
Lab equipment	1,309,070	1,236,233
Leasehold improvements	298,941	298,941
Construction in progress	37,500	—
Total	2,341,056	2,204,580
Accumulated depreciation and amortization	(1,402,575)	(1,081,715)
Property and equipment, net	$ 938,481	$ 1,122,865

Depreciation and amortization expense totaled $324,517 and $355,807 for the years ended December 31, 2025 and 2024, respectively.

Note 6 – Accrued Expenses

Accrued expenses consisted of the following:

	December 31, 2025	December 31, 2024
Accrued professional services	$ 735,772	$ 193,646
Accrued employee expenses	4,245,563	3,583,649
Accrued research and development expenses	2,747,306	1,106,872
Accrued other expenses	113,726	88,962
Total	$ 7,842,367	$ 4,973,129

Note 7 - Common Stock

The Company had 200,000,000 authorized shares of Class A common stock, $0.001 par value per share, as of December 31, 2025 and December 31, 2024, of which 64,648,230 and 31,050,448 shares were issued and outstanding, respectively. The holders of Class A common stock are entitled one vote for each share of common stock. Dividends may be paid when, and if, declared by the Board of Directors, subject to the limitations, powers and preferences granted to the Preferred Stockholders and on a proportionate basis with holders of Class B common stock.

The Company had 20,000,000 authorized shares of Class B common stock, $0.001 par value per share, as of December 31, 2025 and December 31, 2024, of which no shares have been issued nor are outstanding. The holders of Class B common stock have no voting rights. Dividends may be paid when, and if, declared by the Board of Directors, subject to the limitations, powers and preferences granted to the preferred stockholders and on a proportionate basis with holders of Class A common stock.

2022 Shelf Registration Statement & 2022 ATM Program

On August 10, 2022, the Company filed a Registration Statement on Form S-3 (File No. 333-266738) (the "2022 Shelf Registration Statement") with the SEC in relation to the registration of common stock, preferred stock, debt securities, warrants and/or units or any combination thereof in the aggregate amount of up to $200 million for a period of up to three years from the date of its effectiveness on August 19, 2022.

On August 10, 2022, the Company also entered into the 2022 Sales Agreement with the Sales Agent to sell shares of the Company's Class A common stock, par value $0.001 per share, with aggregate gross sales proceeds of up to $50 million, from time to time, through the 2022 ATM Program under the 2022 Shelf Registration Statement. Subject to the terms and conditions of the 2022 Sales Agreement, the Sales Agent may sell the shares by methods deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act, including sales made through the Nasdaq Global Market, on any other existing trading market for the common stock, to or through a market maker, or, if expressly authorized by the Company, in privately negotiated transactions. The Company or Sales Agent could terminate the 2022 Sales Agreement upon notice to the other party and subject to other conditions. The Company paid the Sales Agent a commission equal to 3.0% of the gross proceeds of any Common Stock sold through the Sales Agent under the 2022 Sales Agreement and provided the Sales Agent with customary indemnification rights. The Company sold 5,164,159 shares of common stock under the 2022 ATM program, at a weighted average price per share of $3.03, for aggregate gross proceeds of $15.6 million ($15.0 million net of offering expenses) during the year ended December 31, 2025. The Company sold 1,318,752 shares of common stock under the 2022 ATM Program, at a weighted average price per share of $3.38, for aggregate gross proceeds of $4.5 million ($4.2 million net of offering expenses) during the year ended December 31, 2024. The Company did not sell any shares of common stock under the 2022 ATM Program during the three months ended December 31, 2025 or December 31, 2024, respectively.

Issuance costs incurred related to the 2022 Sales Agreement were recorded as deferred offering costs and classified as long-term assets on the balance sheet. The Company had approximately $0.5 million of deferred offering costs as of December 31, 2024 associated with the 2022 Sales Agreement. The deferred offering costs for the 2022 ATM Program were written off in August 2025, after the 2022 Shelf Registration Statement and the 2022 ATM Program expired, the 2022 Sales Agreement was terminated, and the Company entered into the 2025 Sales Agreement related to the 2025 ATM Program (in each case as defined herein).

2025 Shelf Registration Statement & 2025 ATM Program

On August 13, 2025, the Company filed a Registration Statement on Form S-3 (File No. 333-289589) (the "2025 Shelf Registration Statement") with the SEC in relation to the registration of common stock, preferred stock, debt securities, warrants and/or units or any combination thereof in the aggregate amount of up to $300 million for a period of up to three years from the date of its effectiveness on August 20, 2025.

On August 13, 2025, the Company also entered into the 2025 Sales Agreement with the Sales Agent to sell shares of the Company's Class A common stock, par value $0.001 per share, with aggregate gross sales proceeds of up to $100 million, from time to time, through the 2025 ATM Program under the 2025 Shelf Registration Statement. Subject to the terms and conditions of the 2025 Sales Agreement, the Sales Agent may sell the shares by methods deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act, including sales made through the Nasdaq Global Market, on any other existing trading market for the common stock, to or through a market maker, or, if expressly authorized by the Company, in privately negotiated transactions. The Company or Sales Agent may terminate the 2025 Sales Agreement upon notice to the other party and subject to other conditions. The Company will pay the Sales Agent a commission up to 3.0% of the gross proceeds of any Common Stock sold through the Sales Agent under the 2025 Sales Agreement and has provided the Sales Agent with customary indemnification rights. The Company did not sell any shares of common stock under the 2025 ATM Program during the three months or year ended December 31, 2025 or December 31, 2024, respectively. In connection with the September 2025 Offering, the Company: (i) reduced the maximum aggregate offering price for sales of shares of common stock pursuant to at-the-market transactions under the 2025 ATM Program by $1,250,007 (or the Reduced Amount, as defined above), resulting in a new maximum aggregate offering price of up to $98,749,993 under the 2025 ATM Program, and (ii) suspended the 2025 ATM Program and terminated the continuous offering under the 2025 ATM Program, in each case, as to the Reduced Amount. As of December 31, 2025, the Company had aggregate gross sales proceeds capacity of $98.7 million remaining under the 2025 ATM Program.

Issuance costs incurred related to the 2025 Sales Agreement are recorded as deferred offering costs and are classified as long-term assets on the balance sheet at December 31, 2025. The Company had approximately $0.2 million of deferred offering costs as of December 31, 2025 associated with the 2025 Sales Agreement.

August 2025 Private Placement

On August 21, 2025, the Company entered into the August 2025 Purchase Agreement with the purchasers party thereto, pursuant to which the Company agreed to sell securities to such purchasers in the August 2025 Private Placement. The August 2025 Purchase Agreement provided for the sale and issuance by the Company to the purchasers of: (i) an aggregate of 5,251,349 shares of its common stock at a purchase price of $3.95 per share, (ii) for certain purchasers, in lieu of common stock, an aggregate of 1,077,764 Pre-Funded Warrants to purchase up to the same number of shares of its common stock, and (iii) an aggregate of 2,848,096 Purchase Warrants to purchase up to the same number of shares of its common stock. The Pre-Funded Warrants were issued for a purchase price equating to $3.949 per Pre-Funded Warrant (which was the per share purchase price for the common stock issued in the August 2025 Private Placement, less the $0.001 per share unfunded exercise price for each Pre-Funded Warrant).

On October 6, 2025, certain purchasers from the August 2025 Private Placement exercised an aggregate of 1,077,764 Pre-Funded Warrants previously issued to them pursuant to the August 2025 Purchase Agreement. Each such exercise was made pursuant to the cashless exercise provision of the applicable Pre-Funded Warrant, such that an aggregate of 166 shares of common stock were withheld in lieu of a cash payment of the $0.001 exercise price for each Pre-Funded Warrant, and the exercising purchasers were issued an aggregate of 1,077,598 shares of common stock. The Purchase Warrants were issued with an exercise price of $5.50 per share; as of December 31, 2025, no Purchase Warrants had been exercised. As of December 31, 2025, the Company had received aggregate net proceeds of $23.4 million from the August 2025 Private Placement, after deducting placement expenses of $1.6 million. The August 2025 Private Placement closed on August 26, 2025.

Also on August 21, 2025, in connection with the August 2025 Purchase Agreement, the Company entered into a Registration Rights Agreement (the "Registration Rights Agreement") with the purchasers in the August 2025 Private Placement. Pursuant to the Registration Rights Agreement, the Company agreed to prepare and file a registration statement with the SEC for purposes of registering the resale of the common stock and the shares of common stock issuable upon exercise of the Pre-Funded Warrants and Purchase Warrants (collectively, the "Warrant Shares") purchased by the purchasers in the August 2025 Private Placement, and any shares of common stock issued as a dividend or other distribution with respect to, in exchange for or in replacement of such common stock or Warrant Shares. On September 3, 2025, the Company filed a Registration Statement on Form S-3 (File No. 333-289997) (the "2025 Resale Registration Statement") with the SEC in relation to the registration for re-sale of the common stock and Warrant Shares from the August 2025 Private Placement. The SEC declared the 2025 Resale Registration Statement effective on September 8, 2025.

The Purchase Warrants have an exercise price of $5.50 per share of common stock, are exercisable immediately following their issuance, and will expire on September 8, 2030. The Purchase Warrants contain standard adjustments to the exercise price including for stock splits, stock dividends or distributions, certain other dividends or distributions and certain reorganizations. The Purchase Warrants also include certain rights upon the occurrence of a "fundamental transaction" (as described in the Purchase Warrants).

The foregoing and other related summaries contained herein do not purport to be complete and are qualified in their entirety by reference to the August 2025 Purchase Agreement, the Registration Rights Agreement, the Pre-Funded Warrants and the Purchase Warrants, which are filed as Exhibits 10.18, 10.19, 4.4 and 4.5, respectively, to this Annual Report on Form 10-K.

The proceeds received from the sale of equity classified warrants and shares of common stock in a bundled transaction are allocated based on the relative fair values of warrants and shares of common stock with no changes in fair value of warrants recognized after the issuance date.

The Purchase Warrants and Pre-Funded Warrants were classified as a component of stockholders' equity within additional paid-in-capital and were recorded at the issuance date using a relative fair value allocation method. The Purchase Warrants and Pre-Funded Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, such Purchase Warrants do not provide any guarantee of value or return. The Company valued the Purchase Warrants at issuance using the Black-Scholes valuation model and allocated proceeds from the sale proportionately to the common stock and Purchase Warrants, of which approximately $3.7 million was allocated to the Purchase Warrants and recorded as a component of additional paid-in-capital.

As of December 31, 2025, the Company had 2,848,096 Purchase Warrants issued and outstanding at an exercise price of $5.50 per share to purchase shares of the Company's common stock.

September 2025 Aventis (Sanofi) Private Placement

On September 24, 2025, the Company entered into the September 2025 Purchase Agreement with Aventis, a wholly owned subsidiary of Sanofi, pursuant to which the Company agreed to sell securities to Aventis in the September 2025 Private Placement. The September 2025 Purchase Agreement provided for the sale and issuance by the Company to Aventis of an aggregate of 2,708,559 shares of its common stock at a purchase price of $9.23 per share. The Company received aggregate net proceeds of $23.4 million from the September 2025 Private Placement, after deducting placement agent discounts and commissions of $1.5 million, and placement costs of $0.1 million. The September 2025 Private Placement closed on September 26, 2025.

September 2025 Offering

On September 26, 2025, the Company completed the September 2025 Offering, pursuant to which it issued and sold 18,959,914 shares of its Class A common stock at an offering price of $9.23 per share, with Leerink Partners LLC and Oppenheimer & Co. Inc. acting as underwriters. The aggregate net proceeds received by the Company from the September 2025 Offering were $164.1 million, after deducting underwriting discounts and commissions, as well as offering costs of $0.4 million.

Note 8 - Net Loss Per Share Attributable to Common Stockholders

Basic and diluted net loss per share attributable to common stockholders was calculated at December 31, 2025 and December 31, 2024 as follows:

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (56,024,898)	$ (61,036,608)
Denominator - basic and diluted:		
Weighted-average common shares outstanding, basic and diluted	44,011,830	29,981,565
Net loss per share - basic and diluted	$ (1.27)	$ (2.04)

The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to include them would be anti-dilutive (in common stock equivalent shares) at December 31, 2025 and December 31, 2024:

	2025	2024
Options to purchase common stock	8,250,958	6,382,149
Purchase warrants	2,848,096	—
Total shares of common stock equivalents	11,099,054	6,382,149

Note 9 - Stock-Based Compensation

During 2015, the Company established the Long Term Incentive Plan ("Incentive Plan"), under which incentive stock options, nonqualified stock options, restricted stock or other awards may be awarded to employees, directors or consultants of the Company. The options typically vest over a four-year period. As of December 31, 2025, the maximum number of shares available for issuance under the Incentive Plan was 2,825,173 shares. Upon the effectiveness of the Company's 2021 Incentive Award Plan (the "2021 Plan"), the Company ceased granting awards under the Incentive Plan. However, the Incentive Plan continues to govern awards outstanding thereunder.

On July 23, 2021, the Company's Board of Directors adopted, and on July 23, 2021 its stockholders approved, the 2021 Plan, which became effective on July 29, 2021. The 2021 Plan provides for the grant of incentive stock options, stock appreciation rights, restricted stock awards, restricted stock units, and other stock-based awards. The number of shares reserved for issuance under the 2021 Plan was initially equal to 2,590,000 plus an annual increase on the first day of each calendar year, beginning on January 1, 2022 and ending on and including January 1, 2031, equal to the lesser of (i) 4% of the aggregate number of shares of Class A common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of Class A common stock as determined by the Board of Directors. No more than 15,350,000 shares of Class A common stock may be issued under the 2021 Plan upon the exercise of incentive stock options. Shares issued under the 2021 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares. If an award under the 2021 Plan expires, lapses or is terminated, exchanged for or settled in cash, surrendered, repurchased, cancelled without having been fully exercised/settled or forfeited, any unused shares subject to the award will, as applicable, become or again be available for new grants under the 2021 Plan. In addition, shares subject to stock options issued under the Incentive Plan may become available for issuance under the 2021 Plan to the extent such stock options are canceled, forfeited, exchanged, settled in cash or otherwise terminated. As of December 31, 2025, there were 957,941 shares available for future issuance under the 2021 Plan.

On July 23, 2021, the Company's Board of Directors adopted, and on July 23, 2021 its stockholders approved, the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which became effective on July 29, 2021. A total of 250,000 shares of Class A common stock were initially reserved for issuance under this plan. The number of shares of Class A common stock that may be issued under the 2021 ESPP will automatically increase on the first day of each calendar year, beginning on January 1, 2022 and ending on and including January 1, 2031, equal to the lesser of (i) 1% of the shares of Class A common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of Class A common stock as determined by the Board of Directors, provided that not more than 3,340,000 shares of Class A common stock may be issued under the 2021 ESPP. As of December 31, 2025, there were 849,697 shares of common stock reserved for future issuance under the 2021 ESPP and 530,911 shares had been granted or purchased under the 2021 ESPP.

On May 21, 2024 (the "Effective Date"), based upon the recommendation of the Compensation Committee of the Company's Board of Directors, the Board of Directors approved an option repricing, in accordance with the 2021 Plan, which repricing was effected on the Effective Date. The repricing applied to options to purchase shares of the Company's Class A common stock with an exercise price per share greater than $3.01 that were held by then current employees and certain non-employee service providers under the 2021 Plan (the "Eligible Options"), including E.B. Brakewood, the Company's Chief Business Officer, and Michael Bookman, the Company's Chief Legal Officer.

Options held by Benjamin Zeskind, Ph.D., the Company's President and Chief Executive Officer, Brett Hall, Ph.D., the Company's Chief Scientific Officer and the non-employee members of the Board were not eligible for the repricing.

As a result of the option repricing, as of the Effective Date, the exercise price of all Eligible Options was reduced to $3.01 per share, which represented approximately two times the closing trading price of the Company's Class A common stock on the Nasdaq Global Market on the Effective Date; however, the exercise price for repriced options would revert to the original exercise price for any exercise occurring prior to June 30, 2025 (the "Retention Period"), unless there was a change of control of the Company or the option holder's employment has been terminated (i) by the Company without cause or (ii) by reason of death or disability. The repriced options otherwise remain subject to their existing terms and conditions as set forth in the 2021 Plan and applicable award agreements.

As of the Effective Date, outstanding options to purchase 2,986,354 shares were deemed Eligible Options and were repriced such that the exercise price per share for such outstanding options was reduced to $3.01 per share. There were no changes to the number of shares, the vesting schedule or the expiration date of the Eligible Options.

The effect of the option repricing resulted in a total incremental non-cash stock-based compensation expense of $0.6 million, which was calculated using the Black-Scholes option-pricing model, of which $0.2 million of the incremental non-cash stock-based compensation expense is associated with vested repriced options and will be recognized on a straight-line basis through the 13-month Retention Period. The remaining $0.4 million of the incremental non-cash stock-based compensation expense is associated with unvested repriced options and will be recognized as follows: (a) if the Retention Period is greater than the remaining original vesting period of the repriced option, the incremental cost will be amortized on a straight-line basis through the Retention Period end date or (b) if the Retention Period is less than the remaining original vesting term of the repriced option, the incremental cost will be amortized on a straight-line basis over the remaining original vesting period.

During the twelve months ended December 31, 2025 and December 31, 2024, the Company recognized incremental stock-based compensation expense $0.2 million and $0.2 million, respectively, associated with the option repricing which is included in general and administrative and research and development expense in the consolidated statement of operations and comprehensive loss.

During the years ended December 31, 2025 and December 31, 2024, the Company recognized stock-based compensation expense of $6.3 million and $6.5 million, respectively. As of December 31, 2025, compensation expense remaining to be recognized for outstanding stock options was $6.4 million and to be recognized over a weighted-average period of 2.31 years.

On March 20, 2025, the Company's Board of Directors adopted the Immuneering Corporation 2025 Employment Inducement Award Plan (the "Inducement Award Plan"), without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Stock Market LLC listing rules. The Inducement Award Plan provides for the grant of non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock units, and other stock-based awards. The number of shares reserved for issuance under the Inducement Award Plan was initially equal to 500,000 shares. Shares issued under the Inducement Award Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares. If an award under the Inducement Award Plan expires, lapses or is terminated, exchanged for or settled in cash, surrendered, repurchased, cancelled without having been fully exercised/settled or forfeited, any unused shares subject to the award will, as applicable, become or again be available for new grants under the Inducement Award Plan. As of December 31, 2025, there were 382,000 shares available for future issuance under the Inducement Award Plan.

The fair value of options granted is calculated on the grant date using the Black-Scholes option valuation model. Prior to the Company's IPO on August 3, 2021, the Company was a private company and thus lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own publicly traded stock price. For the year ended December 31, 2025, the Company granted 2,374,294 shares of stock options at a weighted-average grant date fair value of $2.01. For the year ended December 31, 2024, the Company granted 1,555,445 shares at a weighted-average grant date fair value of $3.67.

The Company used the following assumptions in its application of the Black-Scholes option pricing model for grants during the year ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Weighted-average risk-free interest rate	3.76% - 4.55%	3.93% - 4.82%
Expected term (in years)	5.51 - 10.00	5.00 - 10.00
Expected dividend yield	0%	0%
Expected volatility	65.86% - 69.48%	66.08% - 69.85%

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

	Number of Options	Weighted-Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2024	6,382,149	$ 4.40		
Granted	2,374,294	2.01		
Exercised	(136,060)	2.71		
Cancelled	(369,425)	2.90		
Outstanding as December 31, 2025	8,250,958	$ 3.83	7.05	$ 26,144,586
Vested and exercisable at December 31, 2025	5,326,522	$ 4.42	6.32	$ 14,889,780

For the years ended December 31, 2025 and 2024, the Company recognized share-based compensation expense on the accompanying consolidated statements of operations as follows:

	Year Ended December 31,	
	2025	2024
Research and development	$ 2,800,891	$ 2,754,981
General and administrative	3,510,244	3,746,385
Total	$ 6,311,135	$ 6,501,366

Note 10 – Income Taxes

The Company's effective tax rate for the periods ended December 31, 2025 and 2024 were 0% and 0%, respectively. For the each of the periods ended December 31, 2025 and December 31, 2024, the primary drivers of the variance from the statutory rate were state taxes, research and development tax credits, and valuation allowance.

The following table is a reconciliation of our effective income tax rate to the statutory federal income tax rate for the year ended December 31, 2025 in accordance with the guidance in ASU 2023-09:

	2025	
	Amount	Rate
Statutory federal income tax rate	$ (11,765,229)	21.0 %
State tax, net of federal benefit	(1,482,617)	2.6 %
Permanent differences	195,882	(0.3)%
Federal research and development credits	(2,281,572)	4.1 %
Uncertain tax positions	228,157	(0.4)%
Other differences	721,665	(1.3)%
Change in valuation allowance	14,383,714	(25.7)%
Effective income tax rate	$ —	— %

The following table is a reconciliation of our effective income tax rate to the statutory federal income tax rate for the year ended December 31, 2024 in accordance with the guidance prior to the adoption of ASU 2023-09:

	2024
Statutory federal income tax rate	21.0 %
State tax, net of federal benefit	1.9 %
Permanent differences	(0.9)%
Federal research and development credits	6.4 %
Uncertain tax positions	(0.6)%
Other differences	(2.0)%
Change in valuation allowance	(25.8)%
Effective income tax rate	— %

As of December 31, 2025 and 2024, the components and tax effects of each type of item that gave rise to the net deferred tax assets were as follows:

	2025	2024
Deferred tax assets:		
Stock-based compensation expense	$ 2,341,582	$ 855,125
Research expenses	17,055,222	22,286,355
Accrued Bonus	716,509	668,229
R&D credit carryforward	13,443,643	10,228,771
NOL carryforward	40,134,991	25,300,681
Gross deferred tax assets	73,691,947	59,339,161
Valuation allowance	(73,378,421)	(58,994,707)
Net deferred tax assets	313,526	344,454
Net deferred tax liabilities:		
Prepaid expenses deducted for tax	(118,097)	(139,736)
Right-of-use	(109,888)	(108,976)
Tax depreciation in excess of book	(67,745)	(95,742)
Unrealized Gain/Loss	(17,796)	—
Total deferred tax liabilities	(313,526)	(344,454)
Net deferred taxes	$ —	$ —

Federal net operating losses (“NOL”) generated in tax years ended after December 31, 2017 are limited to 80% of taxable income, only carried forward and carried forward indefinitely under the Internal Revenue Code of 1986, as amended (the “IRC”). There was no income tax expense or benefit in 2025. The Company has provided a valuation allowance for the full amount of the net deferred tax assets as, based on all available evidence, it is considered more likely than not that all the recorded deferred tax assets will not be realized in a future period. For the period ended December 31, 2025, the Company's federal, state post-apportioned, and foreign net operating loss carryforwards are approximately $174.8 million, $56.7 million, and $0, respectively. Of the federal amount, $174.8 million is expected to have an indefinite carryforward period. Of the state post-apportioned amount, $56.7 million is expected to have a limited carryforward period that will begin to expire in 2038 For the period ended December 31, 2025, the Company's federal, state, and foreign tax credit carryforwards are approximately $12.0 million, $3.7 million, and $0, respectively. All tax credits are expected to have a limited carryforward period that will begin to expire in 2038.

In accordance with Section 382 and Section 383 of the IRC, utilization of the NOL and tax credit carryforwards may be subject to limitations based on prior or future ownership changes. Additionally, after weighing all available positive and negative evidence for the period ended December 31, 2025, the Company has recorded a valuation allowance of approximately $73.4 million.

As the Company has not yet achieved profitable operations, management believes the tax benefits as of December 31, 2025 did not satisfy the realization criteria set forth in ASC Topic 740, Income Taxes and, therefore, has recorded a full valuation allowance for the entire deferred tax asset. The valuation allowance increased in 2025 by $14.4 million due to the increase in the deferred tax assets by approximately the same amount, primarily due to NOL and research and development expenses.

Utilization of the U.S. net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the IRC, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company is subject to income tax in multiple jurisdictions, including federal, state, and city jurisdictions. The Company has federal, state, and city income tax returns that are open to examination from 2023, 2024, and 2025 forward, respectively. In addition, the utilization of tax carryforwards from periods prior to those previously mentioned may also be audited by taxing authorities once utilized.

As a result, the Company continuously monitors its current and prior filing positions in order to determine if any unrecognized tax positions need to be recorded. The analysis involves considerable judgment and is based on the information available to the Company.

As of December 31, 2025 and December 31, 2024, the Company had uncertain tax positions of $1.5 million and $1.1 million, respectively. The Company has classified the unrecognized tax benefits as reductions of its tax carryforwards. The Company has elected to recognize interest and penalties related to income tax matters as a component of income tax expense, of which no interest or penalties were recorded for the years ended December 31, 2025 and 2024.

As of December 31, 2025 and December 31, 2024, unrecognized tax benefits were as follows:

	2025	2024
Beginning balance	$ 1,136,528	$ 699,527
Increase due to current year tax position	357,208	437,001
Ending balance	$ 1,493,736	$ 1,136,528

The Company has not accrued any interest expense or penalties related to the unrecognized tax benefits for the periods ended December 31, 2025 and 2024. The Company calculated interest and penalties to be immaterial since no NOLs or federal tax credits have been utilized.

The Company files tax returns in the United States including without limitation in: California, New York, Florida, New Jersey and Massachusetts. All tax years from 2018 to 2024 remain open to examination by the major taxing jurisdictions to which the Company is subject, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service ("IRS") or other authorities if they have or will be used in a future period. The Company is not to its knowledge currently under examination by the IRS or in any other jurisdictions for any tax years.

The Company made no income tax payments and received no income tax refunds during the year ended December 31, 2025. All payments made to taxing authorities were for non-income based tax liabilities and were outside the scope of ASC 740.

Note 11 – Commitments and Contingencies

Operating Leases

The Company leases 38,613 square feet of office and laboratory space in San Diego, California, under a lease that terminates on April 30, 2032. As of December 31, 2025, the right-of-use asset balance associated with this lease was $3,322,249.

The Company currently also leases office space in Cambridge, Massachusetts and New York, New York, pursuant to short-term arrangements. In September 2025, the Company executed a one year lease for its existing office space in Cambridge with a term that commenced on December 1, 2025 and ends on November 30, 2026. The New York lease was most recently renewed on October 1, 2025 to extend the lease term through September 30, 2026. These lease agreements include or included payments for lease and non-lease components. The Company has elected to not separate such components and these payments were recognized as rent expense.

As of December 31, 2025, total future minimum lease payments for its short-term leases in Cambridge, Massachusetts and New York, New York were $140,136 due in 2026.

Future minimum lease payments for operating leases with initial or remaining terms in excess of one year at December 31, 2025 were as follows:

	Amount
2026	$ 761,877
2027	784,737
2028	808,278
2029	832,527
2030	857,496
Thereafter	1,184,208
Total future lease payments	5,229,123
Less: Imputed interest	(1,404,698)
Total lease liabilities	$ 3,824,425
Current portion lease liabilities	397,104
Lease liabilities, noncurrent	3,427,321
Total lease liabilities	$ 3,824,425

Quantitative information regarding the Company's leases for the year ended December 31, 2025 and 2024 is as follows:

	December 31, 2025	December 31, 2024
Lease costs:		
Operating lease cost	$ 746,360	$ 760,822
Short-term lease cost	146,422	145,070
Sublease income	—	(19,200)
Total lease costs	$ 892,782	$ 886,692
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 739,689	$ 732,546
Operating cash flows from short-term leases	146,422	145,070
	$ 886,111	$ 877,616
Weighted-average remaining lease term - operating leases	6.33 years	7.33 years
Weighted-average discount rate - operating leases	10.0 %	10.0 %

As the Company's leases typically do not provide an implicit rate, the Company uses an estimate of its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments.

Litigation

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities and may be exposed to litigation in connection with its product candidates and operations. The Company's policy is to assess the likelihood of any adverse judgments or outcomes related to legal matters, as well as ranges of probable losses. When it is probable that future expenditures will be made and can be reasonably estimated, the Company will accrue a liability for such matters. Significant judgment is required to determine both probability and estimated amount. The Company is not aware of any material legal matters.

Clinical Research Contracts

The Company may enter into contracts in the normal course of business with contract research organizations for clinical trials, with contract manufacturing organizations for clinical supplies, and with other vendors for preclinical studies, supplies and other services for the Company's operating purposes. These contracts generally provide for termination with a 30-day notice.

Note 12 - Segments

An operating segment is identified as a component of an enterprise about which separate discrete financial information is available for evaluation by the Chief Operating Decision Maker ("CODM") in making decisions, including regarding resource allocation and assessing performance. The Company's Chief Executive Officer is its CODM.

The Company's CODM uses consolidated single-segment (one) financial information for purposes of: allocating resources, evaluating performance, making operating decisions, setting incentive targets, and planning and forecasting for future periods. The Company's CODM makes such decisions based on consolidated net loss. This measure is used to monitor budget versus actual results to evaluate the performance of the segment. Managing and allocating resources on a consolidated basis enables the CODM to assess the overall level of resources available and how to deploy these resources across functions and operations (including research and development) that align with the Company's strategic goals. All of the Company's long-lived assets are held in the United States.

The following table is representative of the significant expense categories regularly provided to the CODM when managing the Company's single reporting segment.

	Year Ended December 31,	
	2025	2024
Program expenses[1]		
Atebimetinib (IMM-1-104)	$ 17,639,073	$ 18,099,437
Envometinib (IMM-6-415)	2,203,828	6,521,249
Other programs	5,847,842	6,031,280
Non-program expenses[2]	6,133,986	5,397,079
Employee-related costs	20,913,494	21,165,183
Stock-based compensation expense	6,311,135	6,501,366
Depreciation/amortization	324,517	355,807
Other segment items[3]	(3,348,977)	(3,034,793)
Net loss	**$ 56,024,898**	**$ 61,036,608**

(1) Includes direct research and development expenses.
(2) Includes general and administrative expenses, in addition to facilities and other research and development expenses.
(3) Includes interest income and other (income) expense.

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

None.

Item 9A. Controls and Procedures

Limitations on effectiveness of controls and procedures

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer (who serves as our principal executive officer) and our SVP Finance, Chief Accounting Officer and Treasurer (who serves as our principal financial officer), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2025. Based on this evaluation, our Chief Executive Officer and Chief Accounting Officer and Treasurer concluded that, as of December 31, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2025, our internal control over financial reporting was effective. As an "emerging growth company" as defined in the JOBS Act and a non-accelerated filer, we are not required to comply with the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002.

Changes in Internal Control over Financial Reporting

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

Item 9B. Other Information

(a) None.

(b) Insider Trading Arrangements and Policies

Except as set forth in the table below, during the three months ended December 31, 2025, no director or "officer" (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" and / or "non-Rule 10b5-1 trading arrangement", as each term is defined in Item 408 of Regulation S-K.

Name / Title	Date Adopted	Character of Trading Arrangement[1]	Aggregate Number of Shares of Common Stock to be Sold Pursuant to Trading Arrangement	Duration	Other Material Terms	Date Terminated
Michael Bookman, Chief Legal Officer & Secretary	November 17, 2025	Rule 10b5-1 Trading Arrangement	(2)	(3)	Not applicable	Not applicable
Harold Brakewood, Chief Business Officer	November 17, 2025	Rule 10b5-1 Trading Arrangement	(2)	(3)	Not applicable	Not applicable
Brett Hall, Chief Scientific Officer	November 17, 2025	Rule 10b5-1 Trading Arrangement	(2)	(3)	Not applicable	Not applicable
Igor Matushansky, Chief Medical Officer	November 17, 2025	Rule 10b5-1 Trading Arrangement	(2)	(3)	Not applicable	Not applicable
Mallory Morales, SVP Finance, Chief Accounting Officer & Treasurer	November 17, 2025	Rule 10b5-1 Trading Arrangement	(2)	(3)	Not applicable	Not applicable
Leah Neufeld, Chief People Officer	November 17, 2025	Rule 10b5-1 Trading Arrangement	(2)	(3)	Not applicable	Not applicable
Benjamin Zeskind, President & Chief Executive Officer	November 17, 2025	Rule 10b5-1 Trading Arrangement	(2)	(3)	Not applicable	Not applicable

(1) Each trading arrangement marked as a "Rule 10b5-1 Trading Arrangement" is a sell-to-cover instruction letter that provides for sales of a number of shares of common stock as is necessary to cover tax withholding obligations incurred in connection with the vesting or settlement of restricted stock or restricted stock units and is intended to satisfy the affirmative defense of Rule 10b5-1(c), as amended (the "Rule").
(2) To the extent applicable, up to the minimum number of whole shares of vesting restricted stock (or common stock issuable upon vesting or settlement of restricted stock units) of the Company then held by the named individual, in connection with the vesting or settlement of restricted stock awards and/or restricted stock unit awards, if any, granted by the Company to the named individual, in each case that is sufficient to receive proceeds equal to the amount of the minimum statutory withholding obligations due from the named individual in connection with such vesting or settlement event. The total number of shares that may be sold is not determinable.
(3) The trading arrangement has an indefinite duration and may be modified, terminated or amended only by a writing signed by named individual and provided to the Company. Each trading arrangement marked as a "Rule 10b5-1 Trading Arrangement" only permits transactions upon expiration of the applicable mandatory cooling-off period(s) under the Rule.

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 10, including with respect to the Company's Insider Trading Compliance Policy and Procedures, will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item 11 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders 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 12, including information regarding securities authorized for issuance under equity compensation plans pursuant to Item 5(a), Part II of Form 10-K, will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) 1. Financial Statements

For a list of the financial statements included herein, see Index to Consolidated Financial Statements in this Annual Report on Form 10-K, incorporated into this Item by reference.

2. Financial Statement Schedules

Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

3. Exhibits

See the Exhibit Index in Item 15(b) below.

(b) EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
2.1	Share Purchase Agreement by and among Immuneering Corporation, BioArkive, Inc. and BioArkive's shareholders, dated as of December 22, 2021	8-K	001-40675	2.1	12/22/2021	
3.1	Amended and Restated Certificate of Incorporation of Immuneering Corporation	10-Q	001-40675	3.1	09/09/2021	
3.2	Amended and Restated Bylaws of Immuneering Corporation	8-K	001-40675	3.1	02/02/2024	
4.1	Form of Specimen Stock Certificate	S-1/A	333-257791	4.1	07/26/2021	
4.2	Amended and Restated Investors' Rights Agreement, dated December 21, 2020, by and among the Registrant and the other parties thereto.	S-1/A	333-257791	4.2	07/26/2021	
4.3	Description of Securities	10-K	001-40675	4.3	03/10/2022	
4.4	Form of Pre-Funded Warrant	8-K	001-40675	4.1	08/25/2025	
4.5	Form of Purchase Warrant	8-K	001-40675	4.2	08/25/2025	
10.1†	Employment Agreement, dated July 23, 2021, by and between Brett Hall, Ph.D. and Immuneering Corporation	S-1/A	333-257791	10.6	07/26/2021	
10.2†	Employment Agreement, dated July 23, 2021, by and between Benjamin J. Zeskind, Ph.D. and Immuneering Corporation	S-1/A	333-257791	10.8	07/26/2021	
10.3†	Employment Agreement, dated July 23, 2021, by and between Mallory Morales and Immuneering Corporation	10-K	001-40675	10.4	03/01/2024	
10.4†	Letter Agreement, by and between Immuneering Corporation and Mallory Morales, dated as of July 25, 2022	8-K	001-40675	10.1	07/25/2022	
10.5†	Letter Agreement, dated June 14, 2023, by and between Mallory Morales and Immuneering Corporation	10-K	001-40675	10.6	03/01/2024	
10.6†	Employment Agreement, dated March 24, 2023, by and between Harold E. Brakewood and Immuneering Corporation	10-K	001-40675	10.8	03/01/2024	
10.7†	Employment Agreement, Dated July 23, 2021, by and between Michael Bookman and Immuneering Corporation	S-1/A	333-257791	10.9	07/26/2021	
10.8†	Immuneering Corporation 2008 Stock Incentive Plan and form of option agreement thereunder.	S-1	333-257791	10.4	07/09/2021	
10.9†	Immuneering Corporation Long Term Incentive Plan and form of option agreement thereunder	S-1	333-257791	10.5	07/09/2021	
10.10†	Immuneering Corporation 2021 Incentive Award Plan and forms of award agreements thereunder	S-1/A	333-257791	10.10	07/26/2021	
10.11†	Immuneering Corporation 2021 Employee Stock Purchase Plan.	S-1/A	333-257791	10.11	07/26/2021	
10.12†	Immuneering Corporation 2025 Employment Inducement Award Plan and forms of award agreements thereunder	10-K	001-40675	10.14	03/20/2025	
10.13	Equity Distribution Agreement, dated as of August 10, 2022, by and between Immuneering Corporation and Piper Sandler & Co.	S-3	333-266738	1.2	8/10/2022	
10.14†	Form of Indemnification Agreement by and among the Registrant and its directors and officers.	S-1/A	333-257791	10.12	07/26/2021	
10.15†	Immuneering Corporation Non-Employee Director Compensation Program, as amended, effective January 1, 2026					*
10.16	Lease Agreement, by and between BioArkive, Inc. and Thornmint 13, LLC, dated as of July 22, 2021	8-K	001-40675	10.1	12/22/2021	
10.17	Equity Distribution Agreement, dated as of August 13, 2025, by and between Immuneering Corporation and Piper Sandler & Co.	S-3	333-289589	1.2	08/13/2025	
10.18#	Form of Securities Purchase Agreement, dated as of August 21, 2025, by and among Immuneering Corporation and the investors party thereto	8-K	001-40675	10.1	08/25/2025	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.19	Form of Registration Rights Agreement, dated as of August 21, 2025, by and among Immuneering Corporation and the investors party thereto	8-K	001-40675	10.2	08/25/2025	
10.20#	Securities Purchase Agreement, dated as of September 24, 2025, by and between Immuneering Corporation and Aventis Inc.	8-K	001-40675	10.1	09/24/2025	
19.1	Immuneering Corporation Insider Trading Compliance Policy and Procedures	10-K	001-40675	19.1	03/20/2025	
21.1	Subsidiaries of Immuneering Corporation	10-K	001-40675	21.1	03/10/2022	
23.1	Consent of RSM US LLP, Independent Registered Public Accounting Firm					*
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).					*
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).					*
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.					**
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.					**
97.1	Immuneering Corporation Policy for Recovery of Erroneously Awarded Compensation	10-K	001-40675	97.1	03/01/2024	
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

* Filed herewith.
** Furnished herewith.
† Indicates a management contract or compensatory plan or arrangement.
# The representations and warranties contained in this agreement were made only for purposes of the transactions contemplated by the agreement as of specific dates and may have been qualified by certain disclosures between the parties and a contractual standard of materiality different from those generally applicable under securities laws, among other limitations. The representations and warranties were made for purposes of allocating contractual risk between the parties to the agreement and should not be relied upon as a disclosure of factual information relating to the Company, the investor(s) and/or the transactions described herein or therein.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, duly authorized.

IMMUNEERING CORPORATION

Date: March 6, 2026

By: /s/ Benjamin J. Zeskind
Name: Benjamin J. Zeskind, Ph.D.
Title: Co-Founder, President, Chief Executive Officer and Director (Principal Executive Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Benjamin J. Zeskind, and Mallory Morales and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file 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, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Benjamin J. Zeskind **Benjamin J. Zeskind, Ph.D.**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 6, 2026
/s/ Mallory Morales **Mallory Morales**	SVP Finance, Chief Accounting Officer and Treasurer (Principal Financial and Accounting Officer)	March 6, 2026
/s/ Robert J. Carpenter **Robert J. Carpenter**	Director	March 6, 2026
/s/ Peter Feinberg **Peter Feinberg**	Director	March 6, 2026
/s/ Diana F. Hausman **Diana F. Hausman, M.D.**	Director	March 6, 2026
/s/ Laurie B. Keating **Laurie B. Keating**	Director	March 6, 2026
/s/ Thomas J. Schall **Thomas J. Schall, Ph.D.**	Director	March 6, 2026

Immuneering Corporation

Non-Employee Director Compensation Program

(AS AMENDED JANUARY 1, 2026)

Non-employee members of the board of directors (the "***Board***") of Immuneering Corporation (the "***Company***") shall receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this "***Program***"). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any subsidiary of the Company (each, a "***Non-Employee Director***") who is entitled to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. This Program shall become effective on the date first set forth above (the "***Effective Date***").

I. Cash Compensation

A. Annual Retainers. Each Non-Employee Director shall receive an annual retainer of $40,000 (the "***Base Retainer***") for service on the Board.

B. Additional Annual Retainers. In addition, each Non-Employee Director shall receive the following annual retainers:

1. *Chairman of the Board or Lead Independent Director*. A Non-Employee Director serving as Chair of the Board or Lead Independent Director shall receive an additional annual retainer of $30,000 for such service (the "***COB or LID Retainer***").

2. *Audit Committee*. A Non-Employee Director serving as Chair of the Audit Committee shall receive an additional annual retainer of $15,000 for such service. A Non-Employee Director serving as a member other than the Chair of the Audit Committee shall receive an additional annual retainer of $7,500 for such service.

3. *Compensation Committee*. A Non-Employee Director serving as Chair of the Compensation Committee shall receive an additional annual retainer of $12,000 for such service. A Non-Employee Director serving as a member other than the Chair of the Compensation Committee shall receive an additional annual retainer of $6,000 for such service.

4. *Nominating and Corporate Governance Committee*. A Non-Employee Director serving as Chair of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $10,000 for such service. A Non-Employee Director serving as a member other than the Chair of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $5,000 for such service.

C. Payment of Retainers. The retainers described in Sections I(A) and (B) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section I(B), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

D. Annual Retainer Election.

1. *Election*. Beginning with Annual Retainers earned in 2024, each Non-Employee Director may elect (an "***Election***") to receive an option (an "***Elective Option***") to purchase shares of the Company's Class A common stock ("***Shares***") in lieu of all of the amount of the Non-Employee Director's Base Retainer to be earned for a given year. In addition, a Non-Employee Director serving as the Chair or Lead Independent Director of the Board may elect to receive an Elective Option in lieu of all of such Non-Employee Director's COB or LID Retainer to be earned for a given year. An Election must be made in the form determined by the Company and submitted to the Company no later than 5:00 pm Eastern time on November 30 of the calendar year preceding the calendar year to which the Election relates (the "***Election Deadline***"). An Election shall become effective only with respect to the Base Retainer and, if applicable, COB or LID Retainer, earned for the calendar year following the Election Deadline (the "***Service Year***"). A Non-Employee Director who timely makes an Election will be granted an Elective Option for the Base Retainer (a "***Base Retainer Elective Option***") that such Non-Employee Director would, as of the Issue Date (as defined below), otherwise have been entitled to receive under this Program in cash for his or her service on the Board during the applicable Service Year, assuming such Non-Employee Director remained in service throughout the Service Year (the "***Service Year Base Retainer Amount***") and, if applicable, a separate Elective Option for the COB or LID Retainer (an "***Additional Retainer Elective Option***") that such Non-Employee Director would, as of the Issue Date, otherwise have been entitled to receive under this Program in cash for his or her service as the Chair or Lead Independent Director of the Board during the applicable Service Year, assuming such Non-Employee Director remained in service as Chair or Lead Independent Director of the Board throughout the Service Year (the "***Service Year COB or LID Retainer Amount***," and together with the Service Year Base Retainer Amount, the "***Service Year Retainer Amounts***"). If the Base Retainer or COB or LID Retainer is increased after the Issue Date of a corresponding Elective Option, the excess of such increased amount over the applicable Service Year Retainer Amount for the given Service Year will, to the extent earned, be paid in cash under and subject to the terms of Sections I(A), I(B)(1) and I(C), as applicable. If the Base Retainer or COB or LID Retainer is decreased after the Issue Date of a corresponding Elective Option, no reduction in such corresponding Elective Option will be made.

2. *Terms of Elective Option*. Each Elective Option will be granted automatically, without further action of the Board, on January 1 occurring after the Election Deadline (such date, the "***Issue Date***"), under and subject to the terms of the Company's 2021 Incentive Award Plan or any other applicable Company equity incentive plan then maintained by the Company (the "***Equity Plan***") and an award agreement, including attached exhibits, in substantially the form previously approved by the Board to evidence awards of options to Non-Employee Directors under the Company's 2021 Incentive Award Plan. The number of Shares subject to an Elective Option granted to a Non-Employee Director on the Issue Date will be determined by dividing: (i) the Service Year Base Retainer Amount or the Service Year COB or LID Retainer Amount, as applicable, by (ii) the Elective Option's Black-Scholes Value (as defined below) on the Issue Date, rounded down to the nearest whole Share.

3. *Withdrawal and Service*. A Non-Employee Director may withdraw his or her Election at any time prior to the Election Deadline for a given Service Year, and thereafter, any Elections delivered to the Company and not previously withdrawn will become irrevocable with respect to the Service Year. Notwithstanding anything in this Section I(D) or any Election to the contrary, if (a) a Non-Employee Director is not serving as a Non-Employee Director on the Issue Date, (b) a Non-Employee Director is not serving in a position identified in Section I(B)(1) on the Issue Date, or (c) the grant of an Elective Option described in this Section I(D) is prohibited under applicable laws, exchange listing rules or the terms of the Equity Plan, the Non-Employee Director will not be issued an Elective Option, or in the case of a clause (b), an Additional Retainer Elective Option, on the Issue Date. Any Non- Employee Director whose service as a Non-Employee Director commences during a given Service Year shall not be eligible to make an Election under this Program until the first Election Deadline that occurs following the date such Non-Employee Director commences service as a Non-Employee Director.

4. *Black-Scholes Value.* For purposes of this Section I(D), "***Black-Scholes Value***" means, with respect to an Elective Option, the per share fair value of the Elective Option determined as of the applicable Issue Date using the Black-Scholes or other option pricing model that the Company most recently applied when valuing grants of options with service-based vesting conditions for purposes of preparing its (audited or unaudited) consolidated financial statements that have been filed with the Securities Exchange Commission (the "***Financial Statements***") and using as inputs to such model: (i) the Fair Market Value (as defined in the Equity Plan) of a Share on the applicable Issue Date (or, if the Issue Date is not a trading day, the last trading day preceding the Issue Date) and (ii) such other assumptions as were reported by the Company in the Financial Statements for the most recent period covered by the Financial Statements (and if any such assumptions were reported as a range of values, using the arithmetic mean of the reported range).

II. Equity Compensation

In addition to any Elective Options, Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Equity Plan and shall be granted subject to award agreements, including attached exhibits, in substantially the form previously approved by the Board. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of stock options hereby are subject in all respects to the terms of the Equity Plan and the applicable award agreement. For the avoidance of doubt, the share numbers in Sections II(A) and II(B) shall be subject to adjustment as provided in the Equity Plan.

A. Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall receive an option to purchase 66,700 Shares on the date of such initial election or appointment. The awards described in this Section II(A) shall be referred to as "***Initial Awards***." No Non-Employee Director shall be granted more than one Initial Award.

B. Subsequent Awards. A Non-Employee Director who (i) has been serving as a Non-Employee Director on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall receive an option to purchase 33,350 Shares on the date of such annual meeting. Any Non-Employee Director who has been serving as a Non-Employee Director on the Board for less than six months as of the date of any such annual meeting and will continue to serve as a Non-Employee Director immediately following such meeting, shall also receive an option to purchase shares of the Company's common stock on the date of such annual meeting, but the number of shares underlying such option shall be reduced on a pro-rata basis based on the number of months such Non-Employee Director has served as a Non-Employee Director on the Board during the twelve month period ending on the date of such meeting The awards described in this Section II(B) shall be referred to as "***Subsequent Awards***."

C. Termination of Employment of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their employment with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section II(A) above, but to the extent that they are otherwise entitled, will receive, after termination of employment with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section II(B) above.

D. Terms of Awards Granted to Non-Employee Directors

1. *Exercise Price*. The per share exercise price of each option granted to a Non-Employee Director shall equal the Fair Market Value of a Share on the date the option is granted (including on the Issue Date of any Elective Option).

2. *Vesting*. Each Initial Award shall vest and become exercisable in thirty-six (36) substantially equal monthly installments following the date of grant, such that the Initial Award shall be fully vested on the third anniversary of the date of grant, subject to the Non-Employee Director continuing in service as a Non-Employee Director on each such vesting date. Each Subsequent Award shall vest and become exercisable in twelve substantially equal monthly installments following the date of grant, such that the Subsequent Award shall be fully vested on the first anniversary of the date of grant (provided that any portion of a Subsequent Award scheduled to vest after the first annual meeting of the Company's stockholders following the date of grant of such Subsequent Award shall vest on the date of such annual meeting), subject to the Non-Employee Director continuing in service on the Board as a Non-Employee Director on each such vesting date. Each Elective Option shall vest and become exercisable as to 25% of the Shares subject to the Elective Option (each, an "***Elective Option Tranche***") upon the Non-Employee Director completing three months of continuous service as a Non-Employee Director, or in the case of an Additional Retainer Elective Option, in the applicable position, following the Issue Date, such that the fourth and final Elective Option Tranche will vest and become exercisable on the first anniversary of the Issue Date. By way of example, if, during a given Service Year for which a Non-Employee Director received a Base Retainer Elective Option and an Additional Retainer Elective Option, such Non-Employee Director ceases to serve as Chair of the Board but continues to serve as a Non-Employee Director, such Non-Employee Director's Base Retainer Elective Option will continue to vest and become exercisable while such Non-Employee Director continues to serve as a Non-Employee Director and any portion of such Non-Employee Director's Additional Retainer Elective Option that has not become vested and exercisable on or prior to the date such Non-Employee Director ceases to serve as the Chair of the Board shall, unless otherwise determined by the Board, be forfeited on the date such Non-Employee Director ceases to serve as Chair of the Board. Unless the Board otherwise determines, any portion of an Initial Award, Subsequent Award or Elective Option which is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director (or, if applicable, as Chair or Lead Independent Director) shall be immediately forfeited upon such termination of service and shall not thereafter become vested and exercisable. All of a Non-Employee Director's outstanding Initial Awards, Subsequent Awards and Elective Options shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

3. *Term*. The maximum term of each stock option granted to a Non-Employee Director hereunder shall be ten (10) years from the date the option is granted.

4. *Post-Termination Exercise Period*. Unless the Board determines otherwise, and notwithstanding any contrary provision in the Company's applicable Equity Plan, upon a Non-Employee Director's termination of service (such date of termination, the "***Termination Date***"), the portion, if any, of such Non-Employee Director's Initial Award, Subsequent Award(s) and/or Elective Option(s) vested and outstanding as of the Termination Date shall be exercisable: (i) in the case of a Non-Employee Director who has served on the Board for less than three years as of the Termination Date, as set forth in the Company's applicable Equity Plan and applicable stock option agreement(s); (ii) in the case of a Non-Employee Director who has served on the Board for at least three years but less than five years as of the Termination Date, until the earlier of (x) two years following the Termination Date and (y) the original expiration date of the option grant (as set forth in the applicable stock option agreement(s)); and (iii) in the case of a Non-Employee Director who has served on the Board for at least five years as of the Termination Date, until the earlier of (x) three years following the Termination Date and (y) the original expiration date of the option grant (as set forth in the applicable stock option agreement(s)).

* * * * *

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Nos. 333-289589 and 333-289997) on Form S-3 and Registration Statements (Nos. 333-258416 and 333-286973) on Form S-8 of Immuneering Corporation of our report dated March 6, 2026, relating to the consolidated financial statements of Immuneering Corporation and its subsidiaries, appearing in this Annual Report on Form 10-K of Immuneering Corporation for the year ended December 31, 2025.

/s/ RSM US LLP

Boston, Massachusetts
March 6, 2026

Exhibit 31.1

CERTIFICATION

I, Benjamin J. Zeskind, certify that:

1. I have reviewed this Annual Report on Form 10-K of Immuneering Corporation;

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 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 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

By: /s/ Benjamin J. Zeskind

Name: Benjamin J. Zeskind, Ph.D

Title: Co-Founder, President, Chief Executive Officer and Director (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Mallory Morales, certify that:

1. I have reviewed this Annual Report on Form 10-K of Immuneering Corporation;

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 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 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

By: /s/ Mallory Morales

Name: Mallory Morales

Title: SVP Finance, Chief Accounting Officer and Treasurer (Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION 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 on Form 10-K for the fiscal year ended December 31, 2025 of Immuneering Corporation (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or Section 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

By: /s/ Benjamin J. Zeskind

Name: Benjamin J. Zeskind, Ph.D.

Title: Co-Founder, President, Chief Executive Officer and Director (Principal Executive Officer)

Exhibit 32.2

CERTIFICATION 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 on Form 10-K for the fiscal year ended December 31, 2025 of Immuneering Corporation (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or Section 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

By: /s/ Mallory Morales

Name: Mallory Morales

Title: SVP Finance, Chief Accounting Officer and Treasurer
(Principal Financial and Accounting Officer)