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: 001-32587



ALTIMMUNE, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-2726770**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
910 Clopper Road, Suite 201S, Gaithersburg, MD	**20878**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code
(240) 654-1450
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Trading Symbol(s)*	*Name of each exchange on which registered*
Common stock, par value $0.0001 per share	ALT	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 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of voting and non-voting common equity held by non-affiliates, based upon the closing price of the registrant's common stock on the Nasdaq Global Market on June 30, 2025, was approximately $326.8 million. As of February 27, 2026, there were 130,069,983 shares of the registrant's common stock, $0.0001 par value per share, outstanding.

Documents Incorporated by Reference

Part III of this Annual Report on Form 10-K incorporates by reference certain information from the registrant's definitive Proxy Statement for its 2026 annual meeting of shareholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year end of December 31, 2025. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

ALTIMMUNE, INC.

ANNUAL REPORT ON FORM 10-K

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Forward-looking statements

This Annual Report on Form 10-K for the year ended December 31, 2025 (this "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Private Securities Litigation Reform Act of 1995. Written or oral statements that constitute forward-looking statements may be made by us or on our behalf. Words such as "expect," "anticipate," "intend," "plan," "believe," "estimate," "may," "will," "should," "could," "target," "strategy," "intend," "project," "guidance," "likely," "usually," "potential," or the negative of these words or variations of such words, similar expressions, or comparable terminology are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate, and management's beliefs and assumptions. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict and may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by any forward-looking statements. These risks, uncertainties and other factors include, but are not limited to, risks associated with the following:

- our ability to develop and commercialize our current and future product candidates;
- our ability to expand our pipeline of product candidates and the success of future product candidate advancements, including the success of future preclinical studies and clinical trials, and our ability to commercialize our products;
- the reliability of the results of the clinical trials relating to human safety and possible adverse effects resulting from the administration of our product candidates;
- our ability to obtain potential regulatory approvals on the timelines anticipated, or at all;
- our ability to obtain additional patents or extend existing patents on the timelines anticipated, or at all;
- our ability to identify and consummate potential future strategic partnerships or business combinations;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;
- our anticipated financial or operational results;
- our ability to obtain additional capital resources;
- risks related to the conflict in Israel and the Gaza Strip and the conflict in Ukraine on the global economy, including causing or contributing to global supply chain disruption, price fluctuations, including increased costs for raw materials, and other significant economic effects;
- breaches or other data privacy incidents, or disruptions in our information technology systems;
- our ability to continue to satisfy the listing requirements of the Nasdaq Global Market ("Nasdaq"); and
- risks detailed under the caption "Risk Factors" in this Annual Report and in our other reports filed with the U.S. Securities and Exchange Commission ("SEC"), from time to time hereafter.

We have based the forward-looking statements included in this Annual Report on information available to us on the date of this annual report. Except as required by law we undertake no obligation to revise or update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised to consult any additional disclosures that we may make in reports that we, in the future, may file with the SEC, including annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K.

All forward-looking statements included herein are expressly qualified in their entirety by the foregoing cautionary statements. Unless otherwise indicated, the information in this Annual Report is as of December 31, 2025.

Note regarding trademarks

"Altimmune," our logo and any other trademarks, trade names or service marks of the Company appearing in this Annual Report are the property of the Company. The other trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners. We do not intend our use or display of other companies' trademarks, trade names or service marks to imply an endorsement or sponsorship of us by such companies, or any relationship with such companies. Solely for convenience, trademarks and trade names referred to in this Annual Report may appear without the ® or TM symbol.

Summary of Risk Factors

The risk factors detailed in Item 1A entitled "Risk Factors" in this Annual Report on Form 10-K are the risks that we believe are material to our investors and a reader should carefully consider them. Those risks are not all of the risks we face and other factors not presently known to us or that we currently believe are immaterial may also affect our business if they occur. The following is a summary of the risk factors detailed in Item 1A:

Risks Related to Our Business, Financing Requirements, Product Development and Clinical Trials

- we have incurred significant losses since our founding and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability
- our profitability depends on our ability to develop and commercialize our current and future product candidates
- our ability to raise capital may be limited by applicable laws and regulations
- we may encounter substantial delays in our clinical trials, or our clinical trials may fail to demonstrate the safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities
- we may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates
- it may be difficult to predict the time and cost of product development for our product candidates, and unforeseen problems may prevent further development or approval of our product candidates
- we rely, and expect to continue to rely, on third parties to conduct preclinical studies and clinical trials for our product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates
- we face substantial competition from other pharmaceutical and biotechnology companies, which may result in others discovering, developing or commercializing products before, or more successfully, than we do
- we are heavily dependent on the success of our leading product candidate, pemvidutide. If we ultimately are unable to develop, obtain regulatory approval for or commercialize pemvidutide, or any other product candidate, our business will be substantially harmed
- labor shortages and constraints in the supply chain could adversely affect our results of operations
- our overall performance depends in part on global macroeconomic, political and geopolitical uncertainties

Risks Related to the Regulatory Approval Process

- our product candidates may cause undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential
- our ability to obtain regulatory approval and market our products, including in non-U.S. jurisdictions
- ongoing regulatory obligations and review that may result in significant additional expenses and restrictions, even if our product candidates are approved

Risks Related to Our Intellectual Property

- the cost and difficulty of protecting our proprietary rights and the potential that our intellectual property rights do not adequately protect our product candidates
- our ability to protect our intellectual property rights throughout the world

- the adequacy of our patent terms to protect our competitive position on our products for an adequate amount of time
- third-party claims of intellectual property infringement or misappropriation, including circumstances involving our employees, independent contractors or consultants

Risks Related to Commercialization of our Product Candidate

- our ability to attain significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payers and others in the medical community
- our reliance on third parties to manufacture our products in sufficient quantities to meet commercial demand the ability of our contract manufacturers to manufacture any such product to the specifications and the quantities that are needed along the timelines that are specified
- the use of emerging technologies, including artificial intelligence, in our development and commercialization efforts may expose us to cybersecurity, regulatory and liability risks

Risks Related to Reimbursement and Government Regulation

- disruptions and uncertainty at government regulatory agencies, including the FDA
- our ability to obtain coverage and reimbursement in certain market segments for our product candidates, if they are approved
- the imposition of price controls
- our ability to comply with federal and state health care and other laws, and the complexity of our regulatory compliance obligations
- the unknown impact of recent health care reform legislation and other changes in the health care industry and in health care spending

Risks Related to our Securities

- the volatility of the trading price of our common stock and substantial price fluctuations on heavy volume

Risks Related to our Indebtedness

- restrictions on our operating activities due to covenants under our term loan obligation and the risk of repayment upon an event of default
- our level of indebtedness and debt service obligations and their impact on our financial condition and ability to fund operations

PART I

Item 1. Business

Overview

Altimmune, Inc. is a late clinical-stage biopharmaceutical company developing novel therapies for serious liver diseases. Our lead product candidate, pemvidutide (formerly known as ALT-801), is a balanced 1:1 glucagon/GLP-1 dual receptor agonist in development for the treatment of metabolic dysfunction-associated steatohepatitis ("MASH"), alcohol use disorder ("AUD") and alcohol-associated liver disease ("ALD"). We may also pursue additional indications for pemvidutide that leverage its differentiated clinical profile. Except where the context indicates otherwise, references to "we," "us," "our," "Altimmune", or the "Company" refer to the company and its subsidiaries.

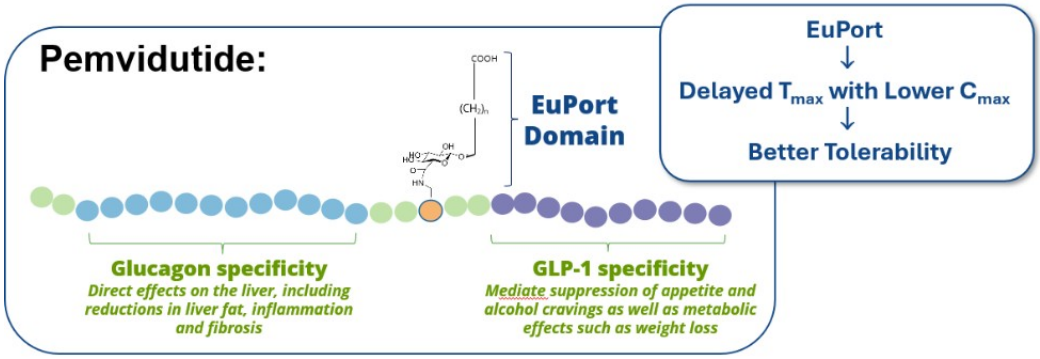
Pemvidutide

We obtained pemvidutide as part of the acquisition Spitfire Pharma Inc., in July of 2019. Pemvidutide was designed as a MASH therapeutic based on the understanding that targeting both metabolic and liver-specific effects could lead to an improved and differentiated candidate. Early work provided compelling preclinical efficacy data obtained from a mouse model of MASH. Following a first-in-human clinical trial where we observed initial signs of weight loss and pronounced liver effects, we evaluated pemvidutide in participants with fatty liver disease, or metabolic-dysfunction associated liver disease (MASLD), where we observed robust reductions in liver fat content and weight loss. These results confirmed the earlier study and paved the way for the biopsy-driven IMPACT Phase 2b trial in MASH. To better characterize the quality of the weight loss and cardiometabolic effects of pemvidutide, the MOMENTUM Phase 2 trial in overweight and obese participants was conducted and showed significant weight loss characterized by relative sparing of lean muscle mass and improvements in serum lipids associated with cardiovascular disease. In addition to the recently completed IMPACT trial, pemvidutide is currently being evaluated in participants with AUD and, separately, ALD. There is evidence that pemvidutide may decrease the craving for alcohol in these individuals, with the added benefit that pemvidutide may reverse the harmful effects that alcohol has on the liver in these patients.

Pemvidutide is a novel, investigational peptide with balanced 1:1 glucagon/GLP-1 dual receptor agonist activity in clinical development for the treatment of MASH, AUD and ALD. We believe pemvidutide is the only glucagon/GLP-1 dual receptor agonist with a balanced 1:1 potency at glucagon and the GLP-1 receptors, in effect placing glucagon activity on an even footing with GLP-1 activity. The activation of glucagon receptors results in direct effects on the liver, including reductions in liver fat, inflammation and fibrosis, whereas the activation of GLP-1 receptors mediates suppression of appetite and reduction of cravings as well as metabolic effects such as weight loss.

Pemvidutide mechanism of action

ALD



As of December 31, 2025, over 700 patients have been exposed to pemvidutide in 8 completed studies and 2 ongoing studies. In clinical trials to date, pemvidutide has demonstrated rapid reductions in liver fat, markers of liver inflammation, and early MASH resolution along with improvements in non-invasive tests ("NITs") such as Enhanced Liver Fibrosis ("ELF") score and Liver Stiffness Measurement ("LSM") demonstrating antifibrotic activity. In addition, pemvidutide has shown clinically meaningful weight loss while exhibiting class-leading lean mass preservation. Pemvidutide has also shown a favorable tolerability and safety profile in clinical trials to date. Based on the clinical data we have accumulated, we believe pemvidutide may be able to address several serious liver diseases, and pemvidutide has received Breakthrough Therapy Designation for MASH from the FDA based on data obtained from IMPACT trial at 24 weeks, indicating it has shown early clinical evidence of substantial improvement over existing therapies.

Pemvidutide is protected by a robust patent portfolio covering its composition, formulation, methods of use and treatment with patent expiration dates extending into the 2040s when the expected patent term extension is included.

MASH

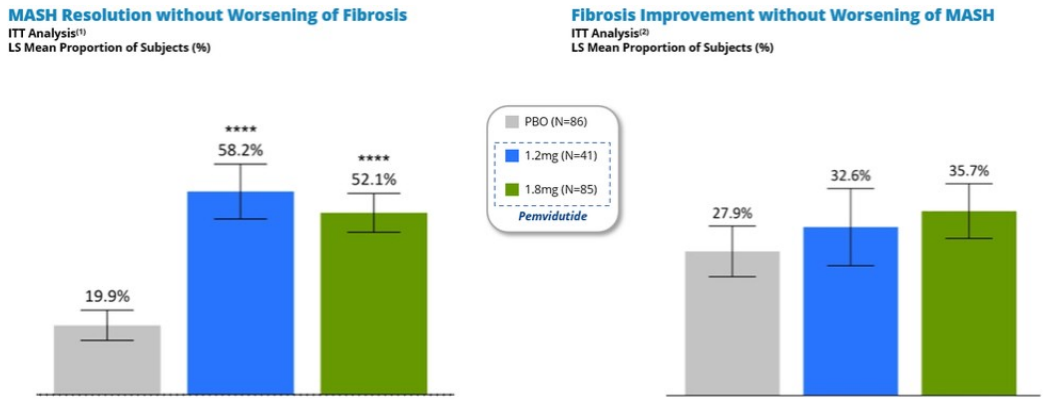
MASH is caused by multiple metabolic pathways that lead to an abnormal accumulation of liver fat, toxic lipid metabolites, and inflammation, that leads to liver fibrosis and increased risk of death due to cardiovascular disease and liver failure. Accumulating clinical evidence suggests that reduction in liver fat and liver inflammation is associated with MASH resolution and improvement in liver fibrosis. Furthermore, considering 80-90% of individuals with MASH are also overweight, we believe that combining a direct liver acting mechanism with weight loss could provide a compelling treatment for MASH patients. In recognition of pemvidutide's potential differentiating benefits, the U.S. Food and Drug Administration ("FDA") has granted both Breakthrough Therapy Designation and Fast Track designation to pemvidutide for the treatment of MASH.

IMPACT Phase 2b MASH Trial – 24 Week Results

On June 26, 2025, we released 24-week topline efficacy results from the IMPACT Phase 2b trial of pemvidutide in MASH and subsequently published those results in the journal Lancet (Noureddin M., et al., Lancet. 2025 Dec 6;406(10520):2644-2655). The Phase 2b trial enrolled 212 subjects with biopsy-confirmed MASH and fibrosis stages F2/F3 with and without diabetes randomized 1:2:2 to receive weekly subcutaneous doses of pemvidutide at 1.2 mg, 1.8 mg or placebo.

In an intent-to-treat ("ITT") analysis, in which subjects with missing biopsies were considered non-responders, the proportions of subjects achieving MASH resolution without worsening of fibrosis at 24 weeks were 58.2% and 52.1%, for pemvidutide 1.2 mg and 1.8 mg, respectively versus 19.9% for placebo ($p < 0.0001$ both doses). The effects on fibrosis improvement without worsening of MASH in an ITT analysis were 32.6% and 35.7% for pemvidutide 1.2 mg and 1.8 mg, respectively compared with 27.9% for placebo (differences not statistically significant). A supplemental AI-based analysis demonstrated statistically significant reductions in fibrosis, including 31% of subjects receiving pemvidutide 1.8 mg achieving a 60% or more reduction in fibrosis compared to 8% receiving placebo ($p < 0.001$). Statistically significant changes in well-established non-invasive tests ("NITs") of fibrosis, including Enhanced Liver Fibrosis ("ELF") score and Liver Stiffness Measurement ("LSM") were also observed compared with placebo at both doses. Together, these data suggest strong evidence of MASH resolution and anti-fibrotic activity of pemvidutide in the MASH population after 24 weeks of treatment.

Pemvidutide Demonstrates Statistically Significant MASH Resolution at 24 Weeks



*Note: **** indicates p<0.0001 vs. placebo (Chi-Square Test). 1. For ITT Analysis, patients without a biopsy at 24 weeks, or those who did not complete treatment, are treated as non-responders. 2. NS vs. placebo (Chi-Square Test).*

Pemvidutide also demonstrated a favorable safety and tolerability profile, with low overall treatment discontinuation rates due to adverse events of less than 1% and 1.2% in the pemvidutide 1.2 mg and 1.8 mg groups versus 2.4% in the placebo group, despite that no dose titration was used in the trial. There were no serious adverse events related to study medication.

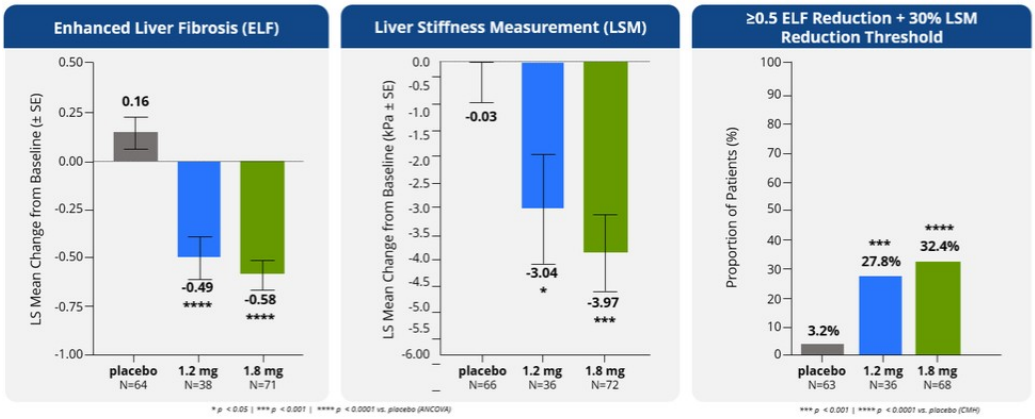
IMPACT Phase 2b MASH Trial – 48 Week Results

On December 19, 2025, we announced positive 48-week topline results from the IMPACT Phase 2b trial of pemvidutide in patients with MASH.

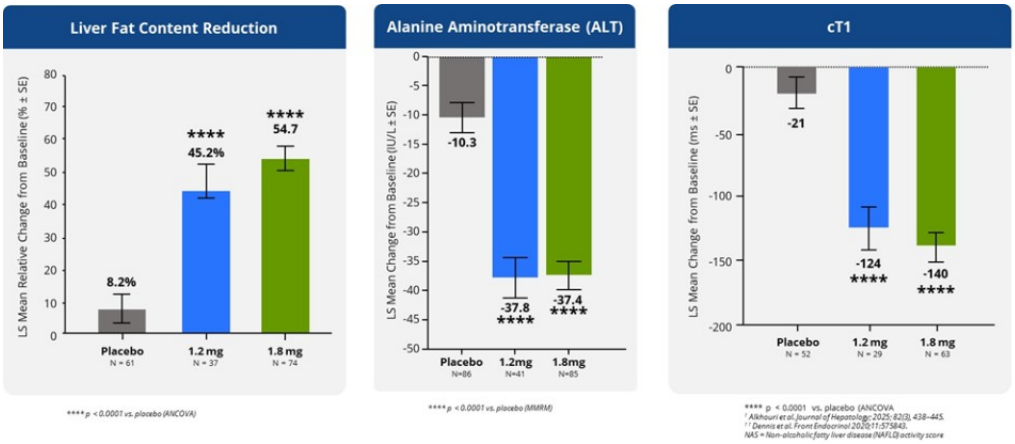
The topline 48-week data from the IMPACT trial, which, by design, did not include histological readout, showed that treatment with pemvidutide achieved statistically significant improvements across treatment arms versus placebo in the key anti-fibrosis NITs of ELF and LSM. Importantly, these data exhibited continued reductions from week 24 in multiple tests including ELF and LSM and provide evidence of improvement in antifibrotic activity. These are well-established markers of fibrosis and are strongly associated with histological changes and liver related events. At 48 weeks, mean weight loss in pemvidutide-treated subjects was observed at the 1.2 mg and 1.8 mg doses, respectively, with no evidence of plateauing in the 1.8mg dose group. The 48-week data also maintained the favorable tolerability profile seen at 24 weeks, including a lower discontinuation rate due to adverse events versus placebo.

A summary of the 48-week topline results is provided below:

- Pemvidutide-treated participants achieved statistically significant reductions in non-invasive markers of fibrosis, including ELF and LSM;
    - ELF: 1.2 mg and 1.8 mg doses achieved a mean reduction from baseline of -0.49 and -0.58 respectively, vs. +0.16 in placebo-treated patients ($p<0.0001$, both doses);
    - LSM: 1.2 mg and 1.8 mg doses achieved a mean reduction from baseline of -3.04 ($p<0.05$) and -3.97 ($p<0.001$), respectively, vs. -0.03 in placebo-treated participants;
    - The proportion of participants receiving pemvidutide 1.2 mg and 1.8 mg that achieved both a ≥0.5 reduction in ELF and a 30% reduction in LSM were 27.8% ($p<0.001$) and 32.4% ($p<0.0001$) respectively, vs. 3.2% in placebo-treated participants.



- Pemvidutide-treated participants also achieved statistically significant reductions in key non-invasive measures of liver health and hepatic inflammation, including liver fat content, alanine aminotransferase ("ALT") and corrected T1 ("cT1");
    - Liver fat content: 1.2 mg and 1.8 mg doses achieved a mean reduction from baseline of 45.2% and 54.7% respectively, compared to 8.2% in participants who received placebo ($p<0.0001$);
    - ALT: 1.2 mg and 1.8 mg achieved a mean reduction from baseline of -37.8 IU/L and -37.4 IU/L respectively, vs -10.3 IU/L in placebo-treated participants ($p<0.0001$, both doses);
    - cT1: Participants receiving pemvidutide 1.2 mg and 1.8 mg achieved a mean reduction from baseline of -124 and -140 milliseconds (ms) respectively, vs -21 ms in placebo-treated participants ($p<0.0001$, both doses).



- Participants receiving pemvidutide 1.2 mg and 1.8 mg achieved weight loss of 4.5% and 7.5%, respectively, vs. 0.2% of placebo-treated participants ($p<0.0001$, both doses), with no plateauing at 48 weeks with the 1.8 mg dose;

- Adverse events ("AEs") leading to treatment discontinuation occurred in 0% and 1.2% of patients treated with pemvidutide 1.2 mg and 1.8 mg, respectively, vs. 3.5% of participants on placebo;
- No serious or severe AEs related to treatment were reported.

In December 2025, we held an End-of-Phase 2 meeting with the FDA to discuss and align on the parameters for a registrational Phase 3 trial of pemvidutide for MASH patients with moderate to advanced fibrosis with biopsy driven endpoints. The FDA provided feedback on trial design, endpoints, and agreed to the use of AIM-MASH AI Assist, the first FDA-qualified AI pathology tool for MASH clinical trials, in our Phase 3 trial. We received final minutes from the End-of-Phase 2 meeting in January 2026, which we believe describe a clear regulatory path for a Phase 3 trial in MASH. We are also in the process of seeking scientific advice from European regulators to further inform the final Phase 3 protocol.

Based on the clinical data obtained from the IMPACT trial and FDA feedback, we are currently preparing to initiate a pivotal, 52-week, Phase 3 clinical trial in MASH in 2026. The registrational program is expected to assess clinical data in support of our key differentiators in MASH including:

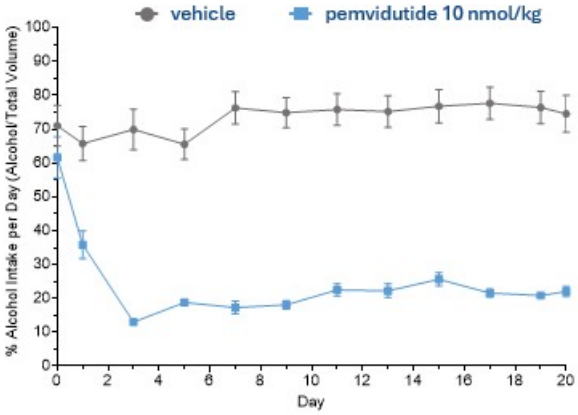
- Rapid and statistically significant improvements in markers of liver inflammation and fibrosis
- Statistically significant responses in both MASH resolution and fibrosis stage
- Statistically significant weight loss
- Statistically significant improvements in lean mass and/or function compared to placebo
- An excellent tolerability profile with low rates of discontinuation from therapy.

Additional Pemvidutide Indications

On March 13, 2025, we announced that we are pursuing AUD and ALD as additional indications for our lead product candidate, pemvidutide.

AUD

AUD is a chronic disease characterized by an impaired ability to stop or control alcohol use despite adverse social, occupational, or health consequences. In addition to the underlying alcohol misuse by AUD patients, AUD patients have comorbidities that pose significant treatment and management challenges (including liver steatosis, overweight, obesity, hypertension and hyperlipidemia). It has been shown that therapies with GLP-1 activity may share neural mechanisms of food and alcohol reward systems and real-world evidence has suggests that the use of GLP-1-containing therapies reduces alcohol consumption. We have conducted a preclinical study of a hamster free-choice model in which pemvidutide demonstrated a maximum decrease of 82% in alcohol intake relative to vehicle controls. The excess alcohol consumption associated with AUD also often leads to an increase in liver fat, i.e., steatotic liver disease. We believe reducing alcohol consumption combined with improving liver health through the effects of glucagon would provide AUD patients with a compelling treatment option.



On May 19, 2025, we announced the enrollment of the first subject in the RECLAIM Phase 2 trial evaluating the efficacy and safety of pemvidutide in subjects with AUD. RECLAIM is a randomized, placebo-controlled trial conducted across approximately 15 sites in the United States, targeting enrollment of approximately 100 subjects. Subjects will be randomized 1:1 to receive either 2.4 mg pemvidutide or placebo weekly for 24 weeks. The trial's primary endpoint is a change in alcohol consumption, measured by the change from baseline in the average number of heavy drinking days per week measured at Week 24, with the key secondary endpoints including the proportion of subjects achieving a 2-level reduction in World Health Organization ("WHO") risk drinking level and the absolute change from baseline in average levels of phosphatidylethanol ("PEth"), a serum biomarker of alcohol intake.

On August 19, 2025, we announced that the U.S. Food and Drug Administration has granted Fast Track designation to pemvidutide for the treatment of AUD. Fast Track designation is intended to accelerate the development and review of new drugs that target serious conditions and address unmet medical needs.

On November 3, 2025, we announced the completion of enrollment in the RECLAIM Phase 2 trial. Enrollment completed ahead of schedule, underscoring strong interest from the patient community in a new therapeutic option for AUD. We are on track to complete the 24-week treatment period and announce topline results in 2026.

ALD

ALD is a disease characterized by damage to the liver due to excessive and chronic alcohol use. ALD progression (like MASH progression) begins with liver steatosis, which may lead to inflammation, fibrosis and, ultimately, to cirrhosis. Given the progression of the disease, ALD is one of the leading cause of liver transplants in the US. Unfortunately, there are currently no approved treatments for ALD.

On July 9, 2025, we announced the enrollment of the first patient in the RESTORE Phase 2 trial evaluating the efficacy and safety of pemvidutide in subjects with ALD. RESTORE is a randomized, placebo-controlled trial enrolling approximately 100 patients across 34 sites in the United States. Subjects will be randomized 1:1 to receive either 2.4mg pemvidutide or placebo weekly for 48 weeks. The trial's primary endpoint is the change from baseline in LSM by vibration-controlled transient elastography ("VCTE") at Week 24. Key secondary endpoints include the change from baseline in LSM by VCTE at Week 48, changes in ELF score at Weeks 24 and 48, and changes in alcohol consumption and body weight at the same time points.

Our Strategy

Our goal is to become a leading biopharmaceutical company offering innovative treatments for serious liver diseases. Key elements of our strategy include the following:

- Initiate the registrational Phase 3 development program in MASH that, provided safety and efficacy are established, provides for an accelerated approval based on data obtained after one year of treatment;
- Continue development of other liver-related indications such as AUD and ALD that may benefit from the dual activity of glucagon and GLP-1a;
- Continue to build and develop our experience and capabilities to support the development and commercialization of pemvidutide;
- Research and develop alternative formulations, doses, and presentations of pemvidutide for the benefit of patients; and
- Assess strategic partnerships and licensing opportunities to help accelerate the development of pemvidutide and achieve our goals.

Competition

The biopharmaceutical industry is intensely competitive and is characterized by rapid technological progress. In general, competition among pharmaceutical products is based in part on product efficacy, safety, reliability, availability, price and patent position. An important factor is the relative timing of the market introduction of our products and our competitors' products. Accordingly, the speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market is an important competitive factor. Our competitive position also depends upon our ability to show differentiation with a product that is either more efficacious, particularly in the relevant target populations, offers a better safety or tolerability profile, is less expensive or quicker to manufacture, or represents a combination of these advantages. We also depend upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often substantial period between technological conception and commercial sale.

Large and established companies such as Eli Lilly, Roche, Novo Nordisk, Pfizer, AstraZeneca, Amgen, Boehringer Ingelheim and Merck, among others, compete in the same general therapeutic areas as our product programs. These companies compete with us with their greater experience and resources to support their research and development efforts, conduct testing and clinical trials, obtain regulatory approvals to market products, manufacture such products on a broad scale and market approved products. These companies also compete with us by having significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the products that we develop obsolete. We also face competition from smaller companies who, like us, rely on investors to fund research and development and compete for co-development and licensing opportunities from large and established pharmaceutical companies.

We face competition for pemvidutide, our glucagon/GLP-1 dual agonist for the treatment of MASH from companies such as Madrigal Pharmaceuticals, Aligos and Viking Therapeutics, which are developing orally administered, thyroid hormone receptor ("THR") β-selective agonists; Novo Nordisk, Roche, and GSK, which are developing fibroblast growth factor 21 ("FGF-21") analogs; Novo Nordisk, which is developing a GLP-1 agonist; Merck/Hanmi Pharmaceutical and Boehringer Ingelheim, which are developing GLP-1/glucagon dual agonists; Eli Lilly, which is developing a glucose-dependent insulinotropic polypeptide receptor ("GIP")/GLP-1 dual agonist and a GLP-1 GIP/glucagon triple agonist; Roche which is developing a GLP-1/GIP dual agonist; AstraZeneca developing a GLP-1/glucagon and amylin combination; Inventiva, which is developing a pan-peroxisome proliferator-activated receptor ("PPAR") agonist; Sagimet which is developing a fatty acid synthetase inhibitor, Apollo Therapeutics Group Limited/HEC Pharma which is developing a GLP-1/FGF-21 dual agonist; and Pfizer, Roche, Gilead, AstraZeneca, and Eli Lilly, which are developing

small molecule GLP-1 agonists. In addition, many other small companies are developing other new technologies directed towards MASH.

Similarly, we face competition for pemvidutide in the AUD and ALD markets. In ALD, GSK is developing GSK4532990, an RNAi targeting HSD17B13; Novo Nordisk is developing NNC0194-0499 (FGF-21), cagrilintide (long acting amylin analogue) and semaglutide (GLP-1). In AUD, Alkermes' vivitrol is an approved product in this market; generic products such as naltrexone, acamprosate and disulfiram are also available; and Eli Lilly is developing mazdutide, a GLP-1/Glucagon dual agonist and brenipatide, a GLP-1/GIP dual agonist. We similarly face competition from smaller entrants in AUD; Adial is developing a serotonin-3 receptor antagonist targeting AG+ genotype AD-04, Imbrium is developing sunobinop, a NOP agonist, and Solvonis is developing SVN-001 for AUD in European markets.

Intellectual Property

We generally seek patent protection for our technology and product candidates in the United States and abroad. The patent coverage available to biotechnology companies is generally uncertain because it involves complex legal and factual considerations. Our success will depend, in part, on whether we can:

- obtain patents to protect our own technologies and product candidates;
- obtain licenses to use the technologies of third parties, which may be protected by patents;
- protect our trade secrets and know-how; and
- operate without infringing the intellectual property and proprietary rights of others.

We have relied upon certain proprietary trade secrets, know-how and continuing technological advances to develop a competitive position. In efforts to maintain confidentiality and ownership of trade secrets, proprietary information and developments, all of our employees are required to execute agreements regarding confidentiality and assign to us all rights to any inventions and processes they develop while they are employed by us. We have and may in the future use license agreements to access external products and technologies and may in the future use license agreements to convey our own intellectual property to others. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

Patent Rights Related to EuPort Technology

EuPort Technology — In-Licensed from Mederis Diabetes, LLC

Pursuant to a license agreement between the Company and Mederis Diabetes, LLC ("Mederis") (the "Mederis IP License Agreement"), we are the exclusive licensee of patent rights owned by Mederis to develop and commercialize surfactant functionalized ("EuPort domain") incretin-based peptide therapeutics, including (GLP-1-glucagon)/oxyntomodulin, and variants thereof, including pemvidutide, for any indication, and Mederis has certain patent rights granted back to it for the use of the EuPort technology outside of the Company's exclusive field of incretin-based peptide therapeutics. The EuPort domain comprises a hydrophobic domain (e.g., substituted or unsubstituted alkyl chain) and a hydrophilic group (e.g., saccharide) conjugated to a non-terminal amino acid of the peptide. Patents under Mederis IP License Agreement have been granted in the United States, Japan and Korea, and applications are pending in the United States, Japan as well as other commercially relevant jurisdictions. The claims are directed to peptides (at least four amino acids in length), including peptides that bind receptors for glucagon and/or GLP-1, conjugated to an alkyl saccharide surfactant, including an alkyl glycoside surfactant. The patents and, if issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than May 2032, not giving effect to any potential extensions and assuming payment of all associated fees. Patents subject to the Mederis IP License Agreement have also been granted in the United States, Canada, Europe, Korea, Australia, Israel and Japan, and applications are pending in the United States, Europe, Japan, China and other commercially relevant jurisdictions, wherein the claims are directed to specific GLP-1 and/or glucagon peptides conjugated to the EuPort domain. The patents and, if issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than May 2035.

Patent Rights Related to our Product Candidates

Pemvidutide, Dual GLP-1/Glucagon Dual Agonist for MASH, AUD and ALD

We are the exclusive licensee of patent rights owned by Mederis to develop and commercialize surfactant functionalized (GLP-1-glucagon)/oxyntomodulin-based peptide therapeutics, and variants thereof, including pemvidutide, for any use including the treatment of metabolic syndrome, insulin resistance, diabetes and cardiovascular disease. Patents under the Mederis IP License Agreement have been granted in the United States, Europe, Japan, Australia and Mexico with pending applications in the United States, Europe, Japan and Korea, as well as other commercially relevant jurisdictions. The claims are directed to GLP-1/glucagon dual agonist peptides conjugated to a surfactant and their use to treat metabolic syndrome and other related diseases. The patents and, if issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than May 2032 and extending to May 2035, with additional patents and patent applications which expire no earlier than 2041 should they be granted, not giving effect to any potential extensions and assuming payment of all associated fees. Use of pemvidutide for treating MASH or MASLD (referred to as NASH or NAFLD in the patent and patent applications) is further covered by, and subject to the Mederis IP License Agreement, with granted patents in the United States, Europe, Japan and Korea and pending applications in the United States, Europe, Japan and other commercially relevant jurisdictions. The patents and, if issued, the patent(s) resulting from the pending patent applications, are expected to have an expiration date of no earlier than January 2039, not giving effect to any potential extensions and assuming payment of all associated fees.

Use of pemvidutide in methods with improved tolerability, dosing, dosing formulations and therapeutic regimens is further covered in pending applications in the United States, Europe, Japan and Korea, as well as other commercially relevant jurisdictions, which are owned by us and not subject to the Mederis IP License Agreement. The claims are directed to liquid formulations and the use of pemvidutide in a therapeutic dosing regimen with improved tolerability. If issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than February 2041 not giving effect to any potential extensions and assuming payment of all associated fees.

Use of pemvidutide in methods for inducing weight loss is further covered in a granted patent in the United States and pending applications in the United States, Europe, Japan and Korea, as well as other commercially relevant jurisdictions owned by us and not subject to the Mederis IP License Agreement. The claims are directed to the use of pemvidutide for reducing body weight and in a therapeutic dosing regimen for chronic weight management. If issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than December 2041, not giving effect to any potential extensions and assuming payment of all associated fees.

Use of pemvidutide in methods for reducing body weight in a human with fatty liver disease is further covered in pending patent applications in the United States, Europe, Japan and Korea, as well as other commercially relevant jurisdictions, which are owned by us and not subject to the Mederis IP License Agreement. The claims are directed to the use of pemvidutide in methods for reducing body weight in a human with MASH or MASLD (referred to as NASH or NAFLD in the patent and patent applications), with or without also having type II diabetes. If issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than September 2043, not giving effect to any potential extensions and assuming payment of all associated fees.

Use of pemvidutide in methods for reducing the risk of cardiovascular (CV) disease is further covered in pending patent applications in the United States Europe, Japan and Korea, as well as other commercially relevant jurisdictions, which are owned by us and not subject to the Mederis IP License Agreement. The claims are directed to the use of pemvidutide in methods for reducing the risk of cardiovascular (CV) disease in a human with or without also having Type 2 diabetes. If issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than November 2043, not giving effect to any potential extensions and assuming payment of all associated fees.

A liquid formulation of pemvidutide for systemic administration and treatment of relevant indications is covered in patent applications owned by us and pending in the United States, Brazil, Canada, China, the European Patent Office, Israel, India, Japan, Korea, and Mexico. These patent applications are not subject to the Mederis IP License Agreement. If issued, the patent(s) resulting from the pending application(s) have expiration date(s) no earlier than November 2043, not giving effect to any potential extensions and assuming payment of all associated fees.

Use of pemvidutide in methods for reducing pathological serum lipids is further covered in pending patents in the United States and corresponding international (PCT) patent applications, owned by us and not subject to the Mederis IP License Agreement, and from which we expect to file National Phase patent applications in commercially relevant jurisdictions. The claims are directed to the use of pemvidutide in methods for reducing/treating high cholesterol, LDL, triglycerides and/or blood pressure. If issued, the patent(s) resulting from the pending application(s) are expected to have expiration date(s) of no earlier than March 2045, not giving effect to any potential extensions and assuming payment of all associated fees.

Use of pemvidutide in methods for treating AUD is further covered in a pending provisional patent application in the United States, owned by us and not subject to the Mederis IP License Agreement, and from which we expect to file a non-provisional application in the United States and a corresponding international (PCT) patent application. The claims are directed to the use of pemvidutide in methods for treating/reducing and/or maintaining reduced alcohol consumption. If issued, the patent(s) resulting from the pending application(s) have expiration date(s) of no earlier than March 2047, not giving effect to any potential extensions and assuming payment of all associated fees.

Use of pemvidutide in methods for treating ALD is further covered in a pending provisional patent application in the United States, owned by us and not subject to the Mederis IP License Agreement, and from which we expect to file a non-provisional application in the United States and a corresponding international (PCT) patent application. The claims are directed to the use of pemvidutide in methods for treatment of ALD and methods of reducing liver fibrosis. If issued, the patent(s) resulting from the pending application(s) have expiration date(s) of no earlier than March 2047, not giving effect to any potential extensions and assuming payment of all associated fees.

Use of pemvidutide in methods for treating MASH in a human with noncirrhotic liver fibrosis is further covered in a pending provisional patent application in the United States, owned by us and not subject to the Mederis IP License Agreement, and from which we expect to file a non-provisional application in the United States and a corresponding international (PCT) patent application. The claims are directed to the use of pemvidutide in achieving MASH resolution within at least 24 weeks. If issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than June 2047, not giving effect to any potential extensions and assuming payment of all associated fees.

The Company, via its wholly-owned subsidiary Spitfire Pharma, LLC, entered into a Collaboration and License Agreement with Adocia S.A. on December 24, 2024 under which the Company has exclusive rights to intellectual property pertaining to oral administration of pemvidutide, with patent applications pending, which if issued, would have an expiration date of no later than June 2043, and a US patent issuing in February 2026 that will have an expiration date no later than December 2044.

United States Government Regulation

The FDA regulates drugs and biological products under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), the Public Health Service Act ("PHS Act"), the regulations under Titles 21 and 42 of the Code of Federal Regulations (21 CFR and 42 CFR), as well as other federal, state and local statutes and regulations. The FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the testing, research, manufacturing, approval, safety, efficacy, labeling, packaging, storage, record keeping, distribution, import, export, reporting, sale, advertising and other promotional practices involving drugs and biological products. An IND application must be in effect before clinical testing of drugs and biological products can begin. FDA approval must be obtained before drugs and biological products can be marketed. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources, and each process may take several years to complete, although certain expedited programs potentially applicable to our product candidates, such as FDA fast track designation for certain new drugs with the potential to address unmet medical needs for certain serious or life-threatening conditions, may potentially expedite development and/or approval processes. Certain federal incentive programs are also potentially applicable to our product candidates, such as for "orphan drugs" that treat rare conditions. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our product candidates. In addition, the FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application

of the products. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval. In addition, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could adversely affect our ability to commercialize our product candidates.

Drug and Biological Products Development Process

The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies according to applicable good laboratory practices ("GLP"), applicable requirements for the humane use of laboratory animals, such as the Animal Welfare Act or other applicable regulations;
- submission to the FDA of an IND application which must become effective before human clinical trials may begin;
- obtaining approval by an independent Institutional Review Board ("IRB") at each clinical site before a clinical trial may be initiated at that site;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices ("GCP") and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed product for its intended use;
- submission to the FDA of a new drug application ("NDA") or biologics license application ("BLA") for marketing approval that includes substantial evidence of safety, purity and potency from results of clinical trials, as well as the results of preclinical testing, detailed information about the chemistry, manufacturing and controls, and proposed labeling and packaging for the product candidate;
- review of the product candidate by an FDA advisory committee, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product candidate is produced to assess compliance with cGMP and to confirm that the facilities, methods and controls are adequate to assure the product candidate's identity, strength, quality and purity;
- satisfactory completion of potential FDA audits of the preclinical study and clinical trial sites that generated the data in support of the NDA or BLA; and
- FDA review and approval, or licensure, of the NDA or BLA, including agreement on post-marketing commitments, if applicable.

Before testing any drug or biological product candidate in humans, the product candidate enters the preclinical study stage. Preclinical studies include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of certain preclinical studies must comply with federal regulations and requirements including GLP and the Animal Welfare Act.

The clinical trial sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical trial protocol, to the FDA as part of the IND. Some preclinical studies may continue even after the IND is submitted. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. The FDA may also place the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Even after the IND has gone into effect and clinical testing has begun, the FDA

may impose a partial or complete clinical hold on clinical trials due to safety concerns or non-compliance. A partial clinical hold can limit a trial, for example, to certain doses or for a certain length of time or to a certain number of subjects. A complete clinical hold order issued by the FDA would delay a proposed clinical study or suspend an ongoing study until all outstanding concerns have been adequately addressed and the FDA has notified the company that clinical investigations may proceed or resume. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once the trials have begun, issues will not arise that suspend or terminate such studies.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain AEs should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND during applicable phases of development. Clinical trials must be conducted and monitored in accordance with the FDA's regulations and GCP requirements, which establish standards for conducting, recording data from, and reporting the results of clinical trials, with the goals of assuring that the data and results are credible and accurate and that study participants' rights, safety, and well-being are protected. GCP requirements include the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. 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, not only from the investigational product itself but also from any required procedures or study visits to be conducted during the trial, are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

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

- *Phase 1*. The drug or biological product is initially introduced into a small group of healthy human subjects (e.g., 10 to 20 volunteers) and tested for safety and to develop detailed profiles of its pharmacological and pharmacokinetic actions, determine side effects associated with increasing doses, and, if possible, gain early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- *Phase 2*. The drug or biological product is evaluated in a larger but limited patient population (e.g., a few hundred patients with the disease or conduction under study) to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- *Phase 3*. These clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency and safety in an expanded patient population (e.g., several hundred to several thousand patients) at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit profile of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected AEs, any findings from other studies, tests in laboratory animals or in *vitro* testing and other sources that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within 7

calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biological product has been associated with unexpected serious harm to patients.

In limited circumstances, FDA also permits the administration of investigational small molecule drug or biological products to patients under its expanded access regulatory authorities. Under the FDA's expanded access authority, patients who are not able to participate in a clinical trial may be eligible for accessing investigational products, including through individual compassionate or emergency use in concert with their requesting physician. Additionally, a manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational drug or, as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

Concurrent with clinical trials, companies usually complete additional animal studies, develop additional information about the physical characteristics of the drug or biological product candidate and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final product. Additionally, 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.

Certain FDA programs are available to facilitate and expedite the development and review of new drugs intended to address unmet needs in the treatment of serious or life-threatening conditions. These expedited programs include fast track designation, breakthrough therapy designation, priority review and accelerated approval. Each of these programs has its own features and qualifying criteria.

The Fast Track designation program is intended to expedite or facilitate the process for reviewing new drug candidates that 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 drug candidate and the specific indication for which it is being studied. The sponsor of a Fast Track designated product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the drug candidate may be eligible for priority review. A Fast Track designated drug 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 NDA.

A drug 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 drug candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the drug 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 designation 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 drug candidate, including involvement of senior managers.

In addition, products tested for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a

surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, 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 disease and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on IMM or other clinical endpoint, and the drug or biologic may be subject to accelerated withdrawal procedures. Further, under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA must specify the conditions for any post-approval trials by the date of accelerated approval and the agency has flexibility in setting forth such conditions, which may include enrollment targets, clinical trial protocol and milestones – including the target date of trial completion. The FDA may also require, as appropriate, that certain confirmatory trials be underway prior to accelerated approval or within a specified time from the date of approval. Accelerated approval sponsors must submit progress reports every six months on required post-approval trials. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress.

A sponsor must submit a request for fast track designation, breakthrough therapy designation, or priority review, which may or may not be granted by the FDA. For fast track and breakthrough therapy designations, FDA may later decide the product no longer meets the conditions for designation and may rescind the designation. For accelerated approval, a sponsor generally discusses the possibility of accelerated approval with the FDA during development, and the FDA may or may not agree that accelerated approval is an appropriate pathway for a particular drug. Some of these expedited programs could potentially apply to our product candidates, although this cannot be assured, and we do not currently have any products with expedited program designations. Even if a product candidate obtains accelerated approval based on surrogate clinical endpoints, the sponsor of such product candidate is still required to complete a more extensive outcomes trial to obtain full regulatory approval. Such outcomes trial may not replicate the early positive results that supported the accelerated approval in which case the FDA will remove the accelerated approval.

The sponsor of a clinical trial or the sponsor's designated responsible party may be required to register certain information about the trial and disclose certain results on government websites, such as ClinicalTrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors and patients may use this publicly available information to gain knowledge regarding the progress of development programs. Failure to timely register a covered clinical study or to submit study results as provided for in the law could lead to consequences such as public notifications of noncompliance and civil monetary penalties.

Review and Approval Processes

After the completion of clinical trials of a drug or biological product candidate, the FDA's approval of an NDA or BLA must be obtained before commercial marketing of the product may begin. The NDA or BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, as amended, an NDA or BLA or supplement to an NDA or BLA generally must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers depending on the designated pathway for submission. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the NDA or BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each NDA or BLA must be accompanied by a significant application fee. PDUFA also imposes an annual prescription drug product program fee for biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Following submission of the application, the FDA reviews the NDA or BLA to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA or BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA or BLA. FDA performance goals generally provide for action on an NDA or BLA within 10 months of the 60-day filing date, which would be within 12 months of its submission. That deadline can be extended under certain circumstances, including by the FDA's requests for additional information. The targeted action date can also be shortened to 6 months of the 60-day filing date, or 8 months after submission, for products that are granted priority review designation because they are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure the product's identity, safety, quality, potency and purity. The FDA may refer applications for drugs or biological products that are novel or that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and 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.

During the NDA or BLA review process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to assure the safe use of the drug or biological product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required. A REMS 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. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products.

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the NDA or BLA unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the NDA or BLA does not satisfy its regulatory criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than how we interpret the same data. If the agency decides not to approve the NDA or BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes; or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant may take for the FDA to reconsider the application. If a complete response letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the complete response letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. In addition, the FDA may require post-marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized. Post-approval modifications to a drug product, such as changes in indications, labeling or manufacturing processes or facilities, may require development and submission of additional information or data in a new or supplemental NDA or BLA, which would also require prior FDA approval.

Post-Approval Requirements

After regulatory approval of a product is obtained, products are subject to extensive continuing regulation and post-approval requirements. For example, as a condition of approval of an NDA or BLA, the FDA may require post-marketing testing and surveillance to monitor the product's safety or efficacy. In addition, holders of an approved NDA or BLA are required to keep extensive records, submit annual reports, report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information, and comply with requirements concerning advertising and promotional labeling for their products.

In addition, quality control and manufacturing procedures must continue to conform to cGMP regulations and practices, as well as the manufacturing conditions of approval set forth in the NDA or BLA. Drug manufacturers and their subcontractors and those supplying products, ingredients, and components are required to register their establishments with the FDA and certain state agencies, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes certain procedural, substantive and recordkeeping requirements. Manufacturers and other parties involved in the drug supply chain for prescription drug products also must comply with product tracking and tracing requirements and notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. 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. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA or BLA), additional regulatory review and approval may be required.

Future FDA inspections may identify cGMP compliance issues at manufacturer facilities or at the facilities of third-party suppliers that may disrupt production or distribution or require substantial resources to correct and prevent recurrence of any deficiencies, and could result in fines or penalties by regulatory authorities. In addition, discovery of problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action, including warning letters, fines, injunctions, civil penalties, license revocations, seizure, total or partial suspension of production or criminal penalties, any of which could delay or prohibit further marketing. Newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications.

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

Certain U.S. Regulatory Incentives and Other Programs

Marketing Exclusivity and Patent Term Restoration

The Drug Price Competition and Patent Term Restoration Act of 1984, also referred to as the Hatch-Waxman Amendments, established certain periods of marketing exclusivity for new drugs approved by the FDA, including a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain 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 accept for review an abbreviated new drug application ("ANDA") or a 505(b)(2) NDA submitted by another applicant for such drug where the applicant does not own or have a right of reference to 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. The Hatch-Waxman Amendment also established a three-year period of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an 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 (e.g., new indications, dosages or strengths of an approved drug). This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active ingredient for other conditions of use.

Additionally, products approved under an NDA or BLA may qualify for the restoration of a portion of the patent term lost during product development and FDA review of the application, if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the NDA or BLA, plus the time between the date of submission of the NDA or BLA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration.

Pediatric Exclusivity

Drugs and biological products, such as our product candidates, may be eligible for pediatric exclusivity, an incentive intended to encourage medical product research for children. Pediatric exclusivity, if granted, may add six months to certain patents or regulatory exclusivity periods applicable to an approved drug and six months to regulatory exclusivity periods applicable to an approved biological product. This additional six months of exclusivity may be granted based on the completion of one or more pediatric trials in response to a Written Request from the FDA. It is possible, but not assured, that certain of our current or future product candidates may be targeted to pediatric populations.

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition" that affects fewer than 200,000 individuals in the United States, or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such a disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation can provide opportunities for grant funding toward clinical trial costs, tax advantages and FDA user fee exemptions. In addition, if a product that has an orphan drug designation subsequently receives FDA approval for the indication for which it has such designation, the product may be entitled to orphan drug exclusivity, which means the FDA would not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. It is possible, but not assured, that certain of our current or future product candidates may target rare diseases or conditions.

U.S. Regulations Affecting Health Care Companies

Pharmaceutical manufacturers with products that are reimbursed by U.S. federally funded health care programs such as Medicare and Medicaid are subject to so-called fraud and abuse laws including false claims and anti-kickback laws.

The federal Anti-Kickback Law prohibits anyone from, among other things, knowingly and willingly, directly or indirectly, soliciting, receiving, offering, or paying any remuneration with the intent of (or in return for) generating referrals of individuals or purchases, leases, orders, or arranging for the purchase, lease, or order of any healthcare item or service reimbursable by federal health care programs like Medicare and Medicaid. Courts have interpreted this law very broadly, including by holding that a violation has occurred if one purpose of the remuneration is to generate referrals even if there are other lawful purposes. Moreover, liability under the Anti-Kickback Law may be established without proving actual knowledge of the law or specific intent to violate. There are statutory exceptions and regulatory safe harbors that protect certain arrangements from prosecution or administrative sanctions, but the exceptions and safe harbors are drawn narrowly. The fact that an arrangement does not fall within a safe harbor does not necessarily render the conduct illegal under the Anti-Kickback Law, but the arrangement may be subject to scrutiny based on the facts and circumstances. Practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical products, including certain discounts, or engaging such individuals as consultants, advisors and speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Moreover, there are no safe harbors for many common practices, such as educational and research grants, charitable donations, product support and patient assistance programs. Violations of the Anti-Kickback Law may be punished by civil and criminal penalties, damages, fines, or exclusion from participation in

federal health care programs like Medicare and Medicaid. Many states have enacted similar laws, some of which apply regardless of payer.

The Federal civil False Claims Act ("FCA") prohibits any person from, among other things, knowingly presenting or causing to be presented a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to the federal government, or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay or transmit money or property to the government. The FCA is commonly enforced against those who submit allegedly false Medicare or Medicaid claims, as well as those who induce or assist others to submit a false claim. "False claims" can result not only from non-compliance with the express requirements of applicable governmental reimbursement programs, such as Medicaid or Medicare, but also from non-compliance with other laws, such as the Anti-Kickback Law or laws that require quality care in service delivery. Actions under the FCA may be brought by the government or by whistleblowers referred to as "relators," who may initiate an action in the name of the government and the individual and may share in any monetary recovery. Violations of the FCA can result in treble damages, mandatory per claim penalties, and exclusion from participation in federal health care programs. Most states have adopted similar state false claims laws, some of which are broader than the FCA, and these state laws have their own penalties which may be in addition to FCA penalties.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, significantly strengthened the FCA and federal Anti-Kickback Law provisions, which could lead to the possibility of increased whistleblower or relator suits, and among other things, made clear that a federal Anti-Kickback Law violation can be a basis for federal FCA liability. The bringing of any FCA or other enforcement investigation or action, even if unsuccessful, could require us to devote resources to investigate and defend the action, as well as result in reputational harm. Failure to comply with fraud and abuse laws could result in significant civil and criminal penalties and costs, including the loss of licenses and the ability to participate in federal and state health care programs, and could have a material adverse effect on our business. In addition, many of these laws are vague, subject to modification, and are subject to evolving interpretation by prosecutorial and regulatory authorities, increasing the risk of noncompliance. We cannot predict whether changes in applicable law, or interpretation of laws, or changes in our services or marketing practices in response to changes in applicable law or interpretation of laws, could have a material adverse effect on our business.

In addition to the above, several other laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. Some state laws restrict whether and when pharmaceutical companies may provide meals to health care professionals or engage in other marketing-related activities; some states require certain compliance program elements and disclosures; and certain states and cities require identification or licensing of sales representatives.

For example, the federal Health Insurance Portability and Accountability Act of 1996, and its implementing regulations (collectively, "HIPAA"), prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the Anti-Kickback Law, a person or entity can be found guilty of violating the HIPAA fraud statute without actual knowledge of the statute or specific intent to violate it. Violations of HIPAA fraud provisions may result in criminal, civil and administrative penalties, fines and damages, including exclusion from participation in federal healthcare programs.

Privacy Laws

In the U.S., we may be subject to data privacy and security laws and regulations by both the federal government and the states in which we conduct our business. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations now govern the collection, use, disclosure, and protection of personal information, including health-related information that we may collect in connection with clinical trials.

At the state level, the California Consumer Privacy Act ("CCPA"), for example, grants individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal information of consumers and households. The CCPA requires covered businesses to provide certain disclosures about its data collection, use and sharing practices, and provide specific notices and opt-out rights to consumers with respect to certain sales and transfers of their personal information. As of January 2026, more than a dozen other U.S. states have enacted similarly comprehensive privacy legislation. Several additional states passed laws specific to consumer health data, such as Washington's My Health My Data Act, and other state laws, such as the Texas Genomic Privacy Act, focus specifically on genetic information.

Additionally, HIPAA imposes requirements relating to the privacy, security and transmission of individually identifiable health information. While many consumer privacy laws contain exceptions for certain activities involving the processing of health information regulated under HIPAA, and for clinical trials conducted in accordance with federal regulations, this has become an increasingly complex regulatory landscape.

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

Outside of the U.S., the legislative and regulatory landscape for privacy and data security is just as complex. The General Data Protection Regulation in the EU and the U.K. and data protection laws in the U.K, for example, impose potentially significant fines, and laws and regulations enacted in Asia and Latin America increase potential enforcement and litigation activity.

Any associated claims, inquiries, or investigations or other actions under these laws could lead to significant penalties or fines, monetary judgments or settlements including criminal and civil liability.

U.S. Health Care Reform Law

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

For example, in the United States there is significant interest in promoting health care reform, as evidenced by the enactment in the United States of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Health Care Reform Law"). The Health Care Reform Law substantially changed the way health care is financed by both governmental and commercial payers and significantly impacts the pharmaceutical industry. The Health Care Reform Law contains provisions that may reduce the profitability of drug products, including, for example, by increasing the minimum rebates owed by manufacturers under the Medicaid Drug Rebate Program, extending the rebate program to individuals enrolled in Medicaid managed care plans, addressing 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, and imposing certain annual fees based on pharmaceutical companies' share of sales to federal health care programs.

The Health Care Reform Law established and provided significant funding for a new Patient-Centered Outcomes Research Institute to coordinate and fund comparative effectiveness research. While the stated intent of comparative effectiveness research is to develop information to guide providers to the most efficacious therapies, outcomes of comparative effectiveness research could influence the reimbursement or coverage for therapies that are determined to be less cost effective than others. Should any of our products be approved for sale, but then determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our financial results.

Certain provisions of the Health Care Reform Law have been subject to judicial challenges, as well as efforts to repeal, replace or otherwise modify them or to alter their interpretation or implementation. Additional legislative changes, regulatory changes and judicial challenges related to the Health Care Reform Law remain possible, but the nature and extent of such potential changes or challenges are uncertain at this time.

Another provision of the Health Care Reform Law, generally referred to as the Physician Payments Sunshine Act or Open Payments Program, requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), to certain non-physician providers such as physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives, and to teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations have been extended to include transfers of value made. CMS publishes information from these reports on a publicly available website. Our compliance with these rules may also impose additional costs and may impact our relationships with physicians, teaching hospitals and the other non-physician health care providers.

In addition, other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. For example, the Budget Control Act of 2011 and subsequent legislation led to aggregate reductions in Medicare payments for all items and services, including prescription drugs and biologics, to service providers of, on average, 2% per fiscal year through 2031.

As another example, the Inflation Reduction Act of 2022 ("IRA") includes several provisions that will impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new mandatory discounts from manufacturers under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost single-source drugs and biologics without generic competition, and require companies to pay rebates to Medicare for drug prices that increase faster than inflation. The IRA delays the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. The effect of IRA on our business and the healthcare industry in general is not yet known.

Additional legislative changes, regulatory changes or guidance could be adopted, or executive orders or other actions undertaken, which may impact the marketing approvals and reimbursement for our product candidates. The One Big Beautiful Bill Act of 2025 ("OBBBA"), for example, imposed significant reductions in Medicaid funding, additional work requirements for Medicaid recipients, and more frequent reenrollment requirements. These changes are expected to place substantial pressure on state Medicaid budgets, reduce enrollment, and limit covered services, which could decrease utilization of, and reimbursement for, our products, if approved.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. To date, there have been several recent U.S. congressional inquiries, as well as proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. The Trump Administration has issued executive orders and supported proposed regulatory initiatives in 2025 that could have a significant impact on the prices that we, or any collaborators, may receive for any approved products.

On May 12, 2025, President Trump signed an executive order directing the Secretary of HHS to set and communicate most-favored-nation ("MFN") price targets to manufacturers and propose a rulemaking plan to impose MFN pricing if "significant progress" is not made, and also directing the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. The executive order further states that the Administration will take additional action (for example, examining whether marketing approvals should be modified or rescinded or considering individual drug importation waiver authorities) should manufacturers fail to offer American consumers the MFN lowest price. In July 2025, President Trump sent letters to certain pharmaceutical companies demanding that these companies extend MFN pricing to Medicaid and newly launched drugs as well as move to direct-to-consumer models priced at MFN pricing, and soliciting binding commitments by September 29, 2025. Since this time, multiple drug manufacturers have announced plans to, for certain of their drugs, lower prices to reflect similar pricing around the world,

and to sell these reduced-price drugs on a direct-to-consumer purchasing platform developed by the federal government; however, it is not known what results will occur to the extent the recipients of these letters do not reduce their U.S. prices.

On December 19, 2025, CMS released two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs. The first proposal, the Global Benchmark for Efficient Drug Pricing Model ("GLOBE") for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GLOBE would begin a five year performance period on October 1, 2026 and GUARD would begin its performance period in 2027. These proposals will likely be subject to legal challenges that could delay their implementation or modify their impact on manufacturer pricing and revenue. Additionally, in November 2025, CMS introduced the GENErating cost Reductions fOr U.S. Medicaid ("GENEROUS") Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers.

Further, there has been increasing legislative, regulatory and enforcement interest in the United States with respect to drug pricing practices. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products.

It is possible that the Health Care Reform Law, as currently enacted or may be amended or otherwise modified in the future, as well as other health care reform measures that may be adopted in the future, may result in additional reductions in Medicare payment and other health care financing, more rigorous coverage criteria, and new payment methodologies and in additional downward pressure on coverage and payment and 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 payers. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. These continuing health care reform initiatives may adversely affect:

- the demand for any product candidates for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

Congress also could enact additional changes that affect our overall rebate liability and the information we report to the government as part of price reporting calculations. In addition, Congress could enact a drug price negotiation program under which the prices for certain high Medicare spend single source drugs would be capped by reference to the non-federal average manufacturer price. This or any other legislative change could impact the market conditions for our products. We further expect continued scrutiny on government price reporting and pricing more generally from Congress, agencies, and other bodies.

Coverage and Reimbursement

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

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

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines may be made by CMS. CMS decides whether and to what extent certain new medicines will be covered and reimbursed under Medicare and private payers tend to follow CMS to a substantial degree.

Environmental Regulations

We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential federal, state or local regulations. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and waste generated by our operations. Our research and development involve the controlled use of hazardous materials, chemicals and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources. Additionally, for formulations containing controlled substances, we are subject to Drug Enforcement Act regulations.

Pricing Regulations

There have been a number of federal and state legislative changes made over the last few years regarding the pricing of pharmaceutical and biological products, government control and other changes to the health care system of the United States. Concerns about drug pricing continue to be expressed by members of Congress and prior presidential administrations. It is uncertain how such legislative changes will be adopted or what actions federal, state or private payers for medical goods and services may take in response to such legislation. We cannot predict the effect such health care changes will have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

Non-U.S. Government Regulations

European Union Drug Development

Our products will also be subject to extensive regulatory requirements in the European Union ("EU"). As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained. See "European Marketing Authorization" below.

In the EU, the Clinical Trials Regulation 536/2014 has been applicable since January 31, 2022. The Clinical Trials Regulation repealed and replaced the Clinical Trials Directive, and introduced a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU, including a new coordinated procedure for authorization of clinical trials that will be conducted in multiple EU Member States, and increased obligations on sponsors to publish clinical trial results. The Regulation is directly applicable in all EU Member States (and so does not require national implementing legislation in each EU Member State) and aims at simplifying and streamlining the approval of clinical

studies in the EU. The main characteristics of the Regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System, or CTIS; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned) of a draft report prepared by a Reference Member State. Part II is assessed separately by each Member State concerned. Strict deadlines have also been established for the assessment of clinical trial applications.

Similar to the FDA, the European Medicines Agency's Committee for Medicinal Products for Human Use ("CHMP") has adopted ICH S6 (R1) as a guideline governing preclinical testing of biologics. Sponsors usually must conduct pharmacodynamic ("PD") studies, such as in *vitro* binding assays and in vivo studies that assess the product's pharmacologic activity and define its mechanism of action. Biologics typically undergo single- and repeat-dose toxicity studies using relevant species. Safety pharmacology studies, which evaluate the product's functional effects on major body systems and specific organs, and local tolerance testing can be done separately or subsumed in toxicity testing. Sponsors also usually conduct single- and multiple-dose pharmacokinetic ("PK") and/or toxicokinetic studies to assess absorption, disposition, exposure and clearance (in particular, antibody-mediated clearance), and explore dose-response relationships. This information is used to predict margins of safety for human studies. Immunogenicity testing might include screening and mechanistic studies.

Good Clinical Practices and Other Considerations for Clinical Trials

Clinical trials of medical products (including biologics) must comply with GCP, as described in Directive 2005/28/EC on Good Clinical Practice and the ICH E6 (R3) guideline, which the CHMP has adopted. The Directive and guideline describe general governing principles for clinical trials. The rights, safety and well-being of trial subjects must prevail over the interests of science and society. Investigators must obtain freely given informed consent from every trial subject before each subject is enrolled. Clinical trial information must be handled, recorded and stored with respect for relevant confidentiality and privacy rules. Trials must comply with the ethical principles of the World Medical Association's Declaration of Helsinki. Specific GCP guidelines apply to trials of advanced therapy medicinal products (i.e. gene therapy, somatic-cell therapy and tissue-engineered medicines). These guidelines regulate issues such as the donation, procurement and testing of human tissues and cells; the implementation of a traceability system; and specific rules on safety reporting and long-term follow-up. Under the Clinical Trials Regulation, special requirements apply to clinical trials conducted on minors and other persons not able to give informed legal consent. These requirements are intended to preserve the dignity of the trial subjects, confirm that the benefits of the trial outweigh the risks and ensure that subjects' representatives give consent with as much involvement of the subject as possible. CHMP has also issued a guideline on quality requirements during the clinical trial period for investigational medicinal products containing biological or biotechnology-derived substances. The guideline describes quality documentation that should be submitted to the competent authority as part of the sponsor's investigational medicinal product dossier ("IMPD"). The IMPD should include, among other things, (i) an adequate description of the process and process controls, including a flow chart of all successive steps and details of in-process testing and (ii) a description and justification of "any reprocessing during manufacture of the drug substance". The guideline also recognizes that sponsors will improve and optimize their manufacturing processes during clinical development and describes the steps sponsors should take following these changes. Specifically, the sponsor must compare the quality attributes of the pre- and post-change biological active substances and relevant intermediates and conduct a comparability exercise where necessary. For first-in-human clinical trials, sponsors should use product representative of the material used during the non-clinical testing phase. Finally, with regard to characterization, the guideline requires details on the biological activity to be provided, recognizing that the extent of characterization data will further increase in later phases.

Study Design Considerations

General regulatory guidance on study design applies to biologics as well as small molecule medicines. According to the guidance, there is a "close, but variable correlation" between phase of development and type of study, but one type of trial can occur in several different phases. The guidance therefore identifies the most typical kind of study for each phase.

Phase 1 usually involves the initial introduction of the investigational product into human subjects, and studies in this phase usually have non-therapeutic objectives. Specifically, Phase 1 studies typically investigate initial safety and tolerability, PK, PD and/or drug activity, to preliminarily determine the potential therapeutic benefit of a medicine. Phase 1 studies may be conducted in healthy volunteers or certain types of patients. If the medicine has significant potential toxicity (e.g., cytotoxic products), the trial will usually be conducted in patients.

The most typical Phase 2 study is a therapeutic exploratory study that explores efficacy in narrowly defined, relatively homogenous groups of patients. Initially, studies may use a variety of designs (e.g., concurrent controls and comparisons with baseline status). Subsequent Phase 2 trials usually are randomized and concurrently controlled, allowing for evaluation of the medicine's safety and efficacy for a particular indication. A major goal of this phase is to determine the dose(s) for Phase 3 trials.

Phase 3 typically involves therapeutic confirmatory studies that are designed to verify the preliminary evidence obtained in Phase 2 and to provide a sufficient basis for marketing authorization. Phase 3 studies may also further explore the dose response relationship, or explore the drug's use in wider populations, in different stages of disease, or in combination with another drug. With regard to medicines administered for long periods, extended exposure trials ordinarily occur during Phase 3, although the sponsor may start them in Phase 2.

To ensure that clinical trials in all three phases of development will be adequate to support a marketing authorization application ("MAA"), sponsors should design these trials with the MAA requirements in mind. Certain biologics products need to comply with the requirements set out in Part III of the Annex I to Directive 2003/63/EC (which amends the core EU medicines legislation, Directive 2001/83/EC), and advanced therapy medicinal products need to comply with the requirements described in Part IV of the Annex I to Directive 2003/63/EC.

Consultation with the European Medicines Agency

A sponsor may obtain, from the EMA, scientific advice regarding the development of a medicinal product. Although this advice does not bind the EMA and is not binding for purposes of a future MAA, it can be useful to guide developers generally in performing the appropriate preclinical and clinical tests for the product, or on more specific aspects such as guiding revisions to a clinical trial protocol. The EMA's remarks will only address scientific issues and will generally focus on matters such as the selection of endpoints and comparators, the duration of treatment or follow-up and the design of pivotal studies. Advice also might address a sponsor's proposal to deviate from a CHMP guideline. If the applicant decides not to follow the EMA's advice, it should justify this decision in its MAA. EMA guidance details the procedures for requesting scientific advice. The fact that an applicant requests advice from EMA does not preclude it from also seeking advice from national competent authorities or from foreign regulators, such as the FDA. The process of obtaining advice from the national competent authorities is often less formal than requesting advice from the EMA, and such advice can prove helpful. Consequently, seeking such advice is a common choice among marketing authorization applicants. Generally, the parallel scientific advice procedure (a program shared by the EMA and FDA) is available for "important medicinal products", that is, products that the EMA and FDA have identified as falling within therapeutic areas of overlapping interest (e.g., oncology products, vaccines and blood products) or products being developed for indications lacking development guidelines. The goal of these meetings is to provide clarity regarding the regulatory requirements of each region and the reasons for any differences between them. A sponsor requesting parallel scientific advice should authorize the agencies to exchange all information about the product, including trade secrets. After the parallel scientific advice procedure, each agency will provide its own independent advice on the questions at issue. There is no guarantee of harmonized advice or identical regulatory decisions on the approvability of the product.

European Marketing Authorization

In the European Economic Area ("EEA"), which includes the 27 member states of the EU plus Norway, Iceland and Liechtenstein, medicinal products can only be placed on the market after the grant of a marketing authorization. The MAA is based on the results of pharmaceutical tests, preclinical tests and clinical trials conducted on the medicinal product in question. There are two types of marketing authorizations:

- The centralized marketing authorization, which is issued by the European Commission through the centralized procedure, based on the opinion of the CHMP and which is valid throughout the entire territory

of the EEA. The centralized procedure is mandatory for certain types of drugs, such as medicinal products derived from biotechnology processes (such as genetic engineering), orphan medicinal products, advanced-therapy medicinal products and medicinal products containing new active substances indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. . The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. To find out whether a product can be evaluated via the centralized procedure, applicants should submit an eligibility request to the EMA, including by a justification of eligibility for evaluation under the centralized procedure.

- National marketing authorizations, which are issued by the competent authorities of the member states of the EEA and only cover their respective territory, are available for medicinal products not falling within the mandatory scope of the centralized procedure. Where a drug has already been authorized for marketing in a member state of the EEA, this national marketing authorization can be recognized in other member states through the mutual recognition procedure. If the drug has not received a national marketing authorization in any member state at the time of application, it can be approved by multiple member states in parallel through the decentralized procedure.

Under the procedures described above, before granting a marketing authorization, the EMA (through the CHMP) or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the medicinal product on the basis of scientific criteria concerning its quality, safety and efficacy.

The Marketing Authorization Application: Contents and Approval Standard

Many biologics fall under the scope of the centralized procedure, which, as mentioned above, is mandatory for medicines developed through biotechnological methods, such as recombinant DNA technology; controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells; and hybridoma and mAb methods. Gene therapy and cell therapy products are also subject to the centralized procedure as advanced therapy medicinal products. Nonetheless, some biologics are still approved at the member state level. For example, certain types of vaccines do not fall within the mandatory scope of the centralized procedure (although they may be eligible for the centralized procedure in the interest of public health). The EMA has published a guideline intended to harmonize the quality aspects to be included in summaries of product characteristics and patient information leaflets for human vaccines.

With respect to the centralized procedure, the approval standards for biotechnology products are the same as for chemically synthesized medicines. Both types of products must be safe and effective and have appropriate quality. Because of their special characteristics, however, biotechnology products must comply with several additional dossier requirements. For example, the applicant must thoroughly describe the manufacturing process and must: (i) provide information on the origin and history of the starting materials; (ii) demonstrate that the active substance complies with specific measures for preventing the transmission of animal and human spongiform encephalopathies; (iii) if cell banks are used, demonstrate that cell characteristics remain unchanged at the passage level for production (and beyond); (iv) provide information as to whether there are adventitious agents in seed materials, cell banks, pools of serum or plasma, and all other materials of biological origin, and, if it is not possible to avoid the presence of potentially pathogenic adventitious agents, show that further processing ensures elimination or inactivation of the agents; (v) if possible, base vaccine production on a seed lot system and established cell banks; (vi) in case of medicines derived from human blood or plasma, describe the origin, criteria and procedures for the collection, transportation and storage of the starting material; and (vii) describe the manufacturing facilities and equipment. Other special rules apply to certain types of biological medicines. For example, for plasma-derived medicinal products, the applicant must provide an information dossier, the Plasma Master File. MAAs for vaccines other than for influenza need to contain a Vaccine Antigen Master File. Special rules also apply to advanced therapy medicinal products, including gene therapies, somatic cell therapies and tissue-engineered products.

Data and Market Exclusivity in the European Union

In the EU, new chemical entities (including both small molecules and biological medicinal products), sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity prevents generic applicants from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic marketing authorization, for a period of eight years from the date on which the reference product was first authorized in the EU. After such eight year period, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed for a further two years. The overall ten-year period may be extended to a maximum of 11 years if, during the period of data exclusivity, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if an innovative medicinal product gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained a marketing authorization based on an application with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Orphan Designation in the European Union

The European Commission is also able to grant orphan designation in respect of medicinal products. To qualify the medicinal product must be intended for the diagnosis, prevention or treatment of (i) a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the EU or (ii) a life-threatening, seriously debilitating or serious and chronic condition in the EU where without incentives it is unlikely that the marketing of the medicinal product in the EU would generate sufficient return to justify the necessary investment in its development. Further, no satisfactory method of diagnosis, prevention or treatment of the condition in question must exist in the EU or, if such method exists, the medicinal product must be of significant benefit to those affected by the condition.

Orphan medicinal products still remain subject to the same regulatory approval process, albeit that they are always assessed through the centralized procedure. Sponsors applying for orphan designation must use EMA's secure online IRIS platform. However, sponsors of orphan medicinal products are eligible to benefit from a number of incentives offered, including certain assistance with development of the medicinal product, reduced fees for MAAs and protection from market competition once the medicinal product is authorized, as described below.

Where a marketing authorization in respect of an orphan medicinal product is granted, the European Commission, EMA and the competent authorities of the EU member states shall not, for a period of ten years, accept another application for a marketing authorization or grant a marketing authorization or accept an application to extend an existing authorization, for the same therapeutic indication, in respect of a similar medicinal product, to an authorized orphan product unless: (i) the holder of the marketing authorization for the original orphan medicinal product has given its consent to the second applicant; (ii) the holder of the marketing authorization for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product; or (iii) the second applicant can establish that its product is safer, more effective or otherwise clinically superior to the authorized orphan product. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication.

All of the aforementioned EU rules are generally applicable in the EEA.

Reform of the Regulatory Framework in the European Union

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). In April 2024, the European Parliament adopted its position on the legislative proposals and, in June 2025, the Council of the European Union adopted its position. A common position on the text has been agreed upon on December 11, 2025, in the context of subsequent inter-institutional trilogue negotiations. The proposed revisions remain to be adopted, and are not expected to become applicable before 2028.

Brexit and the Regulatory Framework in the United Kingdom

Following the end of the Brexit transition period on January 1, 2021 and the implementation of the Windsor Framework on January 1, 2025, the United Kingdom, or UK, is generally no longer subject to EU laws in respect of medicines. EU laws that were transposed into UK law through secondary legislation remain applicable in the UK; however, new EU legislation, such as the EU Clinical Trials Regulation, is not applicable in the UK. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, is 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 England, Wales, and Scotland (together, "Great Britain", or GB) for a period following Brexit, with Northern Ireland continuing to follow certain aspects of the EU regulatory regime. However, on January 1, 2025, a new arrangement called the "Windsor Framework" came into effect and placed medicinal products supplied to Northern Ireland largely under the regulatory authority of the MHRA. The Windsor Framework removes EU licensing processes and certain EU labeling and serialization requirements for medicines supplied to Northern Ireland and introduces a UK-wide licensing process for medicines. In particular, the MHRA is responsible for approving medicinal products placed on the UK market, and the EMA no longer has a role in granting UK marketing authorizations. A single UK-wide MA will be granted by the MHRA for medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. In addition, the new arrangements require, for packs placed on the UK market on or after January 1, 2025, a "UK Only" label, indicating they are not for sale in the EU. However, although a separate authorization is required to market medicinal products in the UK, since January 1, 2024, the MHRA may rely on the International Recognition Procedure, or IRP, when reviewing certain types of MAAs. Pursuant to the IRP, the MHRA may take into account the expertise and decision-making of trusted regulatory partners (e.g., the medicines regulatory authorities in Australia, Canada, Switzerland, Singapore, Japan, the United States and the EMA in the EU), when considering an application for a UK marketing authorization.

Other government regulation in the European Union and United Kingdom

The EU and the EU member states and the U.K. have extensive laws and regulations relating to a variety of other topics that would be of relevance for us if we are active in the EU and U.K., including but not limited to laws and regulations regarding data privacy, drug pricing and reimbursement, advertising and interactions with healthcare professionals.

Other Jurisdictions

In addition to regulations in the United States and the EU, we may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our product. As the United Kingdom is no longer a member state of the EU, this may also apply to the United Kingdom. Whether or not we obtain FDA approval for a product, we must obtain approval from comparable regulatory authorities in foreign countries before we can commence clinical trials in such countries and the approval of the regulators of foreign countries before we may market products in such countries. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Acceptance of Foreign Clinical Trials in the United States and the European Union

The FDA has issued regulations governing its acceptance of foreign clinical data not conducted under an IND to support IND applications or marketing authorizations, such as BLAs. FDA may accept a well-designed, well-conducted, non-IND foreign study as support for an IND or marketing application if the study was conducted in accordance with GCP and if FDA is able to validate the data from the study through an onsite inspection, if necessary. Where a marketing application is based solely on foreign data, additional requirements apply, including a demonstration that the foreign data are applicable to the U.S. population and U.S. medical practice.

EU Directive 2001/83/EC allows for clinical trials conducted outside the EU to be taken into consideration during the review of a marketing authorization in the EU if such trials have been designed, implemented and reported based on principles equivalent to those of the EU Clinical Trials Regulation, including with regard to good clinical practice and ethical principles. Moreover, they should comply with the ethical principles outlined in the Declaration of Helsinki. The

applicant must submit a statement declaring such compliance as part of the marketing authorization. In April 2012, the EMA published a reflection paper on ethical and GCP aspects of clinical trials of medicinal products conducted outside the EU/EEA and submitted in MAAs to EU regulatory authorities. The EMA has called for increased cooperation between international regulatory authorities involved in the supervision of clinical trials and has put forth other proposals to address these issues.

Manufacturing and Source of Supply

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical studies and clinical trials, as well as for commercial manufacture if our product candidates receive marketing approval. To date, we have obtained materials for clinical trials and non-clinical studies from third-party manufacturers who are suppliers to us. We intend to identify and qualify additional contract manufacturers to provide commercial scale manufacturing prior to submission of an NDA or BLA to the FDA.

Employees and Human Capital Management

As of December 31, 2025, we had 57 full-time employees, 16 of whom hold M.D. or Ph.D. degrees and 23 of whom hold other advanced degrees. Of our total workforce, the majority are engaged primarily in research and development, and the remainder are engaged primarily in executive, finance and accounting, and administrative functions. As of December 31, 2025, 56 employees are located in the United States and 1 employee is located in the United Kingdom. None of our employees are represented by labor unions or covered by collective bargaining agreements.

Corporate Culture

Our values – commitment, communicate, collaborate, competence and courage – are built on the foundation that the employees we hire, and the way we treat one another, promote creativity, innovation and productivity, which spur our success. This culture depends in large part on our ability to attract, retain and develop a diverse population of talents and high-performing employees at all levels of our organization. Providing market competitive pay and benefit programs, opportunities to participate in the success they help create, while engaging employees in important dialogue regarding organization performance, we create a culture of inclusion in which all colleagues have the opportunity to thrive. The success of our business is fundamentally connected to the well-being of our employees.

Compensation and Benefits Program

Our compensation program is designed to attract and reward talented individuals who possess the skills necessary to support our business objectives, assist in the achievement of our strategic goals and create long-term value for our stockholders. We provide all of our employees with what we consider to be a very competitive mix of compensation and insurance benefits, as well as participation in our equity programs.

Hybrid Culture

Currently we have a hybrid workplace, which means that we evaluate and determine the optimal work arrangements for our employees on an individual basis including full-time in office, part-time in office or remote depending on our needs and the responsibilities of each employee. This approach allows us to maintain flexibility and retain the best talent for the roles that are the most critical to our strategy and success.

Available Information

Our stock is traded on the Nasdaq Global Market (“Nasdaq”) under the symbol “ALT”. Our principal executive offices located at 910 Clopper Road, Suite 201S, Gaithersburg, Maryland 20878. Our telephone number is (240) 654-1450, and our Internet website is www.altimmune.com and our investor relations website is located under the “Investors” tab. The information on, or that can be accessed through, our website is not part of this Annual Report and is not incorporated by reference herein.

We make available our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, and amendments to these reports, free of charge through our website (www.altimmune.com) as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We also make available on our website reports filed by our executive officers and Directors on Forms 3, 4, and 5 regarding their ownership of our securities. Our Code of Business Conduct and Ethics, and any amendments to our Code of Business Conduct and Ethics, are also available on our website under the "Investors" tab.

The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov.

Item 1A. Risk Factors

In addition to the other information included in this Annual Report, the following risk factors should be carefully considered when evaluating an investment in us. These risk factors and other uncertainties may cause our actual future results or performance to differ materially from any future results or performance expressed or implied in the forward-looking statements contained in this report and in other public statements we make. In addition, because of these risks and uncertainties, as well as other variables affecting our operating results, our past financial performance is not necessarily indicative of future performance. See "Forward-Looking statements" in Item 1 of this Annual Report.

Risks Related to Our Business, Financing Requirements, Product Development and Clinical Trials

We have incurred significant losses since our founding and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are a late clinical-stage biotechnology company and have not yet generated revenues from product sales. To date, substantially all of our revenues have been derived from past grants and contracts with governmental agencies. We have incurred net losses in most periods since our inception, including a net loss of $88.1 million and $95.1 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we have an accumulated deficit of $649.5 million. To date, we have not received regulatory approvals for any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. We do not know whether or when we will generate product revenues or become profitable.

We have devoted most of our financial resources to research and development, including preclinical and clinical development of our product candidates. We have not completed pivotal clinical trials for any product candidate. Our lead product candidate, pemvidutide, has completed Phase 2 development, and we are planning for Phase 3 clinical development but it may be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, our ability to achieve sufficient market acceptance, reimbursement from third-party payers and other factors.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

Our profitability depends on our ability to develop and commercialize our current and future product candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing products 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, forming strategic partnerships and alliances with third parties and manufacturing, marketing and selling any products for which we may obtain regulatory approval. 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 revenues that are significant enough to achieve profitability. If some or all of our product candidates do not prove to be safe, pure and efficacious, then we may have to abandon those product candidates altogether and we will be unable to generate revenues from sales of such products.

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

- continue our development work for our clinical programs;
- initiate additional preclinical studies, clinical trials or other studies or trials for our other product candidates;
- manufacture material for clinical trials and, if any product candidate is approved for marketing, for commercial sale;

- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to discover and develop additional product candidates;
- acquire or in-license other product candidates and technologies;
- make royalty, milestone or other payments under any in-license agreements;
- form strategic partnerships and/or make additional acquisitions;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or other regulatory authorities to perform studies in addition to those currently expected, if there are any delays in completing our clinical trials or the development of any of our product candidates, or if we choose to perform additional studies for marketing purposes our expenses could increase.

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 the value of our company 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 are currently in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by current regulatory activities and economic policies and events related thereto, ongoing military conflicts and geopolitical instability and inflation and interest rates.

U.S. and global markets have recently experienced volatility and disruption caused by economic uncertainty, including as a result of international trade disputes, ongoing military disputes and related geopolitical uncertainty. International trade disputes, including threatened or implemented tariffs by the Trump administration and threatened or implemented tariffs by foreign countries in retaliation, could adversely impact our business. Trade disputes could also adversely impact supply chains which could now or in the future increase costs for us or delay delivery of key inventories and supplies. Trade and other geopolitical disputes can also be highly disruptive to global financial markets. The length and impact of the ongoing trade disputes and military conflicts are highly unpredictable. We are continuing to monitor the trade disputes, inflation, interest rates and military conflicts and the impacts to global capital markets and to our business.

Future conditions might require us to make substantial write-downs in our assets, which would adversely affect our balance sheet and results of operations.

We review our long-lived tangible assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Significant write-downs of our long-lived assets in the future could adversely affect our balance sheet and results of operations.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed would force us to delay, limit, reduce or terminate our product development or commercialization efforts.

We do not expect to generate revenue from product sales, licensing fees, royalties, milestones, contract research or other sources in an amount sufficient to fully fund our operations for the foreseeable future, if ever. Therefore, we will use our existing cash resources, and will require additional funds to maintain our operations, continue our research and development programs, commence future preclinical studies and clinical trials, seek regulatory approvals and manufacture and market our products. As of December 31, 2025, our cash, cash equivalents, restricted cash and short-term investments were $273.5 million. Based on our current operating plan, we believe that our existing cash will be sufficient to fund our projected operating expenses and capital expenditure requirements for at least a twelve-month period from the issuance date of our December 31, 2025 financial statements. However, we do not expect that these funds will be sufficient to enable us to complete the clinical trials needed to seek marketing approval or commercialize any of our product candidates. Furthermore, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned.

We believe that we will continue to expend substantial resources for the foreseeable future developing our product candidates. These expenditures will include costs associated with research and development, maintaining our intellectual property estate, potentially acquiring new technologies, obtaining regulatory approvals and manufacturing products, forming partnerships and strategic alliances, as well as marketing and selling products approved for sale, if any. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the progress, results and costs of our clinical trials for our leading product candidate;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the amount of funding that we receive from other non-dilutive funding sources;
- the number and development requirements of other product candidates that we pursue;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if clinical trials are successful and the outcome of regulatory review of our product candidates;
- our ability to contract with third-party manufacturing facilities for adequate supply and to establish processes that meet regulatory requirements for commercialization;
- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements; and
- the costs involved in preparing, filing and prosecuting patent applications, and maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of such litigation.

We may also 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. Additional funds may not be available when we

need them on terms that are acceptable to us, or at all. If adequate funds are not available to us when needed, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

Our ability to raise capital may be limited by applicable laws and regulations.

Using a shelf registration statement on Form S-3 to raise additional capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S-1 registration statement. However, our ability to raise capital using a shelf registration statement may be limited by, among other things, SEC rules and regulations. Under SEC rules and regulations, if our public float (the market value of our common stock held by non-affiliates) is less than $75.0 million, then the aggregate market value of securities sold by us or on our behalf under our Form S-3 in any 12-month period is limited to an aggregate of one-third of our public float. While our public float is currently more than $75.0 million, we have been subject to this limitation in the past and we may be subject to it again in the future. If our ability to utilize a Form S-3 registration statement for a primary offering of our securities is limited to one-third of our public float, we may conduct such an offering pursuant to an exemption from registration under the Securities Act or under a Form S-1 registration statement, and we would expect either of those alternatives to increase the cost of raising additional capital relative to utilizing a Form S-3 registration statement.

Our ability to timely raise sufficient additional capital also may be limited by Nasdaq's stockholder approval requirements for transactions involving the issuance of our common stock or securities convertible into our common stock. For instance, Nasdaq requires that we obtain stockholder approval of any transaction involving the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value, which (together with sales by our officers, directors and principal stockholders) equals 20% or more of our then outstanding common stock, unless the transaction is considered a "public offering" by Nasdaq. In addition, certain prior sales by us may be aggregated with any offering we may propose in the future, further limiting the amount we could raise in any future offering without stockholder approval. Nasdaq also requires that we obtain stockholder approval if the issuance or potential issuance of additional shares will be considered by Nasdaq to result in a change of control of our company.

Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval for a potential transaction, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital or alter the terms of the transaction, which may materially and adversely affect our ability to execute our business strategy, and there is no guarantee our stockholders ultimately would approve a proposed transaction.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, and license and development agreements through strategic partnerships with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt or preferred stock financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, issuing additional equity, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies or product candidates, future revenue streams, research programs or product candidates, or otherwise grant licenses on terms that are not favorable. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our leading product candidates or our preclinical product candidates, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our product candidates are still in development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenue.

Our preclinical and clinical results are not necessarily predictive of the final results of our ongoing or future clinical trials. Success in preclinical and early clinical studies may not be predictive of similar results in humans during later clinical trials, and successful results from early or small clinical trials of a product candidate may not be replicated in later and larger clinical trials.

Clinical trials are expensive, time consuming and uncertain as to outcome, and we cannot guarantee that any of these activities will be successful. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet our clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates, or we may determine to suspend development of or abandon specific product candidates.

In addition, we can offer no assurances that we have correctly estimated the resources or personnel necessary to seek partners, co-developers or acquirers for our programs. If a larger workforce or one with a different skillset is ultimately required to maintain or build these operations, we may be unable to maximize our existing programs.

Interim and preliminary results 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 additional audit, validation and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim data, including top-line or preliminary data from our preclinical studies and clinical trials. Any interim data and other results from our preclinical studies and clinical trials may materially change as more data become available. We also may make assumptions, estimations, calculations and conclusions as part of our analyses of preliminary or topline data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Preliminary or top-line results also remain subject to audit, validation and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. We may also arrive at different conclusions, or considerations may qualify such results, once we have received and fully evaluated additional data. Material differences between preliminary or interim data and final data could adversely affect our business.

The manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to acquisition of materials, process development or scaling-up of our manufacturing capabilities.

The manufacture of our product candidates is complex, highly regulated and subject to multiple risks. The complex processes associated with the manufacture of our product candidates expose us to various manufacturing challenges and risks, which may include delays in manufacturing our product candidates, limits on our ability to increase manufacturing capacity, and the potential for product failure and product variation that may interfere with our clinical development plans and add additional costs. It is possible that we will make changes to our manufacturing process at various points during product development or commercialization for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes can be costly and carry the risk that they will not achieve their intended objectives, or these changes could cause our product candidates to perform differently and affect the results of current or future clinical trials, or the performance of a commercialized product. In some circumstances, changes in the manufacturing process may require us to perform analytical or clinical comparability studies and to collect additional data prior to undertaking more advanced clinical trials, and such studies may introduce additional costs or delays to the program. We may be required to collect additional clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If clinical data are not ultimately comparable to that seen in the earlier trials in terms of safety or efficacy, we may be required to make further changes to our process and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate.

Compliance with cGMP requirements and other quality or regulatory issues may arise with our current or any future contract manufacturing organizations ("CMOs"). Furthermore, ongoing stability studies subsequent to manufacture must be periodically conducted to demonstrate that each of our product candidates do not undergo unacceptable deterioration over its shelf life. If issues affecting the quality of our product candidates or those of our CMOs are discovered, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the issue. To the extent any adversely affected material is being used in an ongoing clinical trial, the FDA could impose a clinical hold on our trial to investigate and remedy the quality issue. We cannot assure that any manufactured product or product candidate will not suffer a loss in stability or that other issues relating to the manufacture of our product candidates will not occur in the future.

Additionally, our CMOs may experience manufacturing difficulties due to regulatory issues, resource constraints, including manufacturing capacity, material constraints, or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

We may encounter substantial delays in our clinical trials, or our clinical trials may fail to demonstrate the safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, time consuming and uncertain as to outcome. We cannot guarantee that clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays or failure in reaching a consensus with regulatory agencies on trial design;
- delays or failure in reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which may vary significantly among different CROs and clinical trial sites;
- delays or failure in obtaining required approvals from the IRB or other similar committees or bodies at each clinical trial site;
- imposition of a clinical hold by regulatory agencies for any reason, including safety concerns raised by other clinical trials of similar product candidates that may reflect an unacceptable risk with the patient population, technology platform, product stability, or after an inspection of clinical operations or trial sites;
- deviations from the trial protocol by clinical trial sites and investigators, or failure to perform clinical trials in accordance with the FDA's GCP or applicable regulatory guidelines in other relevant countries;
- delays or failure in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites, including as a result of supply chain delays in obtaining materials for the manufacture of our clinical trial materials;
- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate or participants may withdraw from our clinical trials, fail to complete dosing or fail to return for post-treatment follow-up at higher rates than we anticipate, any of which could result in significant delay;
- delays in initiating clinical trial sites or withdrawal of clinical trial sites from our clinical trials, including as a result of changing standards of care or the ineligibility of a site to participate;
- occurrence of serious adverse events in clinical trials that are associated with the product candidate that are viewed to outweigh its potential benefits;

- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators or funders may require us, to conduct additional preclinical testing or clinical trials or to abandon projects that we expected to be promising;
- our third-party contractors (such as CROs, product manufacturers, or investigators) may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- fraudulent activity by a clinical researcher, if discovered, could preclude the submission of clinical data prepared by that researcher and/or lead to the suspension of substantive scientific review of one or more of our marketing applications by regulatory agencies;
- the cost of our clinical trials may be greater than we anticipate;
- additional trials may be necessary, including trials to analyze different dose strengths or dosing schemes;
- the regulatory requirements for product approval may not be explicit, may evolve over time and may diverge by jurisdiction;
- evolution in the standard of care that require amendments to ongoing clinical trials and/or the conduct of additional preclinical studies or clinical trials; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

We, the FDA, other regulatory authorities outside the United States, or an IRB may suspend a clinical trial at any time for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks or if the FDA or one or more other regulatory authorities outside the United States find deficiencies in our IND or similar application outside the United States or the conduct of the trial. Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial.

We cannot give any assurance that we will be able to resolve any future clinical holds imposed by the FDA or other regulatory authorities outside of the United States, or any delay caused by manufacturing failures or other factors described above or any other factors, on a timely basis or at all. If we are not able to successfully initiate and complete clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize our product candidates.

Even if our clinical trials are successfully completed as planned, the results may not support approval of our product candidates under the laws and regulations of the FDA or other regulatory authorities outside the United States. The clinical trial process may fail to demonstrate that our product candidates are both safe and effective for their intended uses. Pre-clinical and clinical data and analyses are often able to be interpreted in different ways. Even if we view our results favorably, if a regulatory authority has a different view, we may still fail to obtain regulatory approval of our product candidates. This, in turn, would significantly adversely affect our business prospects.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying subjects to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit eligible subjects to participate in testing our product candidates. If subjects are unwilling to participate in our trials due to restrictions on travel or healthcare institution policies, negative publicity from adverse events in the biotechnology industries or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting subjects, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of eligible subjects, or those with required or desired characteristics to achieve diversity in a trial, to complete our clinical trials in a timely manner. Subject enrollment and retention is affected by several factors, including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate being tested;
- willingness or availability of subjects to participate in our clinical trials;
- proximity and availability of clinical trial sites for prospective subjects;
- our ability to recruit clinical trial investigators with appropriate competencies and experience;
- availability of competing therapies and related clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- our ability to obtain and maintain subject consents;
- patient referral practices of physicians; and
- ability to monitor subjects adequately during and after treatment.

We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible subjects to participate in the clinical trials required by regulatory agencies. Even if we enroll a sufficient number of eligible subjects to initiate our clinical trials, we may be unable to maintain participation of these subjects throughout the course of the clinical trial as required by the clinical trial protocol, in which event we may be unable to use the research results from those subjects. If we have difficulty enrolling and maintaining the enrollment of a sufficient number of subjects to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

It may be difficult to predict the time and cost of product development for our product candidates, and unforeseen problems may prevent further development or approval of our product candidates.

Because our product candidates involve novel therapeutic approaches, it may be difficult to predict the time and cost of product development. Unforeseen problems with our approaches to therapies may prevent further development or approval of our product candidates. Because of the novelty of our approaches, there may be unknown safety risks associated with the therapies that we develop or the clinical endpoints that we establish in trials may not be generally accepted by regulatory agencies, which may therefore require us to perform large field studies to demonstrate efficacy. There can be no assurance that any development problems we may experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved.

We rely, and expect to continue to rely, on third parties to conduct preclinical studies and clinical trials for our product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates.

We rely, and expect to continue to rely, on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators to assist in managing, monitoring and otherwise carrying out our clinical trials. We compete with many other companies for the resources of these third parties. The third parties on whom we rely

generally may terminate their engagements at any time and causing us to enter into alternative arrangements would delay development and commercialization of our product candidates.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, the FDA and foreign regulatory authorities require compliance with applicable law, regulations and standards, including GCP, for designing, conducting, monitoring, recording, analyzing and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials complies with GCP requirements. Although we rely on third parties to conduct our clinical trials, we are responsible for ensuring that each of these clinical trials is conducted in accordance with applicable law, regulations and standards, including our general investigational plan and protocol.

Furthermore, if these third parties do not successfully carry out their duties under their agreements, if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to clinical trial protocols or to regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, then the clinical trials of our product candidates may not meet regulatory requirements. If clinical trials do not meet regulatory requirements or if these third parties need to be replaced, then preclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates on a timely basis or at all.

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

If any of our relationships with these third parties terminates, we may not be able to enter into arrangements with alternative third parties or to do so on commercially reasonable terms. Switching or adding additional third-party service providers involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third-party service provider begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines.

We face substantial competition from other pharmaceutical and biotechnology companies, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.

The development and commercialization of new drug products is highly competitive. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of our product candidates. Our objective is to design, develop and commercialize new products with superior efficacy, convenience, tolerability and safety. In many cases, the products that we intend to commercialize, if successfully commercialized, will compete with existing market-leading products.

Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products.

Large and established companies such as Eli Lilly, Roche, Novo Nordisk, Pfizer, AstraZeneca, Amgen, Boehringer Ingelheim and Merck, among others, compete in the same general therapeutic areas as our product programs. These companies compete with us with their greater experience and resources to support their research and development efforts, conduct testing and clinical trials, obtain regulatory approvals to market products, manufacture such products on a broad scale and market approved products. These companies also compete with us by having significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the products that we develop obsolete. We also face competition from smaller companies who, like us, rely on investors to fund research and development and compete for co-development and licensing opportunities from large and established pharmaceutical companies.

We face competition for pemvidutide, our glucagon/GLP-1 dual agonist for the treatment of MASH from companies such as Madrigal Pharmaceuticals, Aligos and Viking Therapeutics, which are developing orally administered, thyroid hormone receptor ("THR") β-selective agonists; Novo Nordisk, Roche, and GSK, which are developing fibroblast growth factor 21 ("FGF-21") analogs; Novo Nordisk, which is developing a GLP-1 agonist; Merck/Hanmi Pharmaceutical and Boehringer Ingelheim, which are developing GLP-1/glucagon dual agonists; Eli Lilly, which is developing a GIP/GLP-1 dual agonist and a GIP/GLP-1/glucagon triple agonist; Roche which is developing a GLP-1/GIP dual agonist; AstraZeneca developing a GLP-1/glucagon and amylin combination; Inventiva, which is developing a pan-peroxisome proliferator-activated receptor ("PPAR") agonist; Sagimet which is developing a fatty acid synthetase inhibitor, Apollo Therapeutics Group Limited/HEC Pharma which is developing a GLP-1/FGF-21dual agonist; and Pfizer, Roche, Gilead, AstraZeneca, and Eli Lilly, which are developing small molecule GLP-1 agonists. In addition, many other small companies are developing other new technologies directed towards MASH.

Similarly, we face competition for pemvidutide in the AUD and ALD markets. In ALD, GSK is developing GSK4532990, an RNAi targeting HSD17B13; Novo Nordisk is developing NNC0194-0499 (FGF-21), cagrilintide (long acting amylin analogue) and semaglutide (GLP-1). In AUD, Alkermes' vivitrol is an approved product in this market; generic products such as naltrexone, acamprosate and disulfiram are also available; and Eli Lilly is developing mazdutide, a GLP-1/Glucagon dual agonist and brenipatide, a GLP-1/GIP dual agonist. We similarly face competition from smaller entrants in AUD; Adial is developing a serotonin-3 receptor antagonist targeting AG+ genotype AD-04, Imbrium is developing sunobinop, a NOP agonist, and Solvonis is developing SVN-001 for AUD in European markets.

As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing products before we do. In addition, any new product that we develop that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow, and our financial condition and operations will suffer.

We are heavily dependent on the success of our leading product candidate, pemvidutide. If we ultimately are unable to develop, obtain regulatory approval for or commercialize pemvidutide, or any other product candidate, our business will be substantially harmed.

We currently have no products approved for commercial distribution. Our business strategy is to build a pipeline of product candidates using our proprietary platforms, including our leading product candidate, pemvidutide, and to progress the product candidate through clinical development for the treatment of different types of diseases. We may not be able to develop products that are safe and effective for all or any of the indications that we target. Even if we are successful in building a product pipeline, the potential product candidates that we identify may not be suitable for clinical development for a number of reasons, including causing harmful side effects or demonstrating other characteristics that indicate a low likelihood of receiving marketing approval, or achieving market acceptance. If our methods of identifying potential product candidates fail to produce a pipeline of potentially viable product candidates, then our success as a business will be dependent on the success of fewer potential product candidate programs, which introduces risks to our business model and potential limitations to any success we may achieve.

Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forego or delay pursuit of opportunities

with other product candidates or for other indications that later prove to have greater commercial potential. 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 discovery and preclinical development programs and product candidates for specific indications may not yield any commercially viable products. Furthermore, until such time as we are able to build a broader product candidate pipeline, if ever, any adverse developments with respect to our leading product candidate, pemvidutide, would have a more significant adverse effect on our overall business than if we maintained a broader portfolio of product candidates.

If we fail to establish and maintain strategic partnerships related to pemvidutide, we will bear all of the risk and costs related to its development which could negatively affect the development of pemvidutide and materially affect our business and financial condition.

We may not be able to comply with the requirements of foreign jurisdictions in conducting trials within the United Kingdom, European Union ("EU") or any other foreign country.

We have in the past conducted clinical trials in the U.S. and other countries; and future clinical trials may be conducted in other foreign jurisdictions. Our ability to successfully initiate, enroll and complete a clinical trial in any other foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the approval and conduct of clinical trials;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of the conduct of clinical trials, pharmaceutical and biotechnology products and treatment.

If we fail to successfully meet requirements for the conduct of clinical trials outside of the United States, we may be delayed in obtaining, or be unable to obtain, regulatory approval for our product candidates in the United States or in countries outside of the United States.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our products, conduct our clinical trials and commercialize our product candidates.

We are highly dependent on members of our senior management, including Jerome Durso, our President and Chief Executive Officer, Gregory Weaver, our Chief Financial Officer, Dr. Christophe Arbert-Engels, our Chief Medical Officer, Dr. M. Scot Roberts, our Chief Scientific Officer, Linda Richardson, our Chief Commercial Officer and Robin Abrams, our Chief Legal Officer. Although we have entered into employment agreements with each of these members of senior management and key employees, the loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development, commercialization and business development objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other

entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Labor shortages and constraints in the supply chain could adversely affect our results of operations.

A number of factors may adversely affect the labor force available to us or increase labor costs, including high employment levels, federal unemployment subsidies, increased wages offered by other employers, vaccine mandates and other government regulations and our responses thereto. As more employers offer remote work, we may have more difficulty recruiting for jobs that require on-site attendance. If we are unable to hire and retain employees capable of performing at a high-level, our business could be adversely affected. A sustained labor shortage, lack of skilled labor, or increased turnover within our employee base, caused by a pandemic, epidemic or the spread of infectious disease or as a result of general macroeconomic factors, could have a material adverse impact on our business and operating results.

In addition, recent developments in the national and worldwide supply chain slowdown, including as a result of the geopolitical conflicts such as in Israel and the Gaza Strip, and the conflict in Ukraine, have resulted in increased cost and reduced supply for supplies and materials. It is impossible to predict how long this supply chain slowdown will last or how much it will impact our business operations, but it is likely that our costs will increase for supplies.

Our overall performance depends in part on worldwide economic conditions and uncertainties.

Global inflation rates have increased to levels not seen in several decades, which may result in increases in our operating costs, including our labor costs, constrained credit and liquidity, reduced government spending and volatility in financial markets which may adversely affect our business and financial condition. Such uncertainty, and related increases in interest rates on credit and debt that would increase the cost of any borrowing that we may make from time to time, could impact our ability to access the capital markets.

Tax laws could change.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws resulting from legislative, administrative or judicial decisions may have adverse tax consequences on our business, cash flow, financial condition or results of operations or to a holder of our common stock. Shareholders should consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

We may not be able to utilize a significant portion of our net operating loss carryforwards, which could harm our results of operations.

We had U.S. federal and state net operating loss carryforwards of approximately $366.6 million and $365.0 million, respectively, as of December 31, 2025, of which a portion of the federal and state amount of $7.1 million and $365.0 million, respectively, has a 20-year carry forward period that will expire at various dates beginning in 2024. Under current law, the remaining federal amount of $359.5 million has an indefinite life and generally may not be carried back to prior taxable years. For net operating losses arising in taxable years beginning after December 31, 2017, we are permitted a net operating loss deduction that is limited to 80% of our taxable income in such year. The net operating loss carryforwards are subject to a 382-limitation related to ownership changes. Under Section 382 of the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its net operating losses (“NOLs”), to offset U.S. federal and state taxable income. For these purposes, an ownership change generally occurs in the event of a cumulative change in ownership of us of more than 50% within any three-year period. We have reviewed our stock ownership for any ownership changes as defined under IRC Section 382 from January 1, 2021 through November 3, 2023 and determined that the ownership change was less than 50% during that period. Our existing NOLs are subject to limitations arising from previous ownership changes impacting the timing and amount, and the impact of such changes is reflected in the NOL amounts disclosed above. In addition, future changes in our stock ownership, many of which are

outside of our control, could result in an ownership change. Accordingly, we may not be able to utilize a material portion of our NOLs and this could harm our future operating results by effectively increasing our future tax obligations.

As of December 31, 2025, we have recorded a valuation allowance of $127.1 million against our net deferred tax asset.

Risks Related to the Regulatory Approval Process

We cannot guarantee how long it will take regulatory agencies to review our applications for product candidates, and we may fail to obtain the necessary regulatory approvals to market our product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and foreign jurisdictions. Failure to obtain marketing approval for our product candidates will prevent us from commercializing them in those markets.

We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that neither our current product candidates nor any product candidates that we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales.

We expect to rely on third-party CROs and consultants to assist in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication of each of our product candidates to establish the product candidates' safety and efficacy for such indications. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities, and often certain clinical trial sites by, regulatory authorities.

The pathway to regulatory approvals is time consuming and unpredictable, involves substantial costs and consumes management time and attention. It is not possible to predict the timing or success of obtaining regulatory approvals with any degree of certainty, and as a result, it is difficult to forecast our future financial results or prospects. Any unexpected developments in the regulatory approval process, including delays or denials of regulatory approvals or significant modifications to our product candidates required by regulatory authorities, could materially and adversely affect our business, results of operations and financial condition, and could substantially harm our stock price.

To obtain marketing approval, United States laws require, among other things:

- controlled research and human clinical testing;
- establishment of the safety and efficacy of the product for each use sought;
- government review and approval of a submission containing, among other things, manufacturing, preclinical and clinical data; and
- compliance with cGMP regulations.

The process of reviewing and approving a drug is time-consuming, unpredictable, and dependent on a variety of factors outside of our control. The FDA and corresponding regulatory authorities in other jurisdictions have a significant amount of discretion in deciding whether or not to approve a marketing application. Our product candidates could fail to receive regulatory approval from the FDA or comparable regulatory authorities outside the United States for several reasons, including:

- disagreement with the design or implementation of our clinical trials;

- failure to demonstrate that our candidate is safe and effective for the proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure to demonstrate that the product candidate's benefits outweigh its risks;
- disagreement with our interpretation of preclinical or clinical data; and
- inadequacies in the manufacturing facilities or processes of third-party manufacturers.

The FDA or a comparable regulatory authority outside the United States may require us to conduct additional preclinical and clinical testing, which may delay or prevent approval and our commercialization plans or cause us to abandon the development program. Further, any approval we receive may be for fewer or more limited indications than we request, may not include labeling claims necessary for successful commercialization of the product candidate, or may be contingent upon our conducting costly post-marketing clinical trials. Any of these scenarios could materially harm the commercial prospects of a product candidate, and our operations will be adversely affected.

Our product candidates may cause undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.

Significant adverse events caused by our product candidates or even competing products in development that utilize a common mechanism of action could cause us, an IRB or ethics committee, and/or regulatory authorities to interrupt, delay or halt one or more clinical trials and could result in clinical trial challenges such as difficulties in patient recruitment, retention, and adherence, the denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Serious adverse events deemed to be caused by our product candidates could have a material adverse effect on the development of our product candidates and our business as a whole.

Our understanding of the relationship between our product candidates and these events, as well as our understanding of adverse events reported in future clinical trials of other product candidates, may change as we gather more information, and additional unexpected adverse events may be observed. In addition, the side effect profile of pharmaceutical drugs cannot be fully established based on preapproval clinical trials involving a limited number of patients. Routine review and analysis of post-marketing safety surveillance and clinical trials will provide additional information, for example, potential evidence of rare, population-specific or long-term adverse reactions, and may adversely affect the commercialization of the product, and even lead to the suspension or revocation of product marketing authorization.

If we or others identify undesirable side effects caused by our product candidates either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including:

- our clinical trials may be put on hold;
- we may be unable to obtain regulatory approval for our product candidates or additional indications;
- regulatory authorities may withdraw approvals of our products;
- regulatory authorities may require additional warnings on the label or other label modifications;
- a medication guide outlining the risks of such side effects for distribution to patients may be required;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining marketing approvals for and market acceptance of our product candidates and could have a material adverse effect on our business and financial results.

Breakthrough Therapy Designation and Fast Track Designation by the FDA may not lead to a faster development or regulatory review or approval process, and does not assure FDA approval of any product candidates that we may develop.

FDA's Breakthrough Therapy Designation is intended to expedite the development and review of medicines that are intended to treat a serious or life-threatening condition and have shown preliminary clinical evidence indicating the potential for substantial improvement over available therapies on one or more clinically significant endpoints. In December 2025, the FDA granted Breakthrough Therapy Designation for pemvidutide in MASH based on submission of 24-week data from the IMPACT Phase 2b trial demonstrating statistically significant MASH resolution without worsening of fibrosis, along with early and substantial improvements in liver fat and non-invasive tests of fibrosis and hepatic inflammation. Even with Breakthrough Therapy Designation, we may not experience a faster development process, review or approval for pemvidutide compared to conventional FDA procedures, and Breakthrough Therapy Designation does not ensure that a product candidate will receive marketing approval. In addition, the FDA may withdraw Breakthrough Therapy Designation if it believes that the designation is no longer supported by data from our clinical development program.

FDA's Fast Track Designation program is intended to expedite the development of certain qualifying products intended for the treatment of serious diseases or life-threatening conditions. If a product candidate is intended for the treatment of a serious or life threatening condition and preclinical or clinical data demonstrate the product's potential to address an unmet medical need for this condition, the sponsor may apply for FDA Fast Track Designation. In August 2025, the FDA granted Fast Track Designation for pemvidutide for the treatment of AUD. In October 2023, we announced that the FDA granted Fast Track Designation to our clinical program investigating pemvidutide for the treatment of MASH. Even with Fast Track Designation, we may not experience a faster development process, review or approval for pemvidutide compared to conventional FDA procedures, and Fast Track Designation does not ensure that a product candidate will receive marketing approval at all. In addition, the FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

If we fail to obtain regulatory approval in non-U.S. jurisdictions, we will not be able to market our products in those jurisdictions. Receiving and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in receiving or maintaining regulatory approval of our product candidates in other jurisdictions.

We intend to market certain of our product candidates, if approved, in the United Kingdom and other international markets, in addition to the United States. Such marketing will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, such as certain countries of the European Union, pricing and reimbursement decisions (including the price that can be charged) may affect the timing and extent of commercialization in that country. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product, and additional clinical research may be required to enable comparison of the cost effectiveness of our product candidate to other available alternatives. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, the failure to obtain approval in one jurisdiction may compromise our ability to obtain approval elsewhere. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all.

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

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to conditions of approval. We may also be required to conduct post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product

potentially over many years. If the FDA or other regulatory authority approves any of our product candidates, the manufacturing processes, quality control, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP, including for any clinical trials that we conduct post-approval. Manufacturers and manufacturers' facilities are also required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. Any such restrictions regulatory requirements or may result in significant additional expenses or could limit sales of the approved product. If we, or any of the third parties on which we rely, fail to meet those requirements, the FDA or comparable regulatory authorities outside the United States could initiate enforcement action. Other consequences include the issuance of fines, FDA Form 483s, warning letters, untitled letters or holds on clinical trials, product seizure or detention or refusal to permit the import or export of our product candidates, and permanent injunctions and consent decrees, including the imposition of civil or criminal penalties, among other consequences, that could significantly impair our ability to successfully commercialize a given product.

Later discovery of previously unknown problems with an approved product, including adverse events of unanticipated severity or frequency, or with manufacturing operations or processes, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, FDA Form 483s, warning letters, untitled letters or clinical holds on clinical trials involving related product candidates;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of product license approvals;
- suspension of production or distribution;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil, criminal and/or administrative penalties, damages, monetary fines, debarment, restitution, disgorgement, exclusion from participation in governmental reimbursement programs, such as Medicare, Medicaid and other federal health care programs and curtailment or restructuring of our operations.

In addition, applicable regulatory policies of governmental authorities, such as the FDA, may change and additional government regulations may be enacted that could affect any regulatory approval that we may receive for 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 not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and we or any of our existing or future collaboration partners may not be able to obtain approvals for the commercialization of our current product candidates and any other product candidate we develop.

Any current or future product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, import, export and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any

jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to continue to rely on third-party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and effectiveness. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

If the FDA or comparable foreign regulatory authorities approve generic versions of any of our products that receive marketing approval, or if we do not obtain the exclusivity periods for our approved products that we hope to achieve, the sales of our products could be adversely affected.

If and when approved, our product candidates may face competition from ANDA or 505(b)(2) product candidates referencing our drug product. Certain ANDAs, once approved, may be substituted for our product candidates, subject to applicable state laws.

We may pursue pediatric exclusivity for one or more of our product candidates but may not succeed in obtaining it. There is also a risk that a competitor may achieve pediatric exclusivity that would delay any potential approvals of our product candidates. In the United States, the FDA has the authority to award additional exclusivity for approved products where the sponsor conducts specified testing on pediatric or adolescent populations upon the written request of the FDA. If granted, pediatric exclusivity may add six months to certain patents or regulatory exclusivity periods for an approved drug. In the EU, pediatric studies are also incentivized by the reward of additional exclusivity. Paediatric Investigation Plans ("PIPs") must be agreed with the Paediatric Committee of the EMA, unless a waiver or deferral applies with respect to the product. Where an application for a marketing authorization is submitted in respect of a medicinal product that is not designated as an orphan medicinal product and that application contains the results of studies conducted in compliance with an approved PIP, it may be possible to obtain a six-month extension of a supplementary protection certificate extending patent protection for a medicinal product.

Risks Related to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position and other intellectual property rights do not adequately protect our product candidates, others could compete against us (including directly), which could materially harm our business, results of operations and financial condition.

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates, platform technology and know-how. The patent position of biotechnology companies is generally uncertain, because it involves complex legal and factual considerations.

The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. In addition, some countries do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our product candidates. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries.

The patent prosecution process is expensive and time consuming, and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. 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, covering technology that we license from or license to third parties, making us reliant on our licensors, licensees or collaborators. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be lost or impaired. If our licensors, licensees or collaborators 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 patent applications we hold or have in-licensed with respect to our product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us. We and our licensors have filed several patent applications covering aspects of our product candidates. We cannot offer any assurance about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid or unenforceable or will be successfully challenged by third parties.

Patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued. We cannot be certain that our licensors were the first to satisfy the requirements necessary to secure patent rights relating to any particular invention. Furthermore, if third parties have filed such patent applications, there are pre-grant and post-grant proceedings before the USPTO whereby a third party can challenge a patent grant.

Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Any successful challenge to our patents or patent applications, or to any other patents or patent applications owned by or licensed to us, could deprive us of the rights necessary to prevent competition from third parties, which may impair the commercial success of any product candidate that we may develop. There is no assurance that all potentially relevant prior art relating to our patents and patent applications or those of our licensors has been found, and prior art that we have not identified could be used by a third party to invalidate a patent or prevent a patent from issuing from a pending patent application. Furthermore, even if they are unchallenged, our patents and patent applications, or those of our licensors, may not adequately protect our technology, provide exclusivity for our product candidates, prevent others from designing around our patents with similar products, or prevent others from operating in jurisdictions in which we did not pursue patent protection. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Any loss of, or failure to obtain, patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as our products.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may 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 have patent protection, but enforcement rights are not as strong as

those 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 some foreign jurisdictions. The legal systems of certain 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 patents generally. Proceedings to enforce our 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 patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our 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 license.

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

Patents have a limited lifespan. In most countries, including the United States, the natural expiration of a patent is 20 years from the date that the application for the patent is filed. In some cases, the term of a U.S. patent is shortened by a terminal disclaimer that reduces its term to that of an earlier-expiring patent. Various extensions of patent term may be available in particular countries; however, in all circumstances the life of a patent, and the protection it affords, has a limited term. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. Such possible extensions include those permitted under the Drug Price Competition and Patent Term Restoration Act of 1984 in the United States, which permits a patent term extension of up to five years to cover an FDA-approved product. The actual length of the extension will depend on the amount of patent term lost while the product was in clinical trials. However, the applicable authorities, including the USPTO and FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available and may refuse to grant extensions to our patents, or may grant more limited extensions than we request, or may not grant regulatory exclusivity. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data, and then may be able to launch their product earlier than might otherwise be the case.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary to enforce or defend our intellectual property rights, to protect our trade secrets and/or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Such litigation can be expensive and time consuming, which could divert management resources and harm our business and financial results. Many of our current and potential competitors have the ability to dedicate substantially greater resources to litigate intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property.

Patent assertion, including initiating litigation, increases the likelihood that the accused third party will seek to narrow or invalidate our asserted patent. The scope and validity of our asserted patent may be challenged in a variety of post-grant proceedings before the USPTO and foreign patent offices. In addition, in an infringement proceeding, a court may decide that our asserted patent is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding or other legal proceeding could therefore put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third-party claims of intellectual property infringement or misappropriation may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates, and to use our or our licensors' proprietary technologies without infringing the patents and proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. We may not have identified all U.S. and foreign patents or published patent applications that affect our business either by blocking our ability to commercialize our product candidates or by covering similar technologies that affect our market.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims, for example, to materials, formulations, methods of manufacture, methods of analysis and/or methods for treatment related to the use or manufacture of our product candidates.

In some cases, we may have failed to identify such relevant third-party patents or patent applications. For example, patent applications filed before November 29, 2000 and certain patent applications filed after that date that will not be filed outside the United States remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our platform technology or our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies or product candidates and/or the use, analysis and/or manufacture of our product candidates.

If any third-party patents are held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture, methods of analysis and/or methods for treatment, the holders of any such patents may be awarded monetary damages, obtain injunctive or other equitable relief, or both. An award of monetary damages may be substantial and may include treble damages and attorneys' fees for willful infringement. An award of injunctive relief could block our ability to develop and commercialize the applicable product candidate until such patent expired or unless we obtain a license. Such licenses may not be available on acceptable terms, if at all. Even if we 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. Ultimately, we could be forced to redesign an infringing product, prevented from commercializing a product, or forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business.

We may face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, and we may be required to pay damages.

During the course of any patent or other intellectual property litigation, there could be public announcements of the 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 product candidates, platform technology or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. In addition, the uncertainties associated with litigation could have an 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 partnerships that would help us bring our product candidates to market.

We may be subject to claims that our employees, independent contractors or consultants have wrongfully used or disclosed alleged trade secrets of their former employers, or our employees may challenge the inventorship of our patents.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these individuals, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we use reasonable efforts to ensure that our employees, independent contractors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party.

We may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. In addition, we may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. 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. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We have in-licensed a portion of our intellectual property, and, if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.

We are a party to a number of license agreements that are important to our business, and we may enter into additional license agreements in the future. Certain of our in-licensed intellectual property covers, or may cover, certain of our product candidates including pemvidutide. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other of our obligations. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our ability to utilize the affected intellectual property in our product discovery and development efforts and our ability to enter into collaboration or marketing agreements for an affected product candidate may be adversely affected.

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

A third party may hold intellectual property, including patent rights, that is important or necessary to the development or commercialization of our product candidates. If the patented or proprietary technology of third parties is necessary for us to commercialize our product candidates, we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms or at all, which could materially harm our business.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of proprietary information.

In addition to the protection afforded by patents, we rely on confidentiality agreements to protect trade secrets and proprietary know-how that may not be patentable or that we may elect not to patent, processes for which patents are difficult to enforce and any other elements of our technology and development processes that involve proprietary know-how, information or technology that is not covered by patents. In particular, we seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors and collaborators. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. We also enter into agreements with our employees that provide that any

inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Although we use reasonable efforts to protect our know-how, our employees, consultants, contractors or outside scientific advisors might intentionally or inadvertently disclose our know-how or other proprietary information to competitors. In addition, competitors may otherwise gain access to our know-how or independently develop substantially equivalent information and techniques.

Enforcing a claim that a third party illegally obtained and is using any of our know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect know-how. Misappropriation or unauthorized disclosure of our know-how could impair our competitive position and may have a material adverse effect on our business.

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.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. For example, we have experienced threatened or actual opposition for two trademarks that we were pursuing. We decided to discontinue our use of one of those trademarks, and the other matter was resolved on favorable terms. Although these matters have been resolved on terms that did not materially harm us, we may become subject to other trademark challenges in the future. If we are unable to establish long-term 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.

Risks Related to Commercialization of our Product Candidates

Our future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payers and others in the medical community.

Even if we obtain marketing approval for our product candidates, or any other product candidates that we may develop or acquire in the future, the product may not gain market acceptance among physicians, third-party payers, patients and others in the medical community. Market acceptance of any approved products depends on a number of other factors, including:

- the efficacy and safety of the product, as demonstrated in clinical trials;
- the clinical indications for which the product is approved and the label approved by regulatory authorities for use with the product, including any warnings that may be required on the label;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- the cost, safety and efficacy of treatment in relation to alternative treatments, including generic products;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects, including the tolerability and effect on comorbidities relative to alternative treatments;

- the effectiveness of our sales and marketing efforts and distribution support;
- any distribution and use restrictions imposed by the FDA or other regulatory authorities outside the United States or that are part of a REMS or voluntary risk management plan; and
- the restrictions on the use of our products together with other medications, if any.

Market acceptance is critical to our ability to generate significant revenue. Any product candidate, if approved and commercialized, may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market to the extent that we expect, we may not be able to generate significant revenue and our business would suffer.

We rely on, and expect to continue to rely on, third parties to manufacture our product candidates and related materials for our products, if approved, as well as for our clinical trials and preclinical studies, and these third parties may not perform satisfactorily. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could hinder our ability to commercialize or obtain marketing approval for our current and future candidates in a timely manner or at all.

We do not have any manufacturing facilities or personnel, and we rely on, and expect to continue to rely on, third-party manufacturers and suppliers to manufacture and supply drug substance and drug product for our preclinical studies and clinical trials of pemvidutide. We rely on a small number of third-party manufacturers and suppliers to manufacture and supply bulk drug substance and drug product for our clinical trials. This reliance on a small number of third parties increases the risk that we will not have sufficient quantities of our product candidates or other products needed for our preclinical studies and clinical trials, or that such quantities will be manufactured for us at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Any of these third parties that we rely upon may terminate their engagement with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities. In addition, our reliance on these third parties for manufacturing activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations regarding manufacturing.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourself, including:

- potential limitations on our ability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities, including regulatory compliance and quality assurance. We have limited control over third party manufacturers' compliance with these regulations and standards, but we may ultimately be responsible for any of their failures;
- delays as a result of regulatory issues, manufacturing problems or re-prioritization of projects at a third-party manufacturer;
- our third-party manufacturers might be unable to formulate and manufacture our product candidates in the volume and of the quality required to meet our clinical and commercial needs, if any;
- termination or non-renewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how or infringement of third-party intellectual property rights by our contract manufacturers; and

- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy or change in ownership of the manufacturer or supplier to a potential competitor resulting in a need to seek transfer of certain manufacturing.

Any of these events could lead to preclinical study and clinical trial delays or failure to obtain regulatory approval or affect our ability to successfully commercialize future products. Some of these events could be the basis for FDA or other regulatory authority action, including untitled letters and warning letters, clinical holds, fines, injunctions, civil penalties, license revocations, recall, seizure, total or partial suspension of production, or criminal penalties.

In addition, our product candidates involve technically complex manufacturing processes, and even slight deviations at any point in the production process may lead to production failures and may cause the production of our product candidates to be disrupted, potentially for extended periods of time. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original contract manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. Furthermore, a contract manufacturer may possess technology related to the manufacture of our product candidate that such contract manufacturer owns independently. This would increase our reliance on such contract manufacturer or require us to obtain a license from such contract manufacturer in order to have another contract manufacturer manufacture our product candidates.

Third-party manufacturers may not be able to comply with applicable cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions or enforcement actions being imposed, including warning letters, untitled letters, clinical holds, fines, injunctions, civil penalties, delays, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

In addition, if we are required to change contract manufacturers for any reason, we will be required to verify that the new contract manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new contract manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Our third-party manufacturers may be subject to damage or interruption from, among other things, fire, natural or man-made disaster, power loss, telecommunications failure, unauthorized entry, computer viruses, denial-of-service attacks, acts of terrorism, human error, vandalism or sabotage, financial insolvency, bankruptcy, regulatory action or similar events.

Our current and future product candidates may compete with others' product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We have limited arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers, and it may prove very difficult and time consuming to identify potential alternative manufacturers who could manufacture our product candidates. Accordingly, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

If we are unable to manufacture our product candidates in sufficient quantities, or at sufficient yields, or are unable to obtain regulatory approvals for a manufacturing facility for our product candidates, we may experience delays in product development, clinical trials, regulatory approval and commercial distribution.

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture our product candidates at sufficient yields and at commercial scale, and this manufacturing involves a complicated process with which we have limited experience. Even if clinical trials are successful, we still may be unable to commercialize a product due to difficulties in obtaining regulatory approval for our engineering processes or problems in scaling that process to commercial production. We have no experience manufacturing, or managing third parties in manufacturing, any of our product candidates in the volumes that will be necessary to support large-scale clinical trials or commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency or quality. The FDA may also prevent the import or export of products manufactured in non-compliant facilities or under non-compliant conditions.

We expect to rely on third parties for the manufacture of clinical and, if approved for marketing, commercial quantities of our product candidates. These third-party manufacturers must also receive FDA or other applicable governmental authority approval before they can produce clinical material or commercial products. Our products may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third parties give other products greater priority. We may not be able to enter into any necessary third-party manufacturing arrangements on acceptable terms, or on a timely basis. In addition, we may have to enter into technical transfer agreements and share our know-how with the third-party manufacturers, which can be time consuming and may result in delays.

Our contract manufacturing organizations may encounter technical or scientific issues related to development or manufacturing that we may be unable to resolve in a timely manner or with available funds. If we or our manufacturing partners are unable to scale the manufacturing process to produce commercial quantities of our product candidates, or our manufacturing partners do not pass required regulatory pre-approval inspections, our commercialization efforts may be adversely affected.

Our reliance on contract manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture our products on a commercial scale, replacement of a manufacturer may be expensive and time consuming and may cause interruptions in the production of our product candidates. A third-party manufacturer may also encounter difficulties in production. These problems may include:

- difficulties with production costs, scale-up and yields;
- unavailability of raw materials and supplies;
- insufficient quality control and assurance;
- shortages of qualified personnel;
- failure to comply with strictly enforced federal, state and foreign regulations that vary in each country where product might be sold; and
- lack of capital funding.

Any delay or interruption in the manufacture of our products could have a material adverse effect on our business, financial condition, results of operations and cash flows.

If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing our product candidates if they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, and for which we decide to independently commercialize, we will need to establish a sales and marketing organization.

In the future, we may build a focused sales and marketing infrastructure to market or co-promote some of our product candidates in the United States and in Europe, if and when they are approved. There are risks involved with our establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

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

If we do not establish our own sales, marketing and distribution capabilities and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, could be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our business.

We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize products.

A key part of our strategy is to seek strategic partnerships in the future, including potentially with major biotechnology or pharmaceutical companies for late-stage development and commercialization of our product candidates. We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other products available for licensing from other companies. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product is delayed or sales of an approved product are disappointing. Any delay in entering into strategic partnership agreements related to our product

candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

In addition, any future partnerships we may enter into pose a number of risks, including that our partners may breach their agreements with us, and we may not be able to adequately protect our rights under these agreements. Furthermore, prospective partners will likely negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we would.

If we fail to establish and maintain strategic partnerships related to our product candidates, including pemvidutide, we will bear all of the risk and costs related to the development of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise which we do not have and for which we have not budgeted. This could negatively affect the development of any unpartnered product candidate and materially affect our business and financial condition.

We may acquire other businesses, form joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets or licenses of assets, including preclinical, clinical or commercial stage products or product candidates, businesses, strategic alliances, joint ventures and collaborations, to expand our existing technologies and operations.

In the future, we may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a negative impact on our cash flows, financial condition and results of operations. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could harm our financial condition and results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture.

To finance such a transaction, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings or through the issuance of debt. Additional funds may not be available on terms that are favorable to us, or at all, and any debt financing may involve covenants limiting or restricting our ability to take certain actions.

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates.

Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;

- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigations;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize any product candidates that we may develop; and
- a decline in our stock price.

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry worldwide product liability insurance covering our clinical trials in the amount of $10.0 million in the aggregate. Although we maintain product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

A breakdown in our information technology systems could result in a significant disruption to our business.

While we seek to protect our information technology systems from cybersecurity incidents or breaches, we and our third-party vendors, like other companies in our industry, have in the past and may continue to experience cybersecurity threats and incidents relating to our information technology systems and infrastructure. Our operations and those of our business partners, such as CROs, vendors and others that manage sensitive data, are highly dependent on information technology systems, including Internet-based systems, which may be vulnerable to damage or interruption from, among other things, malicious uses of artificial intelligence, computer viruses, computer hackers, phishing attacks, ransomware, malware, social engineering, malicious code, employee theft, fraud, misconduct or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, breakdown, wrongful intrusions, data breaches, other incidents and malicious attacks. Information security risks have generally increased in recent years, in part facilitated or enhanced by evolving technologies, including artificial intelligence. For example, if we used generative artificial intelligence models in our internal or third-party systems it may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Our systems, and those of our third-party providers, are potentially vulnerable to data security breaches or other incidents, whether by insider employees or others, which may expose sensitive data to unauthorized persons. A data security breach or other incident could lead to the loss of trade secrets or other intellectual property, the value of which may be contingent upon maintaining our confidentiality, or could lead to the public exposure of personal information (including sensitive personal medical information) of clinical trial participants, our employees and others, or adversely impact the conduct of scientific research and clinical trials, including the submission of research results to support marketing authorizations. This could require us to expend significant efforts and resources or incur significant expense to eliminate these problems and address related security concerns. In addition, procedures and safeguards must continually evolve to meet new data security challenges, and enhancing protections, and conducting investigations and remediation, may impose additional costs on us. For example, we may be contractually or statutorily required to notify individuals or counterparties of a cybersecurity incident or data breach. If we or our third-party providers were to experience a cybersecurity compromise or breach or other security incident, or if we suffer a breakdown in our systems, storage, distribution or tracing, we could experience significant disruptions affecting our business, supply chain interruptions,

processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary, personal or confidential information, reputational harm which could negatively impact our relationship with our customers, partners, vendors and other third parties, and fines and penalties resulting from claims against us by private parties and/or governmental agencies. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Additionally, cyber liability insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or breach.

Our use of new and evolving technologies, such as artificial intelligence, may present risks and challenges that can impact our business, including by posing cybersecurity and other risks to our confidential and/or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability.

We may use and integrate artificial intelligence (AI) into our business processes through the adoption of commercially available tools. Use of this technology could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational and other risks and challenges that could affect our business. Specifically, risks related to accuracy, bias, artificial intelligence hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies. If we enable or use solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain such systems to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. The use of certain AI technologies can also give rise to intellectual property risks, including by disclosing or otherwise compromising our confidential or proprietary intellectual property, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of artificial intelligence tools.

A growing number of legislators and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption and use of AI technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of AI and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. For example, Europe began implementing its EU Artificial Intelligence Act (the "AI Act") on August 1, 2024, with a significant part of the law scheduled to come into effect in August 2026. As currently enacted, the AI Act, which may be amended as part of the EU's Digital Omnibus, imposes significant obligations on providers and deployers of AI systems, particularly those considered as "high risk", and encourages providers and deployers of AI systems to account for EU ethical principles in their development and use of these systems. The scope of requirements depends on legal and risk determinations that rely on novel legal provisions that have not yet been interpreted by courts or regulators, and non-compliance can lead to significant fines.

In the U.S., the AI regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI in healthcare settings. At the federal level, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The U.S. Food and Drug Administration, for example, issued guidance on the use of AI in medical devices, requiring detailed risk management and review processes to obtain approvals. If we develop or use AI systems governed by these laws or regulations, we will need to meet various standards of data quality, transparency, monitoring and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non-compliance.

Our vendors may in turn incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security.

Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. The integration of AI systems, by us or by our vendors, may increase cybersecurity risk. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Risks Related to Reimbursement and Government Regulation

Disruption at the FDA, the SEC and other government agencies or comparable regulatory authorities caused by funding shortages, global health concerns, and significant shifts in personnel, policy, and leadership could hinder such government agencies' ability to hire and retain key leadership and other personnel, or otherwise 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 our business operations rely, including timely reviews, which could negatively impact our business.

The ability of the FDA, or comparable foreign regulatory authorities, to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, leadership, and policy changes that may otherwise affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions. In addition, government funding of the SEC and other government agencies or comparable foreign regulatory authorities on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including substantial leadership departures, personnel cuts, and policy changes, may slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would harm our business. Changes and cuts in FDA staffing have impacted the FDA's ability to review IND submissions or applications, issue regulations and guidance, and implement and enforce regulatory requirements.

Similar consequences may also result from another significant shutdown of the federal government. The U.S. federal government has shut down several times and from time to time, certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, or if geopolitical or global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, the ability of the FDA to timely review and take action on our regulatory submissions could be affected, which could materially adversely affect our business. Further, in our operations as a public company, future government shutdowns or substantial leadership, personnel, and policy changes could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. If the FDA is constrained in its ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

With the change in the U.S. presidential administration in 2025, the leadership of the FDA has sought to modify or revise several requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. Such changes could present new challenges and/or opportunities as we navigate development and approval of our product candidates. Some of these efforts have manifested to date in the form of personnel cuts and measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays or limitations on our ability to obtain guidance from the FDA on our product candidates in development and obtain the requisite regulatory approvals in the future. There remains general uncertainty regarding future activities. The Trump administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic products. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we become negatively impacted by future governmental orders, regulations, policies or guidance as a result of the Trump administration, there could be a material adverse effect on our business.

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

Market acceptance and sales of any approved products will depend significantly on the availability of adequate coverage and reimbursement from third-party payers and may be affected by existing and future health care reform measures. Third-party payers, such as government health care programs, and private health insurers and health plans, decide which drugs they will provide coverage for and establish reimbursement levels. Coverage and reimbursement decisions by a third-party payer may depend upon a number of factors, including the third-party payer's determination that use of a product is:

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

Third-party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling health care costs. Coverage and reimbursement can vary significantly from payer to payer. As a result, obtaining coverage and reimbursement approval for any approved product from each government and other third-party payer may require us to provide supporting scientific, clinical and cost-effectiveness data for the use of such products to each payer separately, with no assurance that we will be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates, and we cannot be sure that coverage determinations or reimbursement amounts will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products, even if they are approved by the FDA or other regulatory authorities. In addition, in the United States third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs.

Price controls may be imposed, which may adversely affect our future profitability.

In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on coverage, prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce revenues. In some countries, additional clinical research may be required to enable comparison of the cost-effectiveness of our product candidates, if they are approved, to other available products in order to obtain or maintain coverage, reimbursement or pricing approval. Publication of discounts by third-party payers or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. In the United States, concerns about drug pricing have been expressed by members of Congress and presidential administrations. There can be no assurance that our product candidates, if approved, will be considered cost-effective by third-party payers, that an adequate level of reimbursement will be available or that the third-party payers' reimbursement policies will not adversely affect our ability to sell our products profitably. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

The impact of recent health care reform legislation and other changes in the health care industry and in health care spending on us is currently unknown and may adversely affect our business model.

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

For example, in the United States there is significant interest in promoting health care reform, as evidenced by the enactment in the United States of the Affordable Care Act of 2010 (the "Health Care Reform Law"). The Health Care Reform Law substantially changed the way health care is financed by both governmental and commercial payers and significantly impacts the pharmaceutical industry. The Health Care Reform Law contains provisions that may reduce the profitability of drug products, including, for example, by increasing the minimum rebates owed by manufacturers under the Medicaid Drug Rebate Program, extending the rebate program to individuals enrolled in Medicaid managed care plans, addressing 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, and imposing certain annual fees based on pharmaceutical companies' share of sales to federal health care programs.

The Health Care Reform Law established and provided significant funding for a new Patient-Centered Outcomes Research Institute to coordinate and fund comparative effectiveness research. While the stated intent of comparative effectiveness research is to develop information to guide providers to the most efficacious therapies, outcomes of comparative effectiveness research could influence the reimbursement or coverage for therapies that are determined to be less cost effective than others. Should any of our products be approved for sale, but then determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our financial results.

Certain provisions of the Health Care Reform Law have been subject to judicial challenges, as well as efforts to repeal, replace or otherwise modify them or to alter their interpretation or implementation. For example, the Tax Cuts and Jobs Act of 2017, eliminated the tax-based payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, as amended, commonly referred to as the "individual mandate," effective January 1, 2019. Further, the Bipartisan Budget Act of 2018 among other things, amended the Medicare statute, effective January 1, 2019, to reduce the coverage gap in most Medicare prescription drug plans, commonly known as the "donut hole," by raising the manufacturer discount under the Medicare Part D coverage gap discount program from 50% to 70%, a program that was later replaced under the Inflation Reduction Act of 2022. Additional legislative changes, regulatory changes and judicial challenges related to the Health Care Reform Law remain possible. It is unclear how the Health Care Reform Law and its implementation, as well as efforts to repeal, replace or otherwise modify, or invalidate, the Health Care Reform Law, or portions thereof, will affect our business. We cannot predict what affect further changes to the Health Care Reform Law would have on our business, especially including under the Trump administration.

In addition, other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. For example, the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of on average 2% per fiscal year, which remain in effect until 2032. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers were further reduced starting in 2025 absent further legislation. The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our drug candidates for which we may obtain regulatory approval or the frequency with which any such drug candidate is prescribed or used.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which

manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. The Inflation Reduction Act of 2022 (IRA), for example, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby eliminating the so-called coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge.

Further, there has been increasing legislative, regulatory and enforcement interest in the United States with respect to drug pricing practices. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. To date, there have been several recent U.S. congressional inquiries, as well as proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. The Trump Administration has issued executive orders and supported proposed regulatory initiatives in 2025 that could have a significant impact on the prices that we, or any collaborators, may receive for any approved products.

On May 12, 2025, President Trump signed an executive order directing the Secretary of HHS to set and communicate most-favored-nation ("MFN") price targets to manufacturers and propose a rulemaking plan to impose MFN pricing if "significant progress" is not made, and also directing the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. The executive order further states that the Trump Administration will take additional action (for example, examining whether marketing approvals should be modified or rescinded or considering individual drug importation waiver authorities) should manufacturers fail to offer American consumers the MFN lowest price. In July 2025, President Trump sent letters to certain pharmaceutical companies demanding that these companies extend MFN pricing to Medicaid and newly launched drugs as well as move to direct-to-consumer models priced at MFN pricing and soliciting binding commitments by September 29, 2025. Since this time, multiple drug manufacturers have announced plans to, for certain of their drugs, lower prices to reflect similar pricing around the world, and to sell these reduced-price drugs on a direct-to-consumer purchasing platform developed by the federal government; however, it is not known what results will occur to the extent the recipients of these letters do not reduce their U.S. prices.

On December 19, 2025, CMS released two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs. The first proposal, the Global Benchmark for Efficient Drug Pricing Model ("GLOBE") for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GLOBE would begin a five-year performance period on October 1, 2026 and GUARD would begin its performance period in 2027. These proposals will likely be subject to legal challenges that could delay their implementation or modify their impact on manufacturer pricing and revenue. Additionally, in November 2025, CMS introduced the GENErating cost Reductions fOr U.S. Medicaid ("GENEROUS") Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers.

The effect of these healthcare reform initiatives on our business and the pharmaceutical industry in general is not yet known but could be substantial and materially adverse to our ability to successfully commercialize our product candidates at profitable price points.

It is possible that the Health Care Reform Law, as currently enacted or may be amended or otherwise modified in the future, as well as other health care reform measures that may be adopted in the future, may result in additional reductions in Medicare payment and other health care financing, more rigorous coverage criteria, and new payment methodologies and in additional downward pressure on coverage and payment and 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 commercial payers. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. These continuing health care reform initiatives may adversely affect:

- the demand for any product candidates for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

Certain business practices associated with the commercialization of pharmaceutical products are subject to scrutiny by regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us.

The laws that would govern our conduct in the United States upon the commercialization of our product candidates are enforceable by criminal, civil and administrative penalties. Violations of laws such as the Anti-Kickback Statute and FCA, the FD&C Act, or any regulations promulgated under their authority, may result in jail sentences, fines or exclusion from federal and state programs, as may be determined by Medicare, Medicaid, the Department of Defense, other regulatory authorities and the courts. There can be no assurance that our activities will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws. Our potential exposure under these laws would increase significantly if our product candidates are approved and commercialized, and our costs associated with compliance would also be expected to increase.

In the United States, among the laws that may affect our ability to operate and market our products include, but are not limited to:

- The federal Anti-Kickback Statute prohibits, among other activities, any person from knowingly and willfully, directly or indirectly soliciting, receiving, offering or paying any remuneration with the intent of (or in return for) generating referrals of individuals or purchases, orders or recommendations for services or items reimbursable by federal health care programs like Medicare and Medicaid. Courts have interpreted this law very broadly, including by holding that a violation has occurred if even one purpose of the remuneration is to generate referrals, even if there are other lawful purposes. Moreover, liability under the Anti-Kickback Statute may be established without proving actual knowledge of the law or specific intent to violate. There are statutory exceptions and regulatory safe harbors that protect certain arrangements from prosecution or administrative sanctions, but the exceptions and safe harbors are drawn narrowly. The fact that an arrangement does not fall within a safe harbor does not necessarily render the conduct illegal under the Anti-Kickback Statute, but the arrangement may be subject to scrutiny based on the facts and circumstances. Practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical products, including certain discounts, or engaging such individuals as consultants, advisors and speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Moreover, there are no safe harbors for many common practices, such as educational and research grants, charitable donations,

product support and patient assistance programs. Violations of the Anti-Kickback Statute may be punished by civil and criminal penalties, damages, fines, or exclusion from participation in federal health care programs like Medicare and Medicaid. In addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

- The FCA prohibits any person from, among other things, knowingly presenting or causing to be presented a false or fraudulent claim for payment of government funds, or making, or causing to be made, a false statement material to a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding, or decreasing, an obligation to pay or transmit money or property to the government. The FCA is commonly used to sue those who submit allegedly false Medicare or Medicaid claims, as well as those who induce or assist others to submit a false claim. "False claims" can result not only from non-compliance with the express requirements of applicable governmental reimbursement programs, such as Medicare or Medicaid, but also from non-compliance with other laws, such as the Anti-Kickback Law, FDA laws on off-label promotion, or laws that require quality care in service delivery. Actions under the FCA may be brought by the government or by whistleblowers referred to as relators, who may initiate an action in the name of the government and may share in any monetary recovery. Violations of the FCA can result in treble damages, mandatory per claim penalties, and exclusion from participation in federal health care programs.

- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the Anti-Kickback Law, a person or entity can be found guilty of violating the HIPAA fraud statute without actual knowledge of the statute or specific intent to violate it. In addition, we may be subject to federal and state laws governing the privacy, security, use, and disclosure of health information, many of which differ from each other in significant ways and may impose additional compliance obligations.

- The Physician Payments Sunshine Act, implemented as the Open Payments program, imposes reporting requirements for pharmaceutical, biologic, and device manufacturers regarding payments or other transfers of value made to physicians, teaching hospitals, and other healthcare providers, including investment interests in such manufacturers held by physicians and their immediate family members during the preceding calendar year. Annual reporting of such transfers of value by manufacturers has increased scrutiny of the financial relationships between industry and the physicians, teaching hospitals and other healthcare providers. Failure to submit required annual information may result in civil monetary penalties, which may increase significantly for "knowing failures."

- Federal consumer protection, unfair competition, and similar laws, which broadly regulate marketplace activities and practices that may be deemed misleading, deceptive, or harmful to consumers, including in connection with promotional, educational, and patient-facing materials.

- Federal government price reporting and rebate laws, which, if our product candidates are commercialized, would require us to calculate and report complex pricing metrics, net of discounts, rebates, and other concessions, to CMS and other government authorities for purposes of reimbursement, rebate, and discount obligations. Compliance with these requirements would require us to develop and maintain specialized expertise, systems, and internal controls, and inaccuracies could expose us to significant penalties, including potential FCA liability.

- The Foreign Corrupt Practices Act and similar anti-bribery and anti-corruption laws, which regulate interactions with foreign government officials, including certain healthcare professionals, and impose requirements relating to the accuracy of books and records and internal accounting controls. Enforcement of

these laws has increased in recent years, and violations could result in substantial penalties and reputational harm.

- Analogous state laws and regulations, including anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid or, in several states, regardless of the payer, including private payers. Some state laws require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing related activities including the provision of gifts, meals, or other items to certain health care providers. Some states restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Some states require the posting of information relating to clinical studies and their outcomes. Other states and cities require identification or licensing of sales representatives. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Compliance with these laws may require substantial investment in systems and infrastructure and may result in public disclosure of certain information, increasing enforcement scrutiny or reputational risk.

- The FD&C Act and comparable foreign laws, in addition to prohibiting the promotion of the safety or effectiveness of product candidates not yet approved for commercialization, an act known as pre-approval promotion, also generally restrict companies from promoting approved products for indications other than those indications for which a product is approved, which is also referred to as off-label use. This means, for example, that we may not make claims about the use of our products, should they be approved for sale, outside of their approved indications, and we may not proactively discuss or provide information regarding any of their off-label uses subject to very specific and limited exceptions. If we or our business partners fail to comply with applicable laws and regulations governing off-label uses of our product candidates, if approved, then we could be subject to administrative or judicially imposed sanctions, including, but not limited to: (i) enforcement proceedings by regulatory agencies; (ii) reduced demand for our products; and (iii) civil or criminal sanctions. Furthermore, actions under the FCA have recently been brought against companies for allegedly promoting off-label uses of drugs, because such promotion induces the use and subsequent claims for reimbursement under Medicare and other federal programs. Similar actions for off-label promotion have been initiated by several states for Medicaid fraud.

In addition, the regulatory approval and commercialization of our product candidates outside the United States would subject us to foreign equivalents of many of the laws described above, as well as to local regulatory requirements and industry codes of practice, including those promulgated by trade associations in applicable jurisdictions.

The bringing of any FCA or other enforcement investigation or action, even if unsuccessful, could require us to devote resources to investigate and defend the action, as well as result in reputational harm. Failure to comply with the fraud and abuse laws could result in significant civil and criminal penalties and costs, including the loss of licenses and the ability to participate in federal and state health care programs, and could have a material adverse effect on our business. In addition, many of these laws are vague, subject to modification, and subject to evolving interpretation by prosecutorial and regulatory authorities, increasing the risk of noncompliance. We cannot predict whether changes in applicable law, or interpretation of laws, or changes in our services or marketing practices in response to changes in applicable law or interpretation of laws could have a material adverse effect on our business.

If our product candidates are commercialized, then we would also be required to report detailed and complex pricing information, net of included discounts, rebates and other concessions, to CMS for the purpose of calculating national reimbursement levels, certain federal prices and certain federal and state rebate obligations, and we would need to develop the expertise, as well as the systems for collecting and reporting this data accurately to CMS and have instituted a compliance program to assure that the information collected is complete in all respects. Companies that fail to accurately report this kind of pricing information to the U.S. government could be subject to fines and other sanctions (including potential FCA liability) that could adversely affect their business.

We must comply with data privacy and security laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

We must operate in compliance with various data privacy and security regulations in the United States by both the federal government and the states in which we conduct our business, as well as in other jurisdictions outside of the United States, such as the U.K., the European Economic Area ("EEA") and Asia, where we conduct clinical trials. Our operations entail the collection, use, disclosure, transfer, and processing of sensitive and personal information. Further, our operations extend to commercial partnerships and third-party processors, each of which may be governed by their distinct privacy regulations and cybersecurity laws. These laws are continually evolving and subject to varying interpretations, which requires us to periodically update policies and procedures to maintain compliance.

Regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, Executive Order 14117, Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern, as implemented by Department of Justice regulations issued in December 2024, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

In the U.S., we may be subject to data privacy and security laws and regulations by both the federal government and the states in which we conduct our business, including, for example, state data breach notification laws, state health information and/or genetic privacy laws and federal and state consumer protection laws (including Section 5(a) of the FTC Act and the California Consumer Privacy Act ("CCPA")), which govern the collection, use, disclosure, and protection of health-related and other personal information. Many of these laws and regulations differ from each other in significant ways and the impact of such laws may vary, thus potentially complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming, thus we may be required to incur substantial costs and expenses in order to comply with them. Federal regulators, state attorneys general, and plaintiffs' attorneys, including class action attorneys, have been and will likely continue to be active in this space.

HIPAA, for example, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Failure to comply with these laws and regulations can result in substantial penalties and other liabilities. We may obtain health information from third parties, such as research institutions, that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of the FTC Act. The FTC's current guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA security regulations, but this guidance may change in the future, resulting in increased complexity and the need to expend additional resources to ensure we are complying with the FTC Act.

The CCPA, for example, establishes data privacy rights for individuals located in California and imposes certain requirements for how businesses can collect and use personal data about them. The California Privacy Rights Act, or CPRA, significantly modified the CCPA and imposed additional obligations on covered businesses, including by expanding consumers' rights with respect to their personal data and establishing a state agency vested with the authority to enforce the CCPA. The CCPA provides for civil penalties for violations, as well as a private right of action for certain types of data breaches which may lead to an increased risk of data breach litigation and associated penalties. Numerous other states, including Virginia, Colorado, Utah, Connecticut, Texas, Oregon, Tennessee, Delaware, and Iowa, among others, have recently passed or enacted similarly comprehensive privacy and data protection legislation which differ from each other in significant ways.

Other states have proposed or enacted legislation that may be even more restrictive and not preempted by HIPAA, and may be subject to varying interpretations by the courts and government agencies. Some states have focused on more narrow aspects of privacy. For example, certain states have passed laws that protect biometric information and a smaller number of states have passed or are considering laws that are specifically focused on health privacy, such as Washington's My Health My Data Act ("MHMDA"). The MHMDA imposes new state restrictions and requirements on the processing and sale of consumer health data and creates a private right of action, which further increases compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. These laws and regulations, including their interpretation by governmental agencies, are subject to frequent change and could have a negative impact on our business. Further, these varying interpretations could create complex compliance issues for us and our partners and potentially expose us to additional expense, liability, penalties, negatively impact our client relationships, and lead to adverse publicity, and all of these risks could negatively affect our business in the short and long term. It is not yet fully clear how such laws will be enforced and interpreted. The effects of state and federal privacy laws are potentially significant and may require us to modify our data processing practices which could result in substantial costs and liability in our effort to maintain compliance with them.

In Europe, the collection and use of personal information, including health data, is governed by the EU's General Data Protection Regulation ("EU GDPR") and the United Kingdom's implementation of the same ("UK GDPR" and collectively, the "GDPR"). The GDPR is wide-ranging in scope and imposes numerous requirements on covered companies, including requirements related to individual notice regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the U.K. and the EEA, including the U.S. and permits data protection authorities to impose large penalties for violations of the GDPR. Noncompliance can result in penalties of up to the greater of EUR 20 million (17.5 million GBP for the UK), or 4% of annual global company revenues. 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.

While we expect to have substantially compliant programs and controls in place to comply with GDPR requirements, our efforts toward maintaining compliance with the regulation will likely impose additional costs on us and we cannot accurately predict whether the interpretations of the requirements, or changes in our practices will result in a material adverse effect on our business. We may be subject to fines and penalties, litigation, and reputational harm in connection with any complaints, investigations or charges by European data protection authorities or data subjects which could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical collaboration partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to do business with us due to the potential risk of exposure as a result of the current and future data protection obligations imposed on them by certain data protection authorities in interpretation of European privacy and data protection laws, including the GDPR. Such clients or partners may view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to continue their relationship with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations and prospects, and we may be required to incur substantial costs and expenses in an effort to comply with our legal and regulatory obligations.

While data generally flows freely between the U.K. and the EEA and vice versa as a result of EU Commission and UK government adequacy decisions and regulations, the GDPR imposes strict rules on the transfer of personal data to countries outside the U.K. and the EEA that are not considered by the European Commission and the UK government as providing "adequate" protection to personal data, including the U.S., and, as a result, increases the scrutiny that clinical trial sites located in the U.K. and EEA should apply to transfers of personal data to countries that are considered to lack an adequate level of data protection, including the U.S in certain circumstances. Such transfers of personal data outside of the U.K. or EEA are prohibited unless a valid GDPR mechanism and adequate safeguards are implemented in compliance with the GDPR (e.g. the European Commission Standard Contractual Clauses ("SCCs"), the UK International Data Transfer Agreement/Addendum ("IDTA") or certification to the EU/UK – U.S Data Privacy Framework for U.S specific transfers). Where relying on SCCs or the IDTA for international transfers, we may also be required to carry out transfer impact assessments to determine whether the data importer can ensure sufficient guarantees for safeguarding the personal data under GDPR, including assessing whether the recipient is subject to local laws and practices which allow public authority access to personal data. The international transfer obligations under the U.K. and the EEA data protection regimes

will require significant effort and cost, and may result in us needing to make strategic considerations around where U.K. and the EEA personal data is transferred and which service providers we can utilize for the processing of U.K. and the EEA personal data. Any inability to transfer personal data from the U.K. and the EEA to the U.S. in compliance with the GDPR may impede our ability to conduct trials and may adversely affect our business and financial position.

Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR. For example, the UK Data (Use and Access) Act 2025, which supplements the UK GDPR, has recently come into force and introduces certain provisions that diverge from the EU GDPR. The European Commission has renewed the EU–UK adequacy decision for another six years following the entry into force of the UK Data (Use and Access) Act 2025, meaning the UK's data protection framework is still considered to provide "essentially equivalent" safeguards to the EU's GDPR. While this renewal reduces immediate concerns about a threat to the adequacy decision from the EU Commission which allows free flow of personal data to the U.K, future divergence between the U.K. and EU data protection regimes remains a possibility. Further divergence between the EU GDPR and UK GDPR would create additional regulatory challenges increasing legal risk, uncertainty, complexity and cost to the handling of European personal data and our privacy and data security compliance programs. This may require us to implement different compliance measures for the UK and EEA. In addition, EEA Member States have adopted national laws to supplement the EU GDPR, which may partially deviate from the EU GDPR, and the competent authorities in the EU Member States may interpret EU GDPR obligations slightly differently from country to country, such that we do not expect to operate in a uniform legal landscape in the EEA with respect to data protection regulations.

We are subject to extensive government regulatory compliance and ethics oversight, and we will need to develop more extensive compliance and ethics policies in the future.

Our business is subject to extensive government regulation and ethics oversight, which will become more complex and extensive if we succeed in commercializing products. We have enacted various compliance policies and procedures that govern our business practices as appropriate for a company in our stage of development. These policies and procedures are implemented through education, training and monitoring of our employees, distributors and suppliers. However, our adoption and enforcement of these various policies and procedures does not ensure that we will avoid investigation or the imposition of penalties by applicable government agencies.

In addition, to enhance compliance with applicable health care laws and mitigate potential liability in the event of non-compliance, regulatory authorities, such as OIG, of the HHS have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the U.S. Sentencing Commission Guidelines Manual. Increasing numbers of U.S.-based pharmaceutical companies have such programs. Although we believe our existing compliance policies and procedures are adequate for our current operations, these policies and procedures would not be considered a comprehensive health care compliance program consistent with the HHS OIG's recommendations. Depending upon the nature of our future operations, we anticipate developing a more extensive compliance program in the future.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraudulent or other illegal activity by our employees, independent contractors, principal investigators, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and similar foreign regulatory bodies; fails to comply with manufacturing standards we have established, or with federal, state and foreign health care fraud and abuse laws and regulations; fails to report financial information or data accurately, including to our regulators, such as the FDA and similar foreign regulatory bodies; or fails to disclose unauthorized activities to us. In particular, the promotion, sale and marketing of health care items and services, as well as certain business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and, structuring and commissions, certain customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. We have adopted a Code of Business Conduct and Ethics Policy and other policies and

practices that are designed to help ensure that we, our employees, officers, agents, intermediaries and other third parties comply with applicable laws, but it is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and in some cases regardless of the merits of those actions, those actions could have a significant impact on our business, including the costs of investigation, settlement arrangements, imposition of civil, criminal and administrative penalties (such as additional reporting requirements and oversight if we become subject to Corporate Integrity Agreements and other arrangements, damages, monetary fines, debarment, disgorgement, imprisonment, and possible exclusion from participation in Medicare, Medicaid and other federal health care programs), contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We must comply with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

We may use hazardous chemicals and biological materials in certain aspects of our business and are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, distribution, storage, handling, treatment and disposal of these materials. We cannot eliminate the risk of accidental injury or contamination from the use, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials. In the event of contamination or injury, or failure to comply with environmental, occupational health and safety and export control laws and regulations, we could be held liable for any resulting damages and any such liability could exceed our assets and resources. In addition, we may be required to pay damages or civil judgments related to third-party claims, for which we are uninsured, including those relating to personal injury (including exposure to hazardous chemicals and biological materials), product quality issues, property damage or contribution to remedial obligations.

Risks Related to our Securities

The trading price of our common stock has been volatile with substantial price fluctuations on heavy volume, which could result in substantial losses for purchasers of our common stock and existing stockholders.

Our stock price has been and, in the future, may be subject to substantial volatility. Since our common stock began trading on a post-reverse stock split basis on September 14, 2018 and through December 31, 2025, our stock has traded in a range with a low of $1.51 and a high of $36.25.

Furthermore, the stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- announcements relating to development, regulatory approvals or commercialization of our product candidates or those of competitors;
- results of clinical trials of our product candidates or those of our competitors;
- announcements by us or our competitors of significant strategic partnerships or collaborations or terminations of such arrangements;
- actual or anticipated variations in our operating results and whether we have achieved key business targets;
- sales of our common stock, including sales by our directors and officers or specific stockholders;
- changes in, or our failure to meet, financial estimates by us or by any securities analysts who might cover our stock;
- changes in securities analysts' buy and/or sell recommendations;

- general economic, political, or stock market conditions;
- conditions or trends in our industry;
- changes in laws or other regulatory actions affecting us or our industry;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- investors' general perception of our company, our business, and our prospects;
- disputes concerning our intellectual property or other proprietary rights; and
- recruitment or departure of key personnel.

In the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. For example, in 2025, purported stockholders filed complaints in federal court alleging, among other things, securities laws violations, breaches of fiduciary duty, and other claims relating to alleged false and misleading statements and omissions of material fact. While these actions were subsequently voluntarily dismissed without prejudice, any such future litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

Future sales and issuances of our common stock or rights to purchase common stock could result in substantial dilution to the percentage ownership of our stockholders.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock or other securities convertible into or exchanged for our common stock in one or more transactions, and in a manner we determine from time to time and at prices that may not be the same as the price per share paid by other investors, and dilution to our stockholders could result. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by other investors. New investors could also receive rights, preferences and privileges senior to those of existing holders of our common stock. In addition, in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock, we may be required to proportionally adjust the conversion price, exercise price or number of shares issuable upon exercise of our outstanding warrants.

If we do not meet the continued listing standards of Nasdaq our common stock could be delisted from trading, which could limit investors' ability to make transactions in our common stock and subject us to additional trading restrictions.

Our common stock is listed on Nasdaq, a national securities exchange, which imposes continued listing requirements with respect to listed shares. If we fail to satisfy the continued listing standards, including with respect to the maintenance of a minimum share price, or if Nasdaq in its discretion, determines that a condition exists that makes further dealings of our Company on the exchange unwarranted, Nasdaq may issue a non-compliance letter or initiate delisting proceedings.

If our securities are delisted from trading on the Nasdaq exchange, our securities could be quoted on the OTCQB or on the Pink Open Market. As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;

- a limited amount of news and analyst coverage for us; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3) or obtain additional financing in the future.

Shares that we may issue in the future in connection with certain capital-raising transactions and shares available for future issuance upon exercise of warrants and options could dilute our stockholders and depress the market price of our common stock.

The issuance or even the expected issuance of a large number of shares of our common stock upon purchase, conversion or exercise of the securities described above could depress the market price of our stock and the issuance of such shares will dilute the stock ownership of our existing stockholders. Shares that we may issue in the future in connection with certain capital-raising transactions and shares available for future issuance upon exercise of warrants and options could dilute our stockholders and depress the market price of our common stock and result in the adjustment of the conversion terms of our existing securities.

We can give no assurances that we will ever pay dividends.

We have never paid any dividends on our common stock. While subject to periodic review, our current policy is to retain all earnings, if any, primarily to finance our future growth or ability to consummate strategic transactions, such as a merger or other business combination. We make no assurances that we will ever pay future dividends, cash or otherwise. Whether we pay any dividends in the future will depend on our financial condition, results of operations, and other factors that we will consider.

Risks Related to Our Indebtedness

Our operating activities may be restricted as a result of covenants related to our term loan obligation, which we may be required to repay in an event of default, which could have a materially adverse effect on our business.

On May 13, 2025, we entered into the Loan Agreement with Hercules and the lenders party thereto (as amended, the "Loan Agreement"), pursuant to which the lenders will make available up to four tranches of term loans in an aggregate principal amount of up to $100.0 million, subject to achievement of specified milestones (the "Term Loan"). The Loan Agreement was subsequently amended on November 5, 2025 to increase the aggregate principal amount to up to $125.0 million, structured in four tranches subject to achievement of specified milestones. Until we have repaid such indebtedness, the Loan Agreement subjects us to various customary covenants, including requirements as to financial reporting and insurance, restrictions on our ability to dispose of our business or property, to change our line of business, to liquidate or dissolve, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on our property including intellectual property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock, to redeem capital stock, to enter into licensing agreements, or to engage in transactions with affiliates, and to maintain liquidity of a specified amount. Our business may be adversely affected by these restrictions on our ability to operate our business. The Term Loan will be guaranteed by certain of our subsidiaries and secured by a lien on substantially all of our and the guarantors' assets.

Additionally, we may be required to repay the outstanding indebtedness under the Term Loan if an event of default occurs under the Loan Agreement. Under the Loan Agreement, an event of default will occur if, among other things: we fail to make payments under the Loan Agreement; we breach any of our covenants under the Loan Agreement, subject to specified cure periods with respect to certain breaches; the Lender determines that a material adverse change has occurred; we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings; we are unable to pay our debts as they become due; or we default on contracts with third parties which would permit the holder of indebtedness to accelerate the maturity of such indebtedness or other material agreements. As a result of the occurrence of an event of default, Hercules could accelerate all of the obligations under the Loan Agreement or foreclose on the collateral securing the loan. In the event of an acceleration of amounts due under the Term Loan, we may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In this case, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise

prefer to develop and market ourselves. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.

The Term Loan, provides up to $125.0 million of debt financing and has interest-only payments until December 1, 2027, which will be extended to June 1, 2028, or December 1, 2028, if certain conditions described in the Loan Agreement are met. Thereafter, we are obligated to make payments that will include installments of principal and interest through the Maturity Date.

This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including the fact that:

- we will need to repay our indebtedness by making payments of interest and principal, which will reduce the amount of money available to finance our operations, our research and development efforts, and other general corporate activities; and
- our failure to comply with the restrictive covenants in the Loan Agreement, as amended, could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and Hercules could seek to enforce its security interest in the assets securing such indebtedness.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Governance

As part of its oversight role, the Audit Committee of our Board is responsible for overseeing cybersecurity risk exposure as well as management's actions to identify, assess, mitigate and remediate cybersecurity threats. The Audit Committee receives quarterly reports from our Chief Financial Officer, Chief Legal Officer and Senior Director of Information Technology regarding our cybersecurity risk programs. Our Chief Legal Officer also provides periodic updates to the Board, addressing the Company's expanded Enterprise Risk Management program and assessments, that include summaries of our cybersecurity risk programs to enable discussion of cybersecurity risk management at the Board level. The Audit Committee annually reviews and recommends our information security policy and program to the Board. The Audit Committee is composed of members with financial expertise as well as one member with a cybersecurity oversight certification.

Our Chief Financial Officer has overall responsibility for our cybersecurity and has over 30 years of experience managing information technology, or IT, departments at biotechnology and pharmaceutical companies. Our Chief Legal Officer has over 30 years of experience in federal law enforcement, life sciences legal and compliance programs, risk management and corporate governance responsibilities. Our Senior Director of Information Technology is responsible for the development and implementation of IT department controls, policies, infrastructure, and day-to-day operations, in addition to managing security risk, evaluating safeguards and recommending security improvements, and has over nine years of experience managing IT departments, including with respect to cybersecurity, for a biotechnology company. These individuals are informed of cybersecurity risks on an ongoing basis in part via our utilization of third-party vendors, which we utilize to help strengthen our information security risk management by conducting evaluations of our security controls on at least a quarterly basis.

Enterprise Risk Management and Strategy

In 2025, the Company established its Enterprise Risk Management ("ERM") program, as part of which the Company periodically reviews and assesses the most significant and likely risks to the enterprise, the strategies the Company has implemented to mitigate such risks, and the likelihood that such risks will occur within a defined period of

time. As part of this process, each risk and mitigation is evaluated to determine if any additional steps to address the risk may be warranted. Management shares its ERM assessments on a quarterly basis with the Audit Committee to solicit input and feedback and periodically reports their assessments to the full Board of Directors.

The Company's ERM program includes cybersecurity as a component of the broader risks considered and assessed.

Our cybersecurity risk management program is comprised of the following components:

- Identifying assets at risk from cybersecurity threats and taking mitigation measures including the implementation of data backup, recovery and restore procedures to address business continuity, as well as through IT controls, policies and infrastructure.
- Identifying potential cybersecurity threats that could disrupt our IT systems, cause a data breach or other incident or compromise data security by implementing several protective measures.
- Conducting periodic assessment of protections to prevent or mitigate cybersecurity threats.
- The Company has processes to oversee and identify risks from cybersecurity threats associated with its use of third-party service providers and vendors.
- Retaining third parties to periodically assess our cybersecurity management program, provide cybersecurity training, perform phishing tests, gap analyses and penetration tests, advise on business continuity plans, and to provide additional support in the event of a cybersecurity incident.

While risks from cybersecurity threats or incidents have not materially affected our strategy, results of operations, or financial condition to date, the Chief Financial Officer, Chief Legal Officer and Senior Director of Information Technology work with other groups in the Company to understand the severity of the potential consequences of a cybersecurity incident and to make decisions about how to prioritize mitigation and other initiatives based on, among other things, materiality to the business. All employees and contractors receive cybersecurity training, and we plan to implement additional annual training for all employees and contractors. All trainings are intended to raise awareness of cybersecurity threats in order to reduce our vulnerability as well as to encourage consideration of cybersecurity risks across functions.

Item 2. Properties

Our principal executive offices are located in Gaithersburg, Maryland, where we occupy approximately 19,699 square feet of laboratory and office space. For additional information, see *Note 5. Leases* to our consolidated financial statements. Management believes that these facilities are suitable and adequate to meet our anticipated needs.

Item 3. Legal Proceedings

On August 5, 2025, a class action complaint was filed in federal district court in the District of Maryland, Southern Division, naming as defendants the Company and two of the Company's executive officers, which was captioned *In re Altimmune, Inc. Securities Litigation*, Case No. 8:25-cv-02581 (D. Md.) (the "Securities Class Action"). The Securities Class Action alleged that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 thereunder, by making false and misleading statements and omissions of material fact to the investing public including the plaintiff and class members, who purchased or otherwise acquired the Company's common stock between August 10, 2023 and June 25, 2025, including relating to pemvidutide and our IMPACT Phase 2b trial of pemvidutide in MASH. The plaintiff and class members sought, among other things, to have the action maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure and for the defendants to pay damages, interest, and an award of costs, including attorneys' fees. On October 16, 2025, the court appointed lead plaintiffs for the litigation. On October 29, 2025, the court entered an order requiring lead plaintiffs to file an amended complaint by November 26, 2025, and for defendants to file an answer or notice of intent to file a motion to dismiss such amended complaint by December 10, 2025. Rather than amend, the lead plaintiffs sought voluntary dismissal without prejudice of the action, which the Court granted on November 26, 2025.

On September 29, 2025, a shareholder derivative complaint was filed in federal district court in the District of Maryland, purportedly on behalf of the Company, naming as defendants two of the Company's then-executive officers and eight of the Company's current and former board members, captioned *Alaraidah v. Altimmune, Inc., et al.*, No. 8:25-cv-03223 (D. Md.) (the "Derivative Action"). The complaint was based upon allegations that were similar to those alleged in a class action complaint previously filed against us in the Securities Class Action and alleged claims for violations of Section 14(a) of the Securities Exchange Act of 1934, breaches of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, and contribution under Sections 10(b) and 21D of the Securities Exchange Act of 1934 based on the defendants purportedly making or causing to be made false and misleading statements and omissions of material fact between August 10, 2023 and June 25, 2025. The complaint sought unspecified monetary relief, restitution, costs, and equitable relief. On December 22, 2025, the parties filed a stipulation of dismissal without prejudice, which the Court granted on that date.

From time to time, we may be involved in various legal proceedings or investigations, which could be costly and impose a significant burden on management and employees. The results of any current or future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

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

Holders

As of February 27, 2026, we had 193 record holders of our common stock. The number of record holders is based on the actual number of holders registered on the books of our transfer agent and does not reflect holders of shares in "street name" or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

Dividends

Other than the special dividend immediately prior to the Mergers, we have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not expect to pay any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans 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.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis contains forward-looking statements that involve substantial risks and uncertainties. See "Forward-looking statements" in Part I of this Annual Report and the section entitled "Risk Factors" in Part I, Item 1A of this Annual Report for a discussion of certain factors that could cause actual results or events to differ materially from the forward-looking statements that we make.

Overview

Altimmune, Inc. is a late clinical-stage biopharmaceutical company developing novel therapies for serious liver diseases. Our lead product candidate, pemvidutide (formerly known as ALT-801), is a balanced 1:1 glucagon/GLP-1 dual receptor agonist in development for the treatment of MASH, AUD and ALD. We may also pursue additional indications for pemvidutide that leverage its differentiated clinical profile. Except where the context indicates otherwise, references to "we," "us," "our," "Altimmune", or the "Company" refer to the company and its subsidiaries.

Fiscal Year 2025 Business Update

MASH

On June 26, 2025, we released 24-week topline efficacy results from IMPACT, a Phase 2b trial of pemvidutide in patients with MASH. The Phase 2b trial enrolled 212 subjects with biopsy-confirmed MASH and fibrosis stages F2/F3 with and without diabetes randomized 1:2:2 to receive weekly subcutaneous doses of pemvidutide at 1.2 mg, 1.8 mg or placebo. The topline 24-week data showed that treatment with pemvidutide achieved statistically significant improvements in MASH resolution without worsening of fibrosis, improvements in fibrosis without worsening of MASH, and statistically significant changes in well-established NITs of fibrosis, including ELF score and LSM compared with placebo at both doses.

On December 11, 2025, we held an End-of-Phase 2 meeting with the FDA to discuss and align on the parameters for a registrational Phase 3 trial of pemvidutide for MASH patients with moderate to advanced fibrosis with biopsy driven endpoints. The FDA agreed to the use of AIM-MASH AI Assist, the first FDA-qualified AI pathology tool for MASH clinical trials, in our Phase 3 trial. We received final minutes from the End-of-Phase 2 meeting in January 2026, which we believe describe a clear regulatory path for a Phase 3 trial in MASH. We also intend to seek scientific advice from European regulators to further inform the final Phase 3 protocol. See *Item 1. Business* for additional information.

On December 19, 2025, we announced positive 48-week topline results from the IMPACT Phase 2b trial of pemvidutide in patients with MASH. The topline 48-week data from the IMPACT trial showed that treatment with pemvidutide achieved statistically significant improvements across treatment arms versus placebo in the key anti-fibrosis NITs of ELF and LSM.

Additional Indications for Pemvidutide

On March 13, 2025, we announced that we are pursuing two additional indications for our lead product candidate, pemvidutide. The new indications are AUD and ALD.

AUD

On May 19, 2025, we announced the enrollment of the first subject in the RECLAIM Phase 2 trial evaluating the efficacy and safety of pemvidutide in subjects with AUD. RECLAIM is a randomized, placebo-controlled trial conducted across approximately 15 sites in the United States, targeting enrollment of approximately 100 subjects.

On August 19, 2025, we announced that the U.S. Food and Drug Administration has granted Fast Track designation to pemvidutide for the treatment of AUD. Fast Track designation is intended to accelerate the development and review of new drugs that target serious conditions and address unmet medical needs.

On November 3, 2025, we announced the completion of enrollment in the RECLAIM Phase 2 trial. Enrollment completed ahead of schedule, underscoring strong interest from the patient community in a new therapeutic option for AUD. We are on track to complete the 24-week treatment period and announce topline results in 2026.

ALD

On July 9, 2025, we announced the enrollment of the first patient in the RESTORE Phase 2 trial evaluating the efficacy and safety of pemvidutide in subjects with ALD. RESTORE is a randomized, placebo-controlled trial enrolling approximately 100 patients across 34 sites in the United States. See *Item 1. Business* for additional information.

Recent Global Events

Tariffs and Inflation

The United States recently imposed reciprocal and additional tariffs on many countries around the world. Such tariffs and counter tariffs by other countries against the U.S. have been causing uncertainties in the global markets and supply chain. If the tariffs and counter tariffs continue or escalate, they could have a significant negative effect on the global economy or on our operations, including continued inflationary pressures on raw materials, supply chain and logistics disruptions, and volatility in the capital markets, foreign exchange rates and interest rates.

Inflation generally affects us by increasing our employee-related costs and clinical trial expenses, as well as other operating expenses. Our financial condition and results of operations may also be impacted by other factors we may not be able to control, such as public health crises, global supply chain disruptions, uncertain global economic conditions, global trade disputes or political instability as further discussed in the section "Risk Factors" in this Annual Report on Form 10-K.

Financial Operations Overview

The consolidated financial information presented below includes the accounts of Altimmune, Inc., Altimmune UK, Ltd, Spitfire Pharma, LLC. and Altimmune AU Pty, Ltd. All intercompany accounts and transactions have been eliminated in consolidation.

Revenue

We have not generated any revenue from the sale of any products to date. Our revenues in previous years consisted primarily of government and foundation grants and contracts that supported our efforts on specific research projects.

Research and development expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- expenses incurred under agreements with contract research organizations (“CROs”) and investigative sites that conduct our clinical trials;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- costs associated with preclinical and clinical activities and regulatory operations, including the cost of acquiring, developing and manufacturing clinical trial materials; and
- depreciation and other expenses, which include direct and allocated expenses for insurance, consultants, legal fees and other supplies.

Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, CROs and clinical sites.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when or to what extent we will generate sales from the commercialization of any of our product candidates if they receive regulatory approval. The successful development of our product candidates is highly uncertain and may never result in approved products. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- scope, rate of enrollment and expense of our ongoing, as well as any additional, clinical trials, and other research and development activities;
- significant and potentially changing government regulation; and
- the timing and receipt of regulatory approvals, if any.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, 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 of a product candidate, we could be required to expend significant additional financial resources and time on the completion of clinical development. Additionally, we may conduct additional trials in support of sales and marketing of our product candidates.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of clinical and preclinical candidates. Our current active and planned research and development activities include the following:

- conduct of Phase 3 clinical trial for pemvidutide in MASH;
- conduct of clinical trials for AUD and ALD;
- conduct of clinical trials and nonclinical safety studies for pemvidutide;
- conduct of additional research and discovery projects; and
- manufacture of clinical trial materials in support of our clinical trials.

A significant portion of our research and development efforts have been related to the development of pemvidutide. We do not allocate personnel-related costs, costs associated with our general research platform improvements, depreciation or other indirect costs to specific programs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses for our employees in executive, operational, finance and human resource functions. Other general and administrative expenses include insurance expenses, facility-related costs and professional fees for directors, accounting and legal services, and expenses associated with obtaining and maintaining our intellectual property.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development activities. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and the SEC requirements, director and officer insurance, investor relations costs and other costs associated with being a public company. Additionally, if and when we believe a regulatory approval of the first product candidate appears likely, we anticipate an increase in staffing and related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

Results of Operations

Comparison of years ended December 31, 2025 and December 31, 2024 (in thousands):

	Year Ended December 31,			
	2025	2024	Increase (Decrease)	
Revenues	$ 41	$ 20	$ 21	105 %
Operating expenses:				
Research and development	66,432	82,226	(15,794)	(19)%
General and administrative	28,098	20,966	7,132	34 %
Total operating expenses	94,530	103,192	(8,662)	(8)%
Loss from operations	(94,489)	(103,172)	(8,683)	(8)%
Other income (expense):				
Interest expense	(1,636)	(9)	1,627	* %
Interest income	7,541	8,074	(533)	(7)%
Other income (expense), net	(190)	48	(238)	(496)%
Total other income (expense), net	5,715	8,113	(2,398)	(30)%
Net loss before income taxes	(88,774)	(95,059)	6,285	(7)%
Income tax expense (benefit)	(681)	—	(681)	* %
Net loss	$ (88,093)	$ (95,059)	$ (6,966)	(7)%

*Indicates the percentage change period over period is not meaningful due to zero or negligible amount in the prior period.

Research and development expenses

Research and development expenses for the years ended December 31, 2025 and 2024 consisted primarily of expenses related to product candidate development, summarized as follows:

	Year Ended December 31,			
(in thousands)	2025	2024	Increase (Decrease)	
Pemvidutide				
MASH	$ 20,649	$ 36,965	$ (16,316)	(44)%
ALD	6,956	—	6,956	* %
AUD	6,757	—	6,757	* %
Other pemvidutide expenses	8,027	16,309	(8,282)	(51)%
Total pemvidutide expenses	42,389	53,274	(10,885)	(20)%
HepTcell	—	2,695	(2,695)	(100)%
Additional discovery projects	—	1,336	(1,336)	(100)%
Non-project costs				
Labor	10,475	10,026	449	4 %
Stock compensation	6,166	6,351	(185)	(3)%
Shared service and infrastructure	7,402	8,544	(1,142)	(13)%
Total research and development expenses	$ 66,432	$ 82,226	$ (15,794)	(19)%

*indicates the percentage change period over period is not meaningful due to zero amount in the prior period.

The decrease in research and development expenses for MASH was primarily due to ongoing enrollment for the IMPACT Phase 2b trial in MASH during 2024 which was completed in early 2025. The decrease in other pemvidutide expenses was primarily due to a $5.7 million decrease in manufacturing expenses and a $2.1 million decrease due to winding down of GLP-1 and other nonclinical activities. These decreases were partially offset by the increase in expense associated with the start of the AUD and ALD trials.

The decrease in research and development expenses for HepTcell was due to the termination of HepTcell in March 2024.

General and administrative expenses

General and administrative expenses increased by $7.1 million, or 34%, during the year ended December 31, 2025 as compared to the year ended December 31, 2024, primarily due to a $2.7 million increase in professional services and a $4.9 million increase in stock compensation and other labor-related expenses, including the $1.4 million severance costs for our former executives.

Total other income (expense), net

Total other income (expense), net decreased by $2.4 million during the year ended December 31, 2025 as compared to the year ended December 31, 2024. The net decrease was primarily due to a $1.6 million increase in interest expense related to our Term Loan and a $0.5 million decrease in interest income earned on our cash equivalents and short-term investments.

Income tax expense (benefit)

During the year ended December 31, 2025, we have recorded a discrete tax benefit of approximately $0.7 million related to a portion of carryback claims with the State of Maryland, which we previously held an uncertain tax position against. Other than the discrete tax benefit discussed above, due to a full valuation allowance, the Company did not record an income tax expense (benefit) for either of the years ended December 31, 2025 and 2024.

Liquidity and Capital Resources

Overview

Our primary sources of cash for the year ended December 31, 2025 were from equity transactions, debt, interest income from our money market funds and short-term investments, and proceeds from maturity of our short-term investments. Our cash, cash equivalents, restricted cash and short-term investments were $273.5 million as of December 31, 2025. We believe, based on the operating cash requirements and capital expenditures expected for 2026 and 2027, our cash on hand as of December 31, 2025, together with expected cash receipts from our equity transactions and research and development incentives, are sufficient to fund operations for at least a twelve-month period from the issuance date of our December 31, 2025 consolidated financial statements.

We have not generated any revenues from the sale of any products to date, and there is no assurance of any future revenues from product sales. We have incurred significant losses since we commenced operations. As of December 31, 2025, we had an accumulated deficit of $649.5 million. In addition, we have not generated positive cash flows from operations. We have had to rely on a variety of financing sources, including the issuance of debt and equity securities. As capital resources are consumed to fund our research and development activities, we may require additional capital beyond our currently anticipated amounts. In order to address our capital needs, including our planned clinical trials, we must continue to actively pursue additional equity or debt financing, and monetization of our existing programs through partnership arrangements or sales to third parties.

Sources of Liquidity

Loan Financing

On May 13, 2025 (“Closing Date”), we entered into a Loan and Security Agreement (“Loan Agreement”) with Hercules Capital, Inc. (“Hercules”) and the lenders party thereto, pursuant to which the lenders will make available up to four tranches of term loans in an aggregate principal amount of $100.0 million (the “Term Loan”), subject to certain terms and conditions. The first Term Loan tranche was drawn down on the Closing Date in an aggregate principal amount of $15.0 million.

On November 5, 2025, (the “Amendment Closing”), we entered into an amendment to the Loan Agreement with Hercules and the lenders party thereto, pursuant to which the lenders will, subject to certain terms and conditions, increase the availability under the Term Loan from an aggregate principal amount of $100.0 million to $125.0 million. The Term Loan, as amended, is structured in four tranches. As disclosed above, the first Term Loan tranche was drawn down on the

Closing Date in an aggregate principal amount of $15.0 million. The second Term Loan tranche was drawn down on the Amendment Closing in an aggregate principal amount of $20.0 million. Upon the achievement of certain milestones and subject to other terms and conditions set out in the Loan Agreement, as amended, the third Term Loan tranche will be made available in an aggregate principal amount of up to $10.0 million. The fourth Term Loan tranche will be made available in an aggregate principal amount of up to $80.0 million subject to the approval of the lenders. The Term Loan, as amended, bears interest equal to the greater of (a) 9.70% per annum and (b) the prime rate as reported in The Wall Street Journal plus 2.45% per annum. The interest-only period has been extended to 30 months from May 13, 2025.

Shelf Registrations

On November 13, 2025, we filed a shelf registration statement on Form S-3, as amended, which was declared effective on December 5, 2025. This shelf registration allows us to offer and sell up to $400.0 million of our common stock, preferred stock, debt securities, warrants, rights and units (the "November 2025 Shelf") for a period of 3 years from effectiveness.

On February 27, 2025, we filed a shelf registration statement on Form S-3, which was declared effective on March 13, 2025. This shelf registration allows us to offer and sell up to $400.0 million of our common stock, preferred stock, debt securities, warrants, rights and units (the "February 2025 Shelf") for a period of 3 years from effectiveness.

On February 28, 2023, we filed a shelf registration statement on Form S-3ASR, which was declared effective immediately. This shelf registration allowed us to offer and sell any amount of our common stock, preferred stock, debt securities, warrants, rights and units (the "2023 Shelf"). The 2023 Shelf expired on February 27, 2025

At-the-Market Offerings

On November 6, 2025, we entered into an Equity Distribution Agreement (the "November 2025 Agreement") with Leerink Partners LLC serving as sales agent, with respect to an at-the-market offerings program under which we may offer and sell shares of our common stock having an aggregate offering price of up to $200.0 million through the sales agent from the February 2025 Shelf. Since inception through December 31, 2025, we raised approximately $25.4 million in net proceeds, with $174.2 million remaining available to be sold under the November 2025 Agreement.

On February 27, 2025, we entered into an Equity Distribution Agreement (the "February 2025 Agreement") with Leerink Partners LLC, Piper Sandler & Co. and Stifel, Nicolaus & Company, Incorporated, serving as sales agents, with respect to an at-the-market offerings program under which we offered and sold shares of our common stock having an aggregate offering price of up to $150.0 million through the sales agents from the February 2025 Shelf. Since inception, through the termination of the February 2025 Agreement in November 2025, we raised approximately $118.3 million in net proceeds.

On February 28, 2023, we entered an Equity Distribution Agreement (the "2023 Agreement") with Evercore Group L.L.C., JMP Securities LLC and B. Riley Securities, Inc., serving as sales agents, with respect to an at-the-market offerings program under which we offered and sold shares of our common stock having an aggregate offering price of up to $150.0 million through the Sale Agents from the 2023 Shelf. Since inception through the termination of the 2023 Agreement in February 2025, we raised approximately $126.8 million in net proceeds.

Registered Direct Offering

On January 27, 2026, the Company entered into a securities purchase agreement with a new fundamental institutional investor pursuant to a registered direct offering under the November 2025 Shelf for the purchase and sale of 12,397,920 shares of its common stock and 4,647,534 pre-funded warrants for net proceeds of approximately $70.4 million. The pre-funded warrants were fully exercised on February 13, 2026, resulting in the issuance of 4,647,534 shares of our common stock.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2025 and 2024:

(in thousands)	Year Ended December 31, 2025	2024	Increase (Decrease)
Net cash (used in) provided by:			
Operating activities	$ (67,535)	$ (79,848)	$ (12,313)
Investing activities	(132,473)	(28,386)	(104,087)
Financing activities	206,842	10,044	196,798
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 6,834	$ (98,190)	$ 105,024

Operating Activities

Net cash used in operating activities was $67.5 million for the year ended December 31, 2025 compared to $79.8 million during the year ended December 31, 2024. Our sources of cash provided by operations during the year ended December 31, 2025 were primarily cash receipts of research and development incentive credits. The primary uses of cash from our operating activities include payments for labor and labor-related costs, professional fees, research and development costs associated with our clinical trials and other general corporate expenditures. The decrease in cash used in operating activities of $12.3 million was due to a $10.0 million decrease in net loss as adjusted for noncash items and a $2.3 million change in working capital accounts.

Investing Activities

Net cash used in investing activities was $132.5 million for the year ended December 31, 2025 compared to $28.4 million net cash provided by investing activities during the year ended December 31, 2024. The net cash used in investing activities during the year ended December 31, 2025 was primarily due to $285.4 million purchase of short-term investments, partially offset by $153.0 million proceeds from sale and maturities of short-term investments. The net cash used in investing activities during the year ended December 31, 2024 was primarily due to $115.7 million purchase of short-term investments, partially offset by $87.3 million proceeds from sale and maturities of short-term investments.

Financing Activities

Net cash provided by financing activities was $206.8 million for the year ended December 31, 2025 compared to $10.0 million during the year ended December 31, 2024. The net cash provided by financing activities during the year ended December 31, 2025 was primarily the result of the receipt of $173.3 million in net proceeds from the issuance of common stock from our at-the-market offerings program, $33.9 million in net proceeds from the Term Loan and $0.3 million in proceeds from our ESPP, partially offset by a $0.7 million payment for tax withholding obligations related to share-based compensation. The net cash provided by financing activities during the year ended December 31, 2024 was primarily the result of the receipt of $10.0 million in net proceeds from the issuance of common stock from our at-the-market offerings program, $0.4 million in proceeds from exercise of stock options, $0.3 million in proceeds from our ESPP and $0.2 million proceeds from exercises of stock warrants, partially offset by $0.9 million payment for tax withholding obligations related to share-based compensation.

Capital Resources

We have financed our operations to date principally through our equity offerings and proceeds from issuances of our preferred stock, common stock and warrants. As of December 31, 2025, we had $273.5 million of cash, cash equivalents, restricted cash and short-term investments. Accordingly, management believes that we have sufficient capital to fund our plan of operations for at least a twelve-month period from the issuance date of our December 31, 2025 consolidated financial statements. However, in order to address our capital needs in the long-term, including our planned

clinical trials, we must continue to actively pursue additional equity or debt financing and monetization of our existing programs through partnership arrangements or sales to third parties.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of our consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates.

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

Research and Development

Research and development costs are expensed as incurred. Research and development costs consist of payroll and personnel expense, consulting costs, external contract research and development expenses, which includes fees paid to other entities that conduct certain research and development activities on our behalf, such as clinical research organizations ("CROs") and contract manufacturing organizations ("CMOs"), raw materials, drug product manufacturing costs, laboratory supplies and allocated overhead, including depreciation and amortization, rent and utilities. Material research and development costs that are paid in advance of performance are capitalized as a prepaid expense and amortized over the service period as the services are provided.

Clinical trial costs are a significant component of research and development expenses, and we outsource a significant portion of these costs to third parties. Third-party clinical trial expenses include investigator fees, site and patient costs, CRO costs, costs for central laboratory testing, data management and CMO costs. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the Consolidated Balance Sheets as a prepaid asset or accrued expenses. These third-party agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. Material advance payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the prepaid and accrued balances at the end of any reporting period.

Stock-based Compensation

We account for all stock-based compensation granted to employees and non-employees using a fair value method. Compensation expense related to stock-based awards is recognized over the requisite service period of the awards, usually the vesting period, on a straight-line basis, net of estimated forfeitures. The fair value of stock option awards to employees and directors is estimated using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (1) the expected stock price volatility, (2) the expected term of the award, (3) the risk-free interest rate and (4) expected dividends.

We estimate forfeitures at the time of grant and, if necessary, revise the estimate in subsequent periods if actual forfeitures differ from those estimates. Estimates are based on our historical analysis of actual stock option forfeitures.

The actual expense recognized over the vesting period is only for those options that vest. For each of the years ended December 31, 2025 and 2024, forfeiture rates were approximately 9%.

We calculated the fair value of stock option awards using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the input of subjective assumptions, including stock price volatility and the expected life of stock options. The application of this valuation model involves assumptions that are highly subjective, judgmental and sensitive in the determination of compensation cost. Our stock started being publicly traded under ALT beginning in June 2017, and as such we do not have sufficient history to estimate the volatility of our common stock price or the expected life of our options. The expected stock price volatility for stock option awards is based on a weighted-average volatility rate of historical volatility from a representative peer group of comparable companies and our stock price volatility until such time that we have sufficient history to rely on the volatility of our own stock. The average expected life of stock options was determined according to the "simplified method" as described in SAB 107, which is the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate was determined by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant. We have not paid and do not anticipate paying cash dividends. Therefore, the expected dividend rate is assumed to be 0%.

Modification of stock awards are evaluated and recorded based on the fair value of the award on the modification date. Depending on the type of modifications, we estimate the fair value of modified stock options using the Black-Scholes option pricing model. The fair value of modified restricted stock units is determined based on our stock price at the modification date.

There is a high degree of subjectivity involved when using option pricing models to estimate stock-based compensation. If factors change and we employ different assumptions when valuing our options, the compensation expense that we record in the future may differ significantly from what we have historically reported.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data

ALTIMMUNE, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Altimmune, Inc.

Opinion on the Financial Statements

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

Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

Critical Audit Matter

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

Accrued and Prepaid Research and Development Expenses

Description of the Matter

As disclosed in Note 6, the Company's total accrued research and development expenses were $6.1 million as of December 31, 2025, which represents the estimated obligation for research and development expenses incurred as of December 31, 2025 but not paid as of that date. In addition, the Company's total prepaid expenses and other current assets were $3.0 million as of December 31, 2025, which included amounts that were paid in advance of services incurred pursuant to research and development activities. As discussed in Note 2 of the consolidated financial statements, material advance payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs.

How We Addressed the Matter in Our Audit

Auditing the Company's accrued and prepaid research and development expenses was especially challenging as the amounts are based on various estimates from third-party vendors, as well as other inputs estimated by members of management, such as actual costs incurred but not yet billed, estimated project timelines, and the costs associated with these services. Additionally, due to the timing of invoicing received from third parties, the actual amounts incurred are not always known by the report date.

To evaluate the accrued and prepaid research and development expenses, our audit procedures included, testing the completeness and accuracy of the underlying data used to estimate the amounts recorded. We corroborated the progress of research and development activities through discussion with the Company's research and development personnel that oversee the research and development projects. We inspected the Company's contracts with third parties and any pending change orders to assess the impact on amounts recorded and inspected subsequent disbursements made and invoices received from third parties. Additionally, we independently confirmed research and development costs incurred and prepaid balances held as of December 31, 2025 with a sample of third parties.

/s/ Ernst & Young LLP

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

Iselin, New Jersey
March 6, 2026

ALTIMMUNE, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per-share amounts)

	December 31,	
	2025	2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 43,760	$ 36,926
Restricted cash	42	42
Total cash, cash equivalents and restricted cash	43,802	36,968
Short-term investments	229,696	94,965
Accounts and other receivables	1,219	544
Income tax and R&D incentive receivables	518	2,573
Prepaid expenses and other current assets	2,957	2,204
Total current assets	278,192	137,254
Property and equipment, net	312	413
Other assets	1,425	1,639
Total assets	$ 279,929	$ 139,306
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,717	$ 211
Accrued expenses and other current liabilities	12,280	10,257
Total current liabilities	14,997	10,468
Term loan, noncurrent	34,287	—
Other noncurrent liabilities	5,753	5,330
Total liabilities	55,037	15,798
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 110,882,735 and 72,352,701 shares issued and outstanding as of December 31, 2025 and 2024, respectively	11	7
Additional paid-in capital	879,292	689,864
Accumulated deficit	(649,483)	(561,390)
Accumulated other comprehensive loss, net	(4,928)	(4,973)
Total stockholders' equity	224,892	123,508
Total liabilities and stockholders' equity	$ 279,929	$ 139,306

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

ALTIMMUNE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per-share amounts)

	Year Ended December 31,	
	2025	2024
Revenues	$ 41	$ 20
Operating expenses:		
Research and development	66,432	82,226
General and administrative	28,098	20,966
Total operating expenses	94,530	103,192
Loss from operations	(94,489)	(103,172)
Other income (expense):		
Interest expense	(1,636)	(9)
Interest income	7,541	8,074
Other income (expense), net	(190)	48
Total other income (expense), net	5,715	8,113
Net loss before income taxes	(88,774)	(95,059)
Income tax expense (benefit)	(681)	—
Net loss	(88,093)	(95,059)
Other comprehensive income — unrealized gain on short-term investments	45	31
Comprehensive loss	$ (88,048)	$ (95,028)
Net loss per share, basic and diluted	$ (1.00)	$ (1.34)
Weighted-average common shares outstanding, basic and diluted	88,104,132	71,003,399

The accompanying notes are an integral part of the consolidated financial statements

ALTIMMUNE, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at December 31, 2023	70,677,400	$ 7	$ 665,427	$ (466,331)	$ (5,004)	$ 194,099
Stock-based compensation	—	—	14,393	—	—	14,393
Exercise of stock options	138,386	—	439	—	—	439
Vesting of restricted stock awards including withholding, net	192,537	—	(850)	—	—	(850)
Issuance of common stock from Employee Stock Purchase Plan	86,857	—	300	—	—	300
Issuance of common stock in at-the-market offerings, net	1,207,521	—	9,994	—	—	9,994
Issuance of common stock upon cashless exercise of warrants	50,000	—	161	—	—	161
Unrealized gain on short-term investments	—	—	—	—	31	31
Net loss	—	—	—	(95,059)	—	(95,059)
Balance at December 31, 2024	72,352,701	7	689,864	(561,390)	(4,973)	123,508
Stock-based compensation	—	—	16,076	—	—	16,076
Exercise of stock options	14,167	—	41	—	—	41
Vesting of restricted stock awards including withholding, net	180,958	—	(709)	—	—	(709)
Issuance of common stock from Employee Stock Purchase Plan	71,342	—	291	—	—	291
Issuance of common stock in at-the-market offerings, net	38,263,567	4	173,729	—	—	173,733
Unrealized gain on short-term investments	—	—	—	—	45	45
Net loss	—	—	—	(88,093)	—	(88,093)
Balance at December 31, 2025	110,882,735	$ 11	$ 879,292	$ (649,483)	$ (4,928)	$ 224,892

The accompanying notes are an integral part of the consolidated financial statement

ALTIMMUNE, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (88,093)	$ (95,059)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	16,076	14,393
Depreciation of property and equipment	112	238
Accretion of discounts on short-term investments	(2,224)	(3,850)
Amortization of debt discount and costs	363	—
Loss on foreign currency exchange	160	(48)
Deferred income tax benefit	(681)	—
Changes in operating assets and liabilities:		
Accounts receivable	(675)	567
Prepaid expenses and other assets	(204)	4,713
Accounts payable	2,506	(1,859)
Accrued expenses and other liabilities	2,389	(112)
Income tax and R&D incentive receivables	2,736	1,169
Net cash used in operating activities	(67,535)	(79,848)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sales and maturities of short-term investments	152,986	87,345
Purchases of short-term investments	(285,448)	(115,731)
Purchases of property and equipment	(11)	—
Net cash used in investing activities	(132,473)	(28,386)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments of deferred offering costs	(438)	—
Proceeds from exercises of warrants	—	161
Proceeds from term loan	35,000	—
Payment for debt issuance costs	(1,076)	—
Proceeds from issuance of common stock in at-the-market offerings, net	173,733	9,994
Proceeds from issuance of common stock from Employee Stock Purchase Plan	291	300
Proceeds from exercises of stock options	41	439
Payments for tax withholding in share-based compensation	(709)	(850)
Net cash provided by financing activities	206,842	10,044
Net increase (decrease) in cash and cash equivalents and restricted cash	6,834	(98,190)
Cash, cash equivalents and restricted cash at beginning of period	36,968	135,158
Cash, cash equivalents and restricted cash at end of period	$ 43,802	$ 36,968
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ 975	$ —
Cash received from income tax refunds	$ 1,422	$ —
SUPPLEMENTAL NON-CASH ACTIVITIES:		
Deferred offering costs in accrued expenses and other current liabilities	$ 111	$ —
Operating lease liability and right-of-use asset addition	$ —	$ 1,409

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

ALTIMMUNE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Organization

Altimmune, Inc., headquartered in Gaithersburg, Maryland, United States, together with its subsidiaries (collectively, the "Company" or "Altimmune") is a late clinical-stage biopharmaceutical company incorporated under the laws of the State of Delaware.

The Company is developing novel therapies for serious liver diseases. The Company's lead product candidate is pemvidutide (formerly known as ALT-801), a balanced 1:1 glucagon/GLP-1 dual receptor agonist in development for the treatment of MASH, AUD and ALD. The Company may also pursue additional indications for pemvidutide that leverage its differentiated clinical profile. Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and raising capital, and has financed its operations through the issuance of common and preferred stock, long-term debt, and proceeds from research grants and government contracts. The Company has not generated any revenues from the sale of any products to date, and there is no assurance of any future revenues from product sales.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements are prepared in conformity with generally accepted accounting principles in the United States ("U.S. GAAP") and in accordance with the rules and regulations of the United States Securities and Exchange Commission ("SEC"). The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates and assumptions made in the accompanying consolidated financial statements include, but are not limited to, the valuation of share-based awards, income taxes, prepaids and accruals for research and development ("R&D") activities. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable. However, actual results could differ from those estimates.

Segment Information

The Company is being managed and operated as a single business developing novel therapies for serious liver diseases. The Company is managed by a single management team, and consistent with its organizational structure, the Chief Executive Officer manages and allocates resources at a consolidated level. Accordingly, the Company views its business as one operating segment.

Cash Equivalents

The Company considers all highly liquid investments purchased with remaining maturities of 90 days or less on the purchase date to be cash equivalents, and includes amounts held in money market funds and commercial paper which are actively traded (a Level 1 input).

Restricted Cash

The Company had restricted cash of $42,000 as of each of December 31, 2025 and 2024, held in money market savings accounts as collateral for its facility lease obligation. Restricted cash is classified as a component of cash, cash

equivalents, and restricted cash in the accompanying Consolidated Balance Sheets and Consolidated Statements of Cash Flows.

Short-term Investments

The Company's short-term investments are comprised of U.S. Treasuries, corporate debt securities, certificates of deposit, asset backed securities and agency debt securities that have original maturities less than or equal to one year and are classified as available-for-sale ("AFS") securities. Such securities are carried at estimated fair value, net of allowance for credit loss determined based on the Current Expected Credit Loss. Any unrealized holding gains or losses are reported as accumulated other comprehensive income or loss, which is a separate component of stockholders' equity. In the event that the AFS security's fair value is below the amortized cost and (i) the Company intends to sell the AFS security and (ii) the AFS security is required to be sold before recovery of the loss, the AFS security's amortized cost base will be written down to its fair value and the loss will be recognized in the income statement. If the Company intends not to sell the AFS security and the AFS security is not required to be sold before recovery of the loss, the Company evaluates whether a portion of the unrealized loss is a result of credit loss. The portion of unrealized loss related to credit loss will be recorded as allowance for credit loss in the balance sheet with the corresponding credit loss in the income statement and the portion of unrealized loss not related to credit loss will be recognized in other comprehensive income ("OCI"). Dividend and interest income are recognized in other income when earned. The cost of securities sold is calculated using the specific identification method. The Company places all investments with government agencies, or corporate institutions whose debt is rated as investment grade. As of December 31, 2025 and 2024, none of the unrealized losses on the Company's short-term investments are a result of credit loss, and therefore, any unrealized losses were recognized in OCI.

As of December 31, 2025 and 2024, the Company had $1.1 million and $0.4 million, respectively, accrued interest on short-term investments included in "Accounts and other receivables" on the accompanying Consolidated Balance Sheets.

Accounts and Other Receivables

Accounts and other receivables include interest and other receivables. The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices and the overall quality and age of those invoices not specifically reviewed. The Company believes that the credit risks associated with these receivables are not significant. To date, the Company has not experienced any losses associated with accounts and other receivables and does not maintain an allowance for credit loss.

Fair Value Measurements

The Company records certain financial assets and liabilities at fair value in accordance with the guidance in Financial Accounting Standards Board ("FASB") Accounting Standard Codification Topic 820, *Fair Value Measurements and Disclosures* ("ASC 820"), which defines fair value and establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company can access at the measurement date.

Level 2 — Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable. If the asset or liability has a specified (contractual) term, a Level 2 input must be observable for substantially the full term.

Level 3 — Unobservable inputs developed using estimates of assumptions developed by the Company, which reflect those that a market participant would use.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment that the Company exercises in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. There were no transfers into or out of Level 3 of the fair value hierarchy during the years ended December 31, 2025 and 2024.

Financial Instruments

The Company's financial instruments consist of cash, cash equivalents, restricted cash, accounts receivable, short-term investments, accounts payable, accrued expenses, and a term loan. The carrying amounts of cash, cash equivalents, restricted cash, accounts and other receivables, accounts payables, and accrued expenses approximate their fair value due to the short-term nature of those financial instruments. Short-term investments are recorded at fair value, with any unrealized holding gains or losses reported as accumulated other comprehensive income or loss. The carrying amounts of the Company's debt approximate fair value because the rates are floating rates based on the prime lending rate, which approximates market rates (see Note 7) and represents a Level 2 fair value measurement.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents, restricted cash, short-term investments and accounts receivable. Periodically, the Company maintains deposits in financial institutions in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk as the Company's deposits are held at financial institutions that management believes to be of high credit quality. The Company has not experienced any losses in these deposits.

Property and Equipment, Net

The Company records property and equipment at cost less accumulated depreciation and amortization. Expenditures for maintenance and repairs are charged to operations as incurred, whereas major improvements are capitalized as additions to property and equipment. Costs of assets under construction are capitalized but are not depreciated until the construction is substantially complete and the assets being constructed are ready for their intended use.

Depreciation and amortization are recorded using the straight-line method over the estimated useful lives of the assets, as follows:

Asset Category	Estimated Useful Life
Computer and telecommunications	3 – 5 years
Software	3 years
Furniture, fixtures and equipment	5 years
Laboratory equipment	7 years
Leasehold improvements	Lesser of lease term or estimated useful lives

Impairment or Disposal of Long-lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate the carrying value of such assets may not be recoverable in accordance with the guidance in Financial Accounting Standards Board ("FASB") Accounting Standard Codification Topic 360, Property, Plant and Equipment ("ASC 360"). The Company's long-lived assets include properties and equipment and right of use ("ROU") assets. For long-lived assets, impairment is recognized when the undiscounted cash flows used in the test for recoverability is less than their carrying value. In the event impairment exists, the long-lived asset will be written down to its fair value, and an impairment loss is recorded as the difference between the carrying value and fair value. For the years ended December 31, 2025 and 2024, the Company did not identify indicators of impairment.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are recorded as a current and long-term lease obligation, with a corresponding right of use lease assets.

Lease liabilities represent the Company's obligation to make lease payments arising from leases. ROU assets represent the Company's right to use an underlying asset for the lease term. Lease liabilities and ROU assets are recognized at the lease commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise those options. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Short-term leases are leases having a term of twelve months or less. The Company recognizes short-term leases on a straight-line basis and does not record a related lease asset or liability for such leases.

Lease incentives and allowance provided by our landlord for the construction of leasehold improvements are recorded as lease incentive obligations as the related construction costs are incurred, up to the maximum allowance.

Stock-based Compensation

The Company accounts for all stock-based compensation granted to employees and non-employees using a fair value method. The Company estimates the fair value of stock options granted using the Black-Scholes option pricing model on the dates of grant. For restricted stock and restricted stock units granted, fair value is determined based on the grant date closing price of the Company's common stock.

The expected stock price volatility for stock option awards is based on a weighted-average volatility rate of historical volatility from a representative peer group of comparable companies and the Company's own stock price volatility. The average expected life of stock options was determined according to the "simplified method" as described in SAB 107, which is the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate was determined by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant. We have not paid and do not anticipate paying cash dividends. Therefore, the expected dividend rate is assumed to be 0%.

Stock-based compensation awarded to employees is measured at the grant date fair value of stock option grants and is recognized over the requisite service period of the awards, usually the vesting period, on a straight-line basis, net of estimated forfeitures. The Company estimates forfeitures at the time of grant and, if necessary, revises the estimate in subsequent periods if actual forfeitures differ from those estimates. Estimates are based on the Company's historical analysis of actual stock option forfeitures. The actual expense recognized over the vesting period is only for those options that vest.

If awards are modified, the Company compares the fair value of the affected award measured immediately prior to modification to its value after modification. To the extent that the fair value of the modified award exceeds the original award, the incremental fair value of the modified award is recognized as compensation expense on the date of modification for vested awards, and over the remaining vesting period for unvested awards.

R&D Expense

R&D costs are expensed as incurred. R&D costs consist of payroll and personnel expense, consulting costs, external contract R&D expenses, which includes fees paid to other entities that conduct certain R&D activities on the Company's behalf, such as clinical research organizations ("CROs") and contract manufacturing organizations ("CMOs"), raw materials, drug product manufacturing costs, laboratory supplies and allocated overhead, including depreciation and amortization, rent and utilities. Material R&D costs that are paid in advance of performance are capitalized as a prepaid expense and amortized over the service period as the services are provided.

Clinical trial costs are a significant component of R&D expenses, and the Company outsources a significant portion of these costs to third parties. Third party clinical trial expenses include investigator fees, site and patient costs, CRO costs, costs for central laboratory testing, data management and CMO costs. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the Consolidated Balance Sheets as a prepaid asset or accrued expenses. These third-party agreements are generally cancelable, and related costs are recorded as R&D expenses as incurred. Material advance payments for goods or services that will be used or rendered for future R&D activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the prepaid and accrued balances at the end of any reporting period.

R&D Incentive Credits

The Company is eligible to obtain certain R&D incentive credits, through the participation in the U.K. Merged R&D Expenditure Credit ("U.K. RDEC") and the Australian R&D Tax Incentive (the "Australia R&D credit") program administered through the Australian Tax Office (the "ATO").

The U.K. RDEC are calculated as a percentage of qualifying R&D expenses and are payable in cash by the U.K. government to the Company. Qualifying R&D expenses consist of employment costs for research staff, consumables, a proportion of relevant, permitted sub-contract costs and certain internal overhead costs incurred as part of research projects for which the Company does not receive income. The Australia R&D credits provide for a cash refund based on a percentage of certain R&D activities undertaken in Australia by the Company's wholly owned subsidiary, Altimmune AU Pty, Limited. Qualifying R&D expenses must be incurred within the country.

The U.K. and Australian incentive credits are available on the basis of specific criteria with which the Company must comply. The incentive credits are subject to future audits by the government authorities and a statute of limitations. Although the incentive credits may be administered through the local tax authority, the Company has accounted for the incentives outside of the scope of FASB Accounting Standards Codification Topic 740, *Income Taxes* ("ASC 740"), since the incentives are not linked to the Company's taxable income and can be realized regardless of whether the Company has generated taxable income in the respective jurisdictions. The Company accounts for these incentive credits as a government grant which analogizes with International Accounting Standards 20 ("IAS 20"), *Accounting for Government Grants and Disclosure of Government Assistance*.

The Company records qualifying U.K. R&D expenses as receivable and a corresponding reduction to R&D expense in the Consolidated Statement of Operations and Comprehensive Loss. During the years ended December 31, 2025 and 2024, the Company recognized a negligible amount and $0.6 million, respectively, of R&D credits as a reduction to R&D expense in the Consolidated Statement of Operations and Comprehensive Loss. As of December 31, 2025 and 2024, the Company had $0.5 million and $1.8 million, respectively, of RDEC included in "Income tax and R&D incentive receivables" on the accompanying Consolidated Balance Sheets.

The Company records qualifying Australian R&D credits as receivable with a full valuation reserve. Cash receipts for Australia R&D credits are recorded as noncurrent liability until it either passes an audit performed by the ATO, or the statute of limitations ends, whichever occurs first. Upon successfully passing an audit or the expiration of the statute of limitations, the Company will clear the liability and a corresponding reduction to R&D expense unless recognition criteria is met in a later year, in which case the R&D credit will be recorded as other income in the Consolidated Statement of Operations and Comprehensive Loss. During the years ended December 31, 2025 and 2024, the Company received $0.4 million and $0.1 million in cash for R&D incentive, respectively, related to the R&D costs that the Company incurred during the fiscal years 2024 and 2023, respectively, both through the participation in the Australian R&D credit program, and is included in "Other noncurrent liabilities" on the accompanying Consolidated Balance Sheets.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740. ASC 740 uses the asset and liability approach, which requires the recognition of future tax benefits or liabilities on the temporary differences between the financial reporting and tax bases of our assets and liabilities. Deferred tax assets and liabilities represent future tax consequences of temporary differences between the financial statement carrying amounts and the tax basis of assets and liabilities and for loss carryforwards using enacted tax rates expected to be in effect in the years in which the differences reverse. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized. The Company also recognizes a tax benefit from uncertain tax positions only if it is "more likely than not" that the position is sustainable based on its technical merits. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. To date, the Company has not incurred interest and penalties related to uncertain tax positions. Should such costs be incurred, they would be classified as a component of provision for income taxes.

The Company conducts R&D activities potentially qualified to claim research tax credits for U.S. federal and state purposes under Internal Revenue Code Section 41. The Company has not performed a formal study claiming these credits in the tax returns because the Company does not yet have taxable profits. Once the Company becomes profitable, it will likely have a study prepared, and the amount of R&D tax credits available could generate income tax benefit, subject to an annual Section 383 limitation and valuation allowance for realizability of the deferred tax asset.

Comprehensive Loss

For the years presented, the total comprehensive loss includes net loss and other comprehensive income (loss) which represents unrealized gains or losses on short-term investments.

Net Loss per Share

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period without consideration for potentially dilutive securities.

The Company computes diluted net loss per common share after giving consideration to all potentially dilutive common equivalents, including all unvested restricted stock and stock options outstanding during the period except where the effect of such non-participating securities would be anti-dilutive.

Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods.

Debt discount and issuance costs

The Company accounts for fees paid to lenders, as compensation for services beyond their role as a creditor, and third parties whose costs are directly related to issuing debt as debt issuance cost. Amounts paid to the lender as a reduction in the proceeds received are considered a discount on the issuance. Debt issuance costs and discounts related to term loans are reported as a direct deduction from the outstanding debt and amortized over the term of the loan using the effective interest method as an additional interest expense.

Recently issued accounting pronouncements

Recently Adopted:

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. ASU No. 2023-09 requires public business entities on an annual basis to (i) disclose in the rate reconciliation both percentages and amounts for certain categories in a tabular format, with further disaggregation of certain categories when the individual reconciling items meet a quantitative threshold, (ii) disclose income taxes paid, net of refunds received disaggregated by federal, state and foreign, with further disaggregation by individual jurisdictions that meet a qualitative threshold (iii) eliminates the requirement to disclose certain information when it is reasonably possible that the total

amounts of unrecognized tax benefits will significantly increase or decrease within 12 months of the reporting date or make a statement that an estimate of the range cannot be made and (iv) eliminates the requirement to disclose cumulative amount of each type of temporary difference in certain circumstances. The amendments in ASU 2023-09 are effective for fiscal years beginning after December 15, 2024, with early adoption permitted for annual financial statements that have not yet been issued. The Company adopted ASU No. 2023-09 on this annual report on Form 10-K using a prospective method (See Note 12. Income Taxes).

Not Yet Adopted:

In December 2025, the FASB issued ASU No. 2025-10, *Government Grants – Accounting for Government Grants Received by Business Entities (Topic 832)*. The amendments in ASU No. 2025-10 establish the accounting for a government grant received by a business entity, including guidance for (1) a grant related to an asset and (2) a grant related to income. A grant related to an asset is a government grant, or part of a government grant, that is conditioned on the purchase, construction, or acquisition of an asset (for example, a long-lived asset or inventory). A grant related to income is a government grant, or part of a government grant, other than a grant related to an asset (for example, a grant that reimburses a business entity for operating expenses). The amendment require that a government grant received by a business entity should not be recognized until (1) It is probable that (a) a business entity will comply with the conditions attached to the grant and (b) the grant will be received and (2) business entity meets the recognition guidance for a grant related to an asset or a grant related to income. The amendments in ASU 2025-10 are effective for annual reporting periods beginning after December 15, 2028. Early adoption is permitted. The Company is currently evaluating the impact of this amendment on its Consolidated Financial Statements.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement – Reporting Comprehensive Income-Expense Disaggregation Disclosure (Subtopic 220-40)*. The amendments in ASU No. 2024-03 require that, at each interim and annual reporting period, public business entities disclose in a note to the financial statements the amount of (i) purchases of inventory, (ii) employee compensation, (iii) depreciation, (iv) intangible asset amortization, and (v) depreciation, depletion, and amortization recognized as part of oil and gas-producing activities (DD&A) (or other amounts of depletion expense) included in each relevant expense caption in the statements of operation and comprehensive income. The amendments in ASU 2024-03 are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The amendments should be applied either prospectively to financial statements issued for reporting periods after the effective date or retrospectively to any or all prior periods presented in the financial statements. The amendments in this update are effective on the Company's 2027 annual report, and interim reports thereafter. The Company is currently evaluating the impact of this amendment on its Consolidated Financial Statements.

3. Fair Value Measurement

The Company records cash equivalents and short-term investments at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants based on assumptions that market participants would use in pricing an asset or liability.

The Company's assets measured at fair value on a recurring basis as of December 31, 2025 consisted of the following (in thousands):

	Fair Value Measurement at December 31, 2025			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents - money market funds	$ 23,780	$ 23,780	$ —	$ —
Cash equivalents - commercial paper	5,969	—	5,969	—
Short-term investments	229,696	—	229,696	—
Total	$ 259,445	$ 23,780	$ 235,665	$ —

The Company's assets measured at fair value on a recurring basis as of December 31, 2024 consisted of the following (in thousands):

	Fair Value Measurement at December 31, 2024			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents - money market funds	$ 27,279	$ 27,279	$ —	$ —
Short-term investments	94,965	—	94,965	—
Total	$ 122,244	$ 27,279	$ 94,965	$ —

Short-term investments have been initially valued at the transaction price and subsequently valued at the end of each reporting period utilizing third party pricing services or other market observable data (Level 2). The pricing services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs to determine value.

Short-term investments with quoted prices as of December 31, 2025 as shown below (in thousands):

	December 31, 2025			
	Amortized Cost	Unrealized Gain Unrealized (Loss) Gain	Unrealized Gain Credit loss	Market Value
United States treasury securities	$ 83,730	$ 62	$ —	$ 83,792
Commercial paper and corporate debt securities	127,934	41	—	127,975
Asset backed securities	8,000	7	—	8,007
Agency debt securities	9,920	2	—	9,922
Total	$ 229,584	$ 112	$ —	$ 229,696

Short-term investments with quoted prices as of December 31, 2024 as shown below (in thousands):

	December 31, 2024			
	Amortized Cost	Unrealized Gain Unrealized (Loss) Gain	Unrealized Gain Credit Loss	Market Value
United States treasury securities	$ 21,375	$ 16	$ —	$ 21,391
Commercial paper and corporate debt securities	52,641	15	—	52,656
Asset backed securities	5,951	14	—	5,965
Agency debt securities	14,931	22	—	14,953
Total	$ 94,898	$ 67	$ —	$ 94,965

The carrying amounts of the Company's debt approximate fair value because the rates are floating rates based on the prime lending rate, which approximates market rates (see Note 7) and represents a Level 2 fair value measurement.

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis from those measured at fair value on a non-recurring basis. Assets recorded at fair value on a non-recurring basis, such as property and equipment and intangible assets are recognized at fair value when they are impaired. During the years ended December 31, 2025 and 2024, the Company had no assets or liabilities that were measured at fair value on a non-recurring basis.

4. Property and Equipment, Net

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

	2025	2024
Furniture, fixtures and equipment	$ 164	163
Laboratory equipment	342	342
Computers and telecommunications	204	194
Software	178	178
Leasehold improvements	1,749	1,749
Property and equipment, at cost	2,637	2,626
Less: accumulated depreciation and amortization	(2,325)	(2,213)
Property and equipment, net	$ 312	$ 413

Depreciation expense related to property and equipment for the years ended December 31, 2025 and 2024 was $0.1 million and $0.2 million, respectively.

5. Leases

The Company's operating lease consists of a lease for office and laboratory space in the United States, which expires in April 2030. The lease provides for increases in future minimum annual rental payments as defined in the lease agreement and has no further renewal option.

Short-term leases are leases having a term of twelve months or less. The Company recognizes short-term leases on a straight-line basis and does not record a related lease asset or liability for such leases.

Rent expense under the Company's operating leases during the years ended December 31, 2025 and 2024 was $0.6 million and $0.5 million, respectively. Rent expense includes short-term leases and variable lease costs that are not included in the lease obligation.

The cash paid for operating lease liabilities for the years ended December 31, 2025 and 2024 was $0.4 million and $0.5 million, respectively.

Supplemental balance sheet information related to the operating leases is as follows (in thousands):

	2025	2024	Balance Sheet Classification
Operating lease obligations, current (see Note 6)	$ 256	$ 279	Accrued expenses and other current liabilities
Operating lease obligations, noncurrent (see Note 8)	1,145	1,402	Other noncurrent liabilities
Operating lease right-of-use assets	$ 1,425	$ 1,639	Other assets
Weighted-average remaining lease term (years)	4.3	5.3	
Weighted-average discount rate	9.5 %	9.5 %	

Maturities of operating lease liabilities are as follows (in thousands):

2026	$ 376
2027	387
2028	398
2029	410
2030	138
Total operating lease payments	1,709
Less: imputed interest	(308)
Total operating lease liabilities	$ 1,401

6. Accrued Expenses and Other Current Liabilities

Accrued expense and other current liabilities consist of the following (in thousands):

	December 31,	
	2025	2024
Accrued professional services	$ 923	$ 401
Accrued payroll and employee benefits	4,676	3,079
Accrued research and development	6,110	6,443
Lease obligation, current portion	256	279
Accrued interest and other	315	55
Total accrued expenses and other current liabilities	$ 12,280	$ 10,257

7. Term Loan

On May 13, 2025 ("Closing Date"), the Company and certain of its subsidiaries entered into a Loan and Security Agreement ("Loan Agreement") with Hercules Capital, Inc. ("Hercules") and the lenders party thereto, pursuant to which the lenders will make available up to four tranches of term loans in an aggregate principal amount of $100.0 million (the "Term Loan"), subject to certain terms and conditions. Under the terms of the Loan Agreement, the first Term Loan tranche was drawn down on the Closing Date in an aggregate principal amount of $15.0 million. Upon the achievement of certain milestones and subject to other terms and conditions set out in the Loan Agreement, (i) the second Term Loan tranche was to be made available in an aggregate principal amount of up to $25.0 million and (ii) the third Term Loan tranche was to be made available in an aggregate principal amount of up to $15.0 million. The fourth Term Loan tranche was to be made available in an aggregate principal amount of up to $45.0 million subject to the approval of the lenders. The Term Loan had interest rate equal to the greater of (a) the prime rate as reported in The Wall Street Journal plus 2.45% and (b) (i) 9.95% until December 31, 2025, and (ii) 9.45% thereafter.

On November 5, 2025, (the "Amendment Closing"), the Company entered into an amendment to the Loan Agreement with Hercules and the lenders party thereto, pursuant to which the lenders will, subject to certain terms and conditions, increase the availability under the Term Loan from an aggregate principal amount of $100.0 million to $125.0 million. The Term Loan, as amended, is structured in four tranches. As described above, the first Term Loan tranche was drawn down on the Closing Date in an aggregate principal amount of $15.0 million. The second Term Loan tranche was drawn down on the Amendment Closing in an aggregate principal amount of $20.0 million. Upon the achievement of certain milestones and subject to other terms and conditions set out in the Loan Agreement, as amended, the third Term Loan tranche will be made available in an aggregate principal amount of up to $10.0 million. The fourth Term Loan tranche will be made available in an aggregate principal amount of up to $80.0 million subject to the approval of the lenders. The Term Loan, as amended, bears interest equal to the greater of (a) 9.70% per annum and (b) the prime rate as reported in The Wall Street Journal plus 2.45% per annum. The interest-only period has been extended to 30 months from May 13, 2025.

The Term Loan will mature on January 1, 2029 (the "Maturity Date"). The Company may make payments of interest only through December 1, 2027, which will be extended to June 1, 2028, or December 1, 2028, if certain conditions described in the Loan Agreement, as amended, are met. Thereafter, the Company is obligated to make payments that will include installments of principal and interest through the Maturity Date.

The Loan Agreement includes customary representations and warranties and covenants associated with the Term Loan. Such terms include (1) covenants concerning financial and other reporting obligations, and (2) certain limitations on indebtedness, liens, investments, distributions (including dividends), collateral, transfers, mergers or acquisitions, taxes, corporate changes, and deposit accounts. Compliance with the financial covenant will be conditionally waived pursuant to the terms of the Loan Agreement when the Company's market capitalization exceeds $800 million. The Loan Agreement includes customary events of default, including payment defaults, breaches of representations and warranties, breaches of covenants following any applicable cure period and the occurrence of certain events that could reasonably be expected to have a "material adverse effect" as set forth in the Loan Agreement. As of December 31, 2025, the Company was in compliance with the covenants under the Loan Agreement.

The obligation under the Loan Agreement is secured by a security interest in substantially all of the Company's assets and the assets of its subsidiaries that are co-borrowers or guarantors. Upon the occurrence of an event of default, Hercules will be entitled to exercise remedies, including acceleration of the Term Loan obligations and foreclosure on collateral.

The Loan Agreement, as amended, provides for a prepayment charge equal to 3.0% of the outstanding principal balance of the Term Loan if prepayment is made within the twelve months after Amendment Closing, 2.0% if within the twenty-four months after Amendment Closing, 1.0% if within the thirty-six months after Amendment Closing and 0.0% thereafter. The Loan Agreement provides for an end of term charge of 6.25% of the funded loan amount, due at the earlier of prepayment or maturity. Pro-rata payment of any earned end of term charge will be due upon any partial prepayment (the "End of Term Charge"). In addition, the Loan Agreement requires the Company to pay a facility charge of 1.0% of the Term Loan funded due at the Closing Date and of each subsequent Term Loan tranche at the time such tranche is funded.

The Company accounted for the End of Term Charge, Facility Charge, and other direct costs incurred in connection with the Loan Agreement and its amendment as a debt discount and issuance costs, and they are being amortized over the term of the loan using the effective interest method. The weighted-average effective interest rate on the Term Loan is 13.37%.

The Company incurred interest expense on the Term Loan, including debt discount and issuance costs amortization, of $1.6 million during the year ended December 31, 2025.

The Term Loan consists of the following (in thousands):

	December 31,	
	2025	2024
Term loan principal amount	$ 35,000	$ —
End of term charge	2,188	—
Unamortized discount and issuance costs	(2,901)	—
Total term loan	34,287	—
Less: current portion of term loan	—	—
Total term loan, net of current portion	$ 34,287	$ —

Future principal loan payments on the currently outstanding Term Loan as of December 31, 2025 are as follows (in thousands):

2026	$ —
2027	1,712
2028	21,611
2029	11,677
Total future principal payments	35,000
Add: End of term charge	2,188
Less: Unamortized discount and issuance costs	(2,901)
Less: Current portion of term loan	—
Total term loan, net of current portion	$ 34,287

8. Other Noncurrent Liabilities

The Company's other noncurrent liabilities are summarized as follows (in thousands):

	2025	2024
Research and development incentive credit	$ 4,448	$ 3,746
Lease obligation, long-term portion	1,145	1,402
Conditional economic incentive grants	160	160
Other	—	22
Total other noncurrent liabilities	$ 5,753	$ 5,330

R&D Tax Incentive Program

During the years ended December 31, 2025 and 2024, the Company received a total of $0.4 million and $0.1 million in cash for R&D incentive credit, respectively, related to R&D costs that the Company incurred during the fiscal year 2024 and 2023, respectively, through the participation in the Australian R&D credit program administered through the ATO. The Company recorded the receipt as noncurrent liability until there is reasonable assurance that the Company complies with the conditions attached to the incentive credit.

Economic Incentive Grants

The Company had two conditional economic incentive grants for a total of $250,000 from Montgomery County, Maryland and the State of Maryland. The Montgomery County grant of $100,000 was received in May 2018, with a term expiring on February 28, 2028. The State of Maryland grant of $150,000 was received in October 2019, with a 10-year term expiring on December 31, 2029. These grants are conditional primarily based on the Company maintaining its current headquarter locations in addition to employing a required number of employees at different reporting dates through the term of the grants. The annual interest rate on both economic incentive grants is 3%. During the year ended December 31, 2023, the Company repaid approximately $99,000 of the State of Maryland grant, including accrued interest, as the Company didn't meet the required number of employees as of December 31, 2022 as per terms of the grant.

9. Stockholders' Equity

The Amended and Restated Certificate of Incorporation, as amended ("Charter"), authorized the Company to issue 200,000,000 shares of common stock, par value $0.0001 per share. As of December 31, 2025, the Company had 110,882,735 shares of common stock issued and outstanding.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends, unless declared by the board of directors.

The Charter also authorized the Company to issue 1,000,000 shares of preferred stock, par value $0.0001 per share. As of December 31, 2025, the Company had no shares of preferred stock issued and outstanding.

At-the-Market Offerings

On November 6, 2025, the Company entered into an Equity Distribution Agreement (the "November 2025 Agreement") with Leerink Partners LLC serving as sales agent (the "November 2025 Sales Agent") with respect to an at-the-market offerings program under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, having an aggregate offering price of up to $200.0 million (the "November 2025 Shares") through the November 2025 Sales Agent (the "November 2025 Offering"). All Shares offered and sold in the November 2025 Offering will be issued pursuant to the Company's Registration Statement on Form S-3 filed with the SEC on February 27, 2025, which was declared effective on March 13, 2025, and the prospectus supplements related to the November 2025 Offering that form a part of the Registration Statement. The Company capitalized approximately $0.2 million of other offering costs which will offset the proceeds received from the shares sold under the November 2025 Agreement. During the year ended December 31, 2025, the Company has sold 5,899,059 shares of common stock under the November 2025 Agreement resulting in approximately $25.4 million in proceeds, net of $0.4 million commission and other offering costs, and as of December 31, 2025, $174.2 million remained available to be sold under the November 2025 Agreement. As of

December 31, 2025, there was $0.2 million deferred offering costs included in prepaid expenses and other current assets on the accompanying consolidated balance sheets.

On February 27, 2025, the Company entered into an Equity Distribution Agreement (the "February 2025 Agreement") with Leerink Partners LLC, Piper Sandler & Co. and Stifel, Nicolaus & Company, Incorporated, serving as sales agents (the "February 2025 Sales Agents") with respect to an at-the-market offerings program under which the Company offered and sold, shares of its common stock, having an aggregate offering price of up to $150.0 million (the "February 2025 Shares") through the February 2025 Sales Agents (the "February 2025 Offering"). All Shares offered and sold in the 2025 Offering were issued pursuant to the Company's Registration Statement on Form S-3 filed with the SEC on February 27, 2025, which was declared effective on March 13, 2025, and the prospectus supplements related to the February 2025 Offering that form a part of the Registration Statement. During the year ended December 31, 2025, the Company has sold 27,896,642 shares of common stock under the February 2025 Agreement resulting in approximately $118.1 million in proceeds, net of $3.9 million commission and other offering costs. The February 2025 Agreement was terminated upon the execution of the November 2025 Agreement disclosed above.

On February 28, 2023, the Company entered into an Equity Distribution Agreement (the "2023 Agreement") with Evercore Group L.L.C., JMP Securities LLC and B. Riley Securities, Inc., serving as sales agents (the "2023 Sales Agents"), with respect to an at-the-market offerings program under which the Company offered and sold shares of its common stock, having an aggregate offering price of up to $150.0 million (the "2023 Shares") through the Sales Agents (the "2023 Offering"). All Shares offered and sold in the 2023 Offering were issued pursuant to the Company's Registration Statement on Form S-3 filed with the SEC on February 28, 2023, which was declared effective immediately, and the prospectus supplements relating to the 2023 Offering filed with the SEC on February 28, 2023. Since inception through the termination of the 2023 Agreement in February 2025, the Company has sold 26,129,903 shares of common stock under the 2023 Agreement resulting in approximately $126.8 million in proceeds, net of $4.1 million commission and other offering costs. During the years ended December 31, 2025 and 2024, we have sold 4,467,866 and 1,207,521 shares of common stock under the 2023 Agreement, resulting in approximately $30.2 million and $10.3 million in net proceeds, respectively.

10. Stock-Based Compensation

Stock-based Compensation Plans

The Company established the 2017 Omnibus Incentive Plan (the "Omnibus Plan") to provide incentive stock options, non-qualified stock options, restricted stock, and other stock-based awards denominated in shares of the Company's common stock, and performance-based cash awards to eligible employees, consultants and directors. In 2018, the Company's shareholders approved an amendment to the Omnibus Plan to increase the number of shares reserved for issuance from 1,500,000 to 5,000,000. The aggregate share reserve will be increased on January 1 of each year commencing in 2019 and ending on and including January 1, 2027 up to an amount equal to the lowest of (i) 4% of the total number of shares of common stock outstanding on a fully diluted basis as of December 31 of the immediately preceding calendar year, and (ii) such number of shares of common stock, if any, determined by the Company's board of directors. Accordingly, on January 1, 2026, the number of shares of Common Stock reserved and available for issuance under the Omnibus Plan increased by 4,969,458. The maximum number of shares of common stock that may be issued under the Omnibus Plan in respect of Incentive Stock Option ("ISO") is 5,000,000 shares. The maximum number of shares of common stock that may be granted to non-employee directors under the Omnibus Plan during any fiscal year is 2,000,000 shares.

On November 29, 2018, the Board approved and adopted the Altimmune Inc. 2018 Inducement Grant Plan (the "Inducement Plan"). The Inducement Plan provides for the grant of equity or equity-based awards in the form of non-qualified stock options, restricted stock awards and other stock-based awards. The Inducement Plan was adopted by the Board without stockholder approval pursuant to Rule 5635I(4) of the Nasdaq Listing Rules.

The Board has reserved 2,000,000 shares of the Company's common stock for issuance pursuant to awards granted under the Inducement Plan (subject to customary adjustments in the event of a change in capital structure of the Company), and the Inducement Plan will be administered by the Compensation Committee. In accordance with

Rule 5635I(4) of the Nasdaq Listing Rules, awards under the Inducement Plan may be only made to an employee who has not previously been an employee or member of the Board or any parent or subsidiary, or following a bona fide period of non-employment by the Company or a parent or subsidiary, if he or she is granted such award in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary.

The Omnibus Plan and the Inducement Plan are collectively referred to as the "Plans." Under both Plans, the shares of common stock underlying any awards that are expired, terminated, forfeited or canceled for any reason without having been exercised in full, except shares surrendered to satisfy tax withholding obligations, will be added to the shares of common stock available under each of the Plans. During the year ended December 31, 2025 under the Plans, a total of 5,468,350 options to purchase shares of common stock were granted. As of December 31, 2025, there were 316,510 and 409,575 shares of common stock available for future grants under the Omnibus Plan and the Inducement Plan, respectively.

Stock Options

The fair value of stock option issued to employees was estimated at the date of grant using Black-Scholes with the following weighted-average assumptions:

	Year Ended December 31,	
	2025	2024
Expected volatility	98.3 %	101.4 %
Expected term (years)	6.0	6.0
Risk-free interest rate	4.0 %	4.0 %
Expected dividend yield	0.0 %	0.0 %

A summary of stock option activity under the Plans is presented below (in thousands, except share and per share data):

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2024	6,630,477	$ 9.32	6.0	$ 5,839
Granted	5,468,350	$ 5.21		
Exercised	(14,167)	$ 2.91		
Forfeited or expired	(794,740)	$ 9.34		
Outstanding, December 31, 2025	11,289,920	$ 7.33	5.6	$ 877
Exercisable, December 31, 2025	4,828,718	$ 9.08	5.9	$ 876
Vested and expected to vest, December 31, 2025	9,850,832	$ 6.72	5.6	$ 877

The per share weighted-average grant date fair value of stock options granted during the years ended December 31, 2025 and 2024 were $4.16 and $7.07 per share, respectively. The total intrinsic value of stock options exercised during the years ended December 31, 2025 and 2024 was $0.1 million and $1.1 million, respectively. The total fair value of options vested during the years ended December 31, 2025 and 2024 was $11.7 million and $11.6 million, respectively. As of December 31, 2025, there was $19.7 million of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted-average period of 3.1 years.

Restricted Stock Units (RSUs)

During the year ended December 2025, the Company granted 1,524,300 shares of RSUs with a weighted-average grant date fair value of $5.25 per share which vest over four years. During the year ended December 31, 2025, the Company issued 180,958 shares of common stock as a result of the vesting of 286,653 RSUs net of 105,695 shares of common stock withheld to satisfy tax withholding obligations. The total fair value of RSUs vested during the years ended December 31, 2025 and 2024 was $1.8 million and $2.5 million, respectively.

A summary of RSUs activities is presented below:

	Shares	Weighted-average Grant Date Fair Value
Unvested, December 31, 2024	858,290	$ 10.12
Granted	1,524,300	5.25
Vested	(286,653)	10.60
Forfeited or expired	(32,137)	8.00
Unvested, December 31, 2025	2,063,800	$ 6.49

As of December 31, 2025, total unrecognized compensation expense related to RSUs was $6.2 million, which the Company expects to recognize over a weighted-average period of approximately 3.1 years.

2019 Employee Stock Purchase Plan

On March 29, 2019, the Board adopted the 2019 Employee Stock Purchase Plan (the "2019 ESPP"). A total of 403,500 shares of the Company's common stock have been reserved for issuance under the 2019 ESPP. Subject to any plan limitations, the 2019 ESPP allows eligible employees to contribute through payroll deductions up to 10% of their earnings for the purchase of the Company's common stock at a discounted price per share. The offering periods begin in February and August of each year, with the initial offering period starting on August 1, 2019. The common shares issuable under the 2019 ESPP were registered pursuant to a registration statement on Form S-8 on April 4, 2019.

Unless otherwise determined by the administrator, the Company's common stock will be purchased for the accounts of employees participating in the 2019 ESPP at a price per share that is the lesser of 85% of the fair market value of the Company's common stock on the first trading day of the offering period or 85% of the fair market value of the Company's common stock on the last trading day of the offering period. The fair value of estimated shares to be purchased under the 2019 ESPP is included in stock-based compensation expense.

Employees have the ability to purchase shares of the Company's common stock at a price equal to the lower of the first or last trading day of the offering period, which represents an option and, therefore, the 2019 ESPP is a compensatory plan under ASC 718-50, *Employee Stock Purchase Plans*. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value, employee contributions, and the Company's stock price and is recognized over the requisite service period of the option. The Company used the Black-Scholes valuation model to determine the fair value of ESPP.

During the year ended December 31, 2025, employees purchased 71,342 shares for $0.3 million under the 2019 ESPP. As of December 31, 2025, there were 60,585 shares of common stock available for future issuance under the 2019 ESPP Plan. The Company recognized stock-based compensation expense related to this plan of $0.1 million and $0.2 million for the years ended December 31, 2025 and 2024, respectively.

Stock-based Compensation Expense

During each of the years ended December 31, 2025 and 2024, the Company recorded $1.0 million in net incremental stock-based compensation expense as a result of the modifications of stock awards upon termination of the former executive officers. The 2025 modification extended the option exercise period for these former executive officers by a period of six to eighteen months, and extended the vesting period by six months, whereas the 2024 modification

changed the vesting conditions of the awards by accelerating the vesting of certain unvested awards that would have otherwise been forfeited upon termination of an executive office.

Stock-based compensation expense is classified in the accompanying Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2025 and 2024 as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	$ 6,167	$ 6,351
General and administrative	9,909	8,042
Total	$ 16,076	$ 14,393

11. Employee Benefit Plans

The Company has a 401(k)-retirement plan in which substantially all of our employees in the United States are eligible to participate in. Eligible employees may elect to contribute up to the maximum limits, as set by the Internal Revenue Service, of their eligible compensation. During each of the years ended December 31, 2025 and 2024, the Company made discretionary plan contributions of $0.4 million.

12. Income Taxes

The components of net loss before income tax benefit are as follows (in thousands):

	Year Ended December 31,	
	2025	2024
U.S. operations	$ (85,248)	$ (88,401)
Non-U.S. operations	(3,526)	(6,658)
Net loss before income tax benefit	$ (88,774)	$ (95,059)

The components of the income tax provision (benefit) consisted of the following for the years ended December 31, 2025 or 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
U.S. state and local		
Current	$ (681)	$ —
Income tax expense (benefit)	$ (681)	$ —

Reconciliation between the effect of applying the federal statutory rate and the effective income tax rate used to calculate the Company's income tax benefit is as follows (in thousands, except tax rate):

	Year Ended December 31,			
	2025		2024	
Federal statutory rate	$ (18,646)	21.00 %	$ (19,962)	21.00 %
Domestic Federal				
Nontaxable or nondeductible items				
Non-taxable - Section 162(m) compensation	1,367	(1.50)	1,087	(1.10)
Non-taxable - Other	1,418	(1.60)	928	(1.00)
Change in valuation allowance	14,804	(16.70)	16,546	(17.40)
Other	314	(0.40)	3	—
State income tax expense, net of federal income tax effect*	—	—	—	—
Foreign				
United Kingdom				
Credit	—	—	1,258	(1.30)
Other	362	(0.40)	(220)	0.20
Australia				
Credit	—	—	—	—
Other	381	(0.40)	360	(0.40)
Change in Unrecognized Tax Benefits	(681)	0.80		—
Effective tax rate	$ (681)	0.80 %	$ —	(0.00)%

*During the year ended December 31, 2025, state and local income taxes in Maryland make up the majority (greater than 50%) of the domestic state income taxes, net of federal effect category. During the year ended December 31, 2024, state and local income taxes in Maryland make up the majority (greater than 50%) of the domestic state income taxes, net of federal effect category.

During the year December 31, 2025, the Company received a refund from the State of Maryland for $1.4 million. No federal, state or foreign income taxes were paid in 2025.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income and for tax carryforwards. Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating losses	$ 115,761	$ 64,779
Capitalized research and development costs	6,936	37,043
Stock compensation	3,442	3,529
Accrued expenses	823	726
Amortization	148	199
Lease liability	386	463
Depreciation	41	67
Other	73	68
Total deferred tax assets	127,610	106,874
Valuation allowance	(127,141)	(106,423)
Deferred tax assets, net	469	451
Deferred tax liabilities:		
Right of use asset	(392)	(451)
Other	(77)	—
Total deferred tax liabilities	(469)	(451)
Total deferred tax assets (liabilities), net	$ —	$ —

The Company assesses the need for a valuation allowance against our deferred tax assets and considers both positive and negative evidence related to the likelihood of realization of the deferred tax assets to determine, based on the weight of available evidence, whether it is more-likely-than-not that some or all of the deferred tax assets will not be realized. This determination requires significant judgment, including assumptions about future taxable income that are based on historical and projected information. The increase in the valuation allowance during the year ended December 31, 2025 primarily relates to increases for current year losses in both the U.S. and foreign locations. The Company has recorded a valuation allowance against its net U.S. and net non-U.S. deferred tax assets which it believes are not more likely than not realizable. Deferred tax liabilities will be applied in the future to offset against net operating losses ("NOLs") that have an indefinite life.

The Company has U.S. federal and state net operating loss carryforwards of approximately $366.6 million and $365.0 million, respectively, as of December 31, 2025, of which a portion of the federal and state amount of $7.1 million and $365.0 million, respectively, has a 20-year carry forward period that will expire at various dates beginning in 2027. Under current law, the remaining federal amount of $359.5 million has an indefinite life and amounts utilized in the future may not exceed 80% of taxable income. The Company also has foreign net operating loss carryforward of approximately $59.9 million which carryforward indefinitely.

Under Section 382 of the Internal Revenue Code of 1986 ("IRC 382"), as amended, substantial changes in the Company's ownership may limit the amount of NOLs that can be utilized annually in the future to offset its U.S. federal and state taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of the Company of more than 50% within any three-year period. The amount of the annual limitation is determined based on the value of the Company immediately before the ownership change. The Company has reduced the NOL and related valuation allowance in historical periods for NOLs that cannot be utilized in the future because of IRC 382.

The Company has reviewed for any ownership changes as defined under IRC Section 382 from January 1, 2021 through November 3, 2023 and determined that the ownership change was less than 50% during that period. The Company's existing NOLs are subject to limitations arising from previous ownership changes impacting the timing and amount, and the impact of such changes is reflected in the NOL amounts disclosed above. In addition, future changes in the Company's stock ownership, many of which are outside of the Company's control, could result in an ownership change.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA"), which includes a broad range of tax reform provisions, was signed into law in the United States, which includes a new Internal Revenue Code ("IRC") Section 174A. Under Section 174A, commencing with tax years beginning after December 31, 2024, domestic research or experimental expenditures may be deducted in the current period rather than capitalized and amortized over multiple years, as previously required under IRC Section 174. The OBBBA does not have a material impact on our effective tax rate, financial condition, or results of operations in 2025.

Significant judgment is required in evaluating tax positions and determining the provision for income taxes. The Company establishes liabilities for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes may be due. These liabilities are established when the Company believes that its tax return positions are more-likely-than-not to be sustained upon audit by taxing authorities. The Company adjusts these liabilities in light of changing facts and circumstances, such as the outcome of a tax audit. The provision for income taxes includes the impact of changes to these liabilities.

The Company had $0.7 million in unrecognized tax benefits as of December 31, 2024. Any changes in the next twelve months are not anticipated to have a significant impact on the results of operations, financial position or cash flows of the Company. The Company had no remaining uncertain tax positions as of December 31, 2025.

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits excluding related interest and penalties (in thousands):

	Year Ended December 31,	
	2025	2024
Beginning balance	$ 711	$ 711
Decreases for prior year tax positions	(711)	—
Ending balance	$ —	$ 711

The Company files income tax returns in the United States, various U.S. states, U.K. and Australia. The Company is still open to examination by the applicable taxing authorities from 2021 forward, although tax attributes that were generated prior to 2021 may still be adjusted upon examination by federal, state, foreign or local tax authorities if they either have been or will be used in a future period.

13. Net Loss Per Share

Because the Company has reported net loss attributable to common stockholders for the years ended December 31, 2025 and 2024, basic and diluted net loss per share attributable to common stockholders in each year are the same.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average numbers of shares of common stock outstanding for the period.

Diluted net loss per share is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period. As such, all unvested RSUs, common stock warrants, and stock options have been excluded from the computation of diluted weighted-average shares outstanding because such securities would have an anti-dilutive impact for all periods presented.

Potential common shares issuable upon conversion, vesting or exercise of unvested RSUs, common stock warrants, and stock options that are excluded from the computation of diluted weighted-average shares outstanding, as they are anti-dilutive, are as follows:

	Year Ended December 31,	
	2025	2024
Common stock options	11,348,778	6,666,131
Restricted stock units	2,063,800	858,290

14. Commitments and Contingencies

Spitfire Acquisition

In July 2019, the Company entered into the Spitfire merger agreement to acquire all of the equity interests of Spitfire Pharma, Inc. ("Spitfire"). Spitfire was a privately held, preclinical pharmaceutical company developing novel peptide products for pharmaceutical indications, including pemvidutide for the treatment of MASH. As part of the agreement, the Company is obligated to make payments of up to $80.0 million upon the achievement of specified worldwide net sales of all products developed using the technology acquired from Spitfire Pharma Inc. (the "Sales Milestone") within ten years following the approval of a new drug application filed with the U.S. Food and Drug Administration (the "FDA").

The contingent payments related to the Sales Milestones are predominately cash-based payments accounted for under FASB Accounting Standards Codification Topic 450, Contingencies. Accordingly, the Company will recognize the Sales Milestones when the contingency is probable and the amount can be reasonably estimated.

Litigation

On August 5, 2025, a class action complaint was filed in federal district court in the District of Maryland, Southern Division, naming as defendants the Company and two of the Company's executive officers, which was captioned *In re Altimmune, Inc. Securities Litigation*, Case No. 8:25-cv-02581 (D. Md.) (the "Securities Class Action"). The Securities Class Action alleged that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 thereunder, by making false and misleading statements and omissions of material fact to the investing public including the plaintiff and class members, who purchased or otherwise acquired the Company's common stock between August 10, 2023 and June 25, 2025, including relating to pemvidutide and our IMPACT Phase 2b trial of pemvidutide in MASH. The plaintiff and class members sought, among other things, to have the action maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure and for the defendants to pay damages, interest, and an award of costs, including attorneys' fees. On October 16, 2025, the court appointed lead plaintiffs for the litigation. On October 29, 2025, the court entered an order requiring lead plaintiffs to file an amended complaint by November 26, 2025, and for defendants to file an answer or notice of intent to file a motion to dismiss such amended complaint by December 10, 2025. Rather than amend, the lead plaintiffs sought voluntary dismissal without prejudice of the action, which the Court granted on November 26, 2025.

On September 29, 2025, a shareholder derivative complaint was filed in federal district court in the District of Maryland, purportedly on behalf of the Company, naming as defendants two of the Company's then-executive officers and eight of the Company's current and former board members, captioned *Alaraidah v. Altimmune, Inc., et al.*, No. 8:25-cv-03223 (D. Md.) (the "Derivative Action"). The complaint was based upon allegations that were similar to those alleged in a class action complaint previously filed against us in the Securities Class Action and alleged claims for violations of Section 14(a) of the Securities Exchange Act of 1934, breaches of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, and contribution under Sections 10(b) and 21D of the Securities Exchange Act of 1934 based on the defendants purportedly making or causing to be made false and misleading statements and omissions of material fact between August 10, 2023 and June 25, 2025. The complaint sought unspecified monetary relief, restitution, costs, and equitable relief. On December 22, 2025, the parties filed a stipulation of dismissal without prejudice, which the Court granted on that date.

The Company is a party in various contracts that are subject to potential disputes, litigation, and claims arising in the ordinary course of business, none of which are currently reasonably possible or probable of material loss.

15. Segment Information

The Company is a late clinical-stage biopharmaceutical company developing novel therapies for serious liver diseases. The Company's lead product candidate is pemvidutide, a balanced 1:1 glucagon/GLP-1 dual receptor agonist in development for the treatment of MASH, AUD and ALD. To date, the Company has not generated any revenue from the sale of any products.

As described in Note 2, the Chief Executive Officer is the chief operating decision maker (CODM). The CODM assesses the performance of the Company and decides how to allocate resources based solely on net (loss) income, which is also reported on the consolidated statements of operations and consolidated loss as net (loss) income. The measure of segment assets is reported on the consolidated balance sheet as total assets.

16. Subsequent Events

The Company evaluated subsequent events through the issuance date of the financial statements. During January and February 2026, the Company raised $8.2 million in net proceeds through the issuance of 1,874,597 shares of common stock from the Company's at-the-market offerings program under the November 2025 Agreement.

On January 27, 2026, the Company entered into a securities purchase agreement with a new fundamental institutional investor pursuant to a registered direct offering under the November 2025 Shelf for the purchase and sale of 12,397,920 shares of its common stock and 4,647,534 pre-funded warrants for net proceeds of approximately $70.4

million. The pre-funded warrants were fully exercised on February 13, 2026, resulting in the issuance of 4,647,534 shares of the Company's common stock.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934, as of December 31, 2025. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2025, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

Our management, including our principal executive and principal financial officer, has evaluated any changes in our internal control over financial reporting that occurred during the year ended December 31, 2025, and has concluded that there was no change that occurred during the year ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act as of December 31, 2025. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management has concluded that our internal control over financial reporting was effective as of December 31, 2025.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

We are a smaller reporting company, and therefore our independent registered public accounting firm has not issued a report on the effectiveness of internal control over financial reporting.

Item 9B. Other Information

Insider Trading Arrangements

During the three months ended December 31, 2025, none of our officers or directors adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" as defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors

Except as set forth below, the information required by this item is incorporated by reference to our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

Our Board has adopted a Code of Business Conduct and Ethics (the "*Code of Ethics*") that applies to all officers, directors and employees and relevant consultants. The Code of Ethics, as well as any amendments to, or waivers under, the Code of Ethics as it applies to the Company's officers, can be accessed in the *Investor Relations — Corporate Governance section of our website at https://ir.altimmune.com/investors/governance/documents-and-charters*.

We have adopted an insider trading policy that governs the purchase, sale, and/or other transactions of our securities by our securities by directors, officers, and employees that we believe are reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to the Company. Our Insider Trading Policy is filed as Exhibit 19 to this Annual Report on Form 10-K.

Item 11. Executive Compensation

The information called for by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025.

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

The information called for by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025.

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

The information called for by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025.

Item 14. Principal Accountant Fees and Services

The information called for by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Financial Statements

Reference is made to the Index to the Consolidated Financial Statements included in Item 8 of this report.

Financial Statement Schedules

Required information is included in the notes to the consolidated financial statements.

Exhibit Index

Exhibit No.	Description
1.1	Equity Distribution Agreement, dated November 6, 2025 among the Registrant and Leerink Partners LLC (incorporated by reference to Exhibit 1.1 to the Registrant's Form 8-K filed on November 6, 2025)
1.2	Equity Distribution Agreement, dated February 27, 2025 among the Registrant and Leerink Partners LLC, Piper Sandler & Co. and Stifel, Nicolaus & Company, Incorporated (incorporated by reference to Exhibit 1.2 to the Registrant's Form S-3 filed on February 27, 2025)
1.3	Equity Distribution Agreement, dated February 28, 2023 among the Registrant and Evercore Group L.L.C., JMP Securities LLC and B. Riley Securities, Inc. (incorporated by reference to Exhibit 1.2 to the Registrant's Form S-3ASR filed on February 28, 2023)
2.1	Agreement and Plan of Merger and Reorganization, dated July 8, 2019, by and among Altimmune, Inc., Springfield Merger Sub, Inc., Springfield Merger Sub, LLC, Spitfire Pharma, Inc. and David Collier, as the Stockholder Representative (incorporated by reference to Exhibit 2.1 to Registrant's Form 8 K filed on July 9, 2019)
3.1	Amended and Restated Certificate of Incorporation, dated October 17, 2017 (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on October 18, 2017)
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation regarding a reverse stock split (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on September 13, 2018)
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation regarding an increase in authorized shares (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed on September 13, 2018)
3.4	Amended and Restated Bylaws of Altimmune, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed on October 18, 2017)
3.5	Certificate of Designations of the Series B Convertible Preferred Stock, dated August 21, 2017 (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on August 21, 2017)
4.1*	Description of Registrant's Securities
10.1†	Altimmune, Inc. 2017 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 8, 2017)
10.2†	Amendment No. 1 to the Altimmune, Inc. 2017 Omnibus Incentive Plan (incorporated by reference to Appendix A to the Registrant's definitive proxy statement on Schedule 14A filed on July 26, 2018)
10.3†	Altimmune, Inc. 2018 Inducement Grant Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed on December 3, 2018)

Exhibit No.	Description
10.4†	Altimmune, Inc. 2019 Employee Stock Purchase Plan (incorporated herein by reference to Appendix A to the Registrant's Definitive Proxy Statement, filed on August 22, 2019)
10.5†	Altimmune, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.7 to the Registrant's Form 10 K filed on February 27, 2025)
10.6§	Amended and Restated License Agreement, dated July 12, 2019, by and between Mederis Diabetes, LLC and Spitfire Pharma, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-Q filed on November 13, 2019)
10.7	Form of Director and Officer Indemnification Agreement (incorporated by reference to Exhibit 10.12 to the Registrant's Form 10-Q filed on August 14, 2017)
10.8†	Employment Agreement, dated November 16, 2018 between Dr. Vipin K. Garg and Altimmune, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on November 27, 2018)
10.9†	Transitional Services and Release Agreement, dated November 30, 2025, by and between Altimmune, Inc. and Vipin Garg (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on December 1, 2025)
10.10†	Employment Agreement, dated December 7, 2015, between M. Scot Roberts and Altimmune, Inc. (incorporated by reference to Exhibit 10.17 to the Registrant's Form 10-Q filed on August 14, 2017)
10.11†	Employment Agreement, dated September 9, 2019, by and between Altimmune, Inc. and M. Scott Harris (incorporated by reference to Exhibit 10.4 to the Registrant's Form 10-Q filed on November 13, 2019)
10.12†	Transitional Services and Release Agreement, dated September 30, 2025, by and between Altimmune, Inc. and M. Scott Harris (incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-Q filed on November 6, 2025)
10.13†	Employment Agreement, dated November 6, 2024, by and between Altimmune, Inc. and Gregory Weaver (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on November 12, 2024)
10.14*†	Employment Agreement, dated September 23, 2025, by and between Altimmune, Inc. and Christophe Arbet-Engels
10.15†	Employment Agreement, dated November 30, 2025, by and between Altimmune, Inc. and Jerome Durso (incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on December 1, 2025)
10.16	Consulting Agreement, dated February 6, 2025, by and between Altimmune, Inc. and Catherine Sohn (incorporated by reference to Exhibit 10.15 to the Registrant's Form 10-K filed on February 27, 2025)
10.17§	Loan and Security Agreement, dated May 13, 2025, by and between Altimmune, Inc. and Hercules Capital, Inc. (incorporated by reference to Exhibit 10.3 to the Registrant's Form 10-Q filed on May 13, 2025)
10.18§	Amendment to Loan and Security Agreement, dated November 5, 2025, by and between Altimmune, Inc. and Hercules Capital, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on November 6, 2025)
19	Insider Trading Policies and Procedures (incorporated by reference to Exhibit 19 to the Registrant's Form 10-K filed on February 27, 2025)
21*	Subsidiaries
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
24*	Power of Attorney

Exhibit No.	Description
31.1*	Certification of Principal Executive Officer Pursuant to SEC Rule 13a-14(a)
31.2*	Certification of Principal Financial Officer Pursuant to SEC Rule 13a-14(a)
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350
97	Policy Relating to Recovery of Erroneously Awarded Compensation (incorporated by reference to Exhibit 97 to the Registrant's Form 10-K filed on March 27, 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.

† Management contract or compensatory plan or arrangement.

§ Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment.

Financial Statements and Schedules of Subsidiaries and Affiliates

None.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in the city of Gaithersburg, State of Maryland, on the 6th day of March 2026.

ALTIMMUNE, INC.

By: /s/ Jerome Durso
Jerome Durso
President and Chief Executive Officer

POWER OF ATTORNEY

BY THESE PRESENTS, each person whose signature appears below constitutes and appoints Jerome Durso and Gregory Weaver his true and lawful attorney-in-fact and agents, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute, each acting alone, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jerome Durso Jerome Durso	Chairman of the Board of Directors, President and Chief Executive Officer (Principal Executive Officer)	March 6, 2026
/s/ Gregory Weaver Gregory Weaver	Chief Financial Officer, (Principal Financial Officer and Principal Accounting Officer)	March 6, 2026
/s/ John Gill John Gill	Director	March 6, 2026
/s/ Philip Hodges Philip Hodges	Director	March 6, 2026
/s/ Diane Jorkasky, M.D. Diane Jorkasky, M.D.	Director	March 6, 2026
/s/ Teri Lawver Teri Lawver	Director	March 6, 2026
/s/ Wayne Pisano Wayne Pisano	Director	March 6, 2026
/s/ Mitchel Sayare, Ph.D. Mitchel Sayare, Ph. D.	Director	March 6, 2026
/s/ Klaus O. Schafer, M.D. Klaus O. Schafer, M.D.	Director	March 6, 2026
/s/ Catherine Sohn, Pharm D. Catherine Sohn, Pharm D.	Director	March 6, 2026