UPSTREAM BIO, INC.

2025 ANNUAL REPORT

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: 001-42366

Upstream Bio, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**38-4187694**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. employer identification no.)**
890 Winter Street, Suite 200 Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip code)**

Registrant's telephone number, including area code: (781) 208-2466

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 $0.001 per share	UPB	The Nasdaq Global Select Market

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

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

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

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

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

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

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

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

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

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

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

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

As of June 30, 2025, the last business day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Global Select Market on June 30, 2025, was approximately $467,859,469.

The number of shares of Registrant's common stock outstanding as of March 20, 2026 was 54,419,986.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2026 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A within 120 days of the end of the Registrant's fiscal year ended December 31, 2025 are incorporated by reference in Part III of this Annual Report on Form 10-K to the extent stated herein.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- the initiation, timing, progress, and results of our planned and future clinical trials for verekitug, for the treatment of severe asthma, chronic rhinosinusitis with nasal polyps ("CRSwNP") and chronic obstructive pulmonary disease ("COPD");
- our ability to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties in current or future clinical trials;
- our ability to demonstrate that verekitug and any potential future product candidates are safe and effective for their proposed indications and our expectations around their beneficial characteristics and therapeutic effects;
- our ability to advance verekitug and any potential future product candidates through applicable regulatory approval processes, including timing of Investigational New Drug ("IND") applications and final U.S. Food and Drug Administration ("FDA") approval of verekitug or any future product candidate;
- our estimates of the number of patients that we will enroll and our ability to initiate, recruit and enroll patients in and conduct and successfully complete our clinical trials at the pace we project;
- the implementation of our business model and strategic plans;
- our ability to rely on third-party manufacturers and successfully manufacture verekitug for preclinical use, for clinical trials and on a larger scale for commercial use, if approved;
- our ability to commercialize verekitug, if approved, and obtain favorable pricing and reimbursement;
- the size and growth potential of the markets for verekitug and our ability to serve those markets;
- our ability to realize the benefits of collaborations for the development and commercialization of verekitug or any other potential future product candidates;
- our ability to maintain, expand and protect our intellectual property;
- developments relating to our competitors and our industry;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- general economic, industry, and market conditions and geopolitical developments, including interest rates, capital market disruptions, changes in or disruptions of U.S. governmental agencies, new or increased tariffs and retaliatory tariffs, trade protection measures, economic sanctions and economic slowdowns or recessions, and inflation;
- our ability to attract, hire, and retain our key personnel and additional qualified personnel;
- our anticipated use of our existing cash, cash equivalents and short-term investments;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and

- other risks and uncertainties, including those listed under the caption “Risk Factors.”

In some cases, forward-looking statements can be identified by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology. These statements are only predictions. Investors should not rely on such forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from those implied or projected by forward-looking statements include, among other things, those listed under the section titled “Risk Factors” and elsewhere in this Annual Report. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. Investors should read this Annual Report, the documents that we reference in this Annual Report and the other documents that we file with the Securities and Exchange Commission (“SEC”) with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

While we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. Investors should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

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

RISK FACTORS SUMMARY

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

- We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future success and viability. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.

- We will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

- Verekitug is our only product candidate, and we are dependent on a third party having accurately generated, collected and reported data from certain preclinical studies that were previously conducted for verekitug.

- If we are unable to advance verekitug in clinical development for one or more of the indications that we are pursuing, obtain regulatory approval and ultimately commercialize verekitug, or experience significant delays in doing so, our business will be materially harmed.

- The successful development of pharmaceutical products involves a lengthy and expensive process and is highly uncertain.

- The regulatory approval processes of the FDA, the European Medicines Agency, and the European Commission and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for verekitug or any other potential future product candidates, our business will be substantially harmed.

- Verekitug represents a novel approach to the treatment of inflammatory diseases, which makes it difficult to predict its likelihood of success and the timing and cost of development and obtaining regulatory approval.

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

- We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of verekitug or any other potential future product candidates, which could prevent us from achieving our projected development and commercialization goals in the timeframes we announce and expect, and harm our business and results of operations. Many of the factors that cause or lead to a delay in the initiation or completion of clinical trials may also lead to the denial of regulatory approval or limit market acceptance of verekitug or any other potential future product candidates.

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

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

- Competitive products may reduce or eliminate the commercial opportunity for verekitug or any other potential future product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize verekitug or any other potential future product candidates may be adversely affected. Our

competitors may have significantly greater financial resources and expertise such that they may be more successful than us in obtaining regulatory approval and achieving widespread market acceptance.

- We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

- Our ability to develop verekitug or any other potential future product candidates and our future growth depends on attracting, hiring and retaining our key personnel and recruiting additional qualified personnel.

- We currently rely, and plan to rely in the future, on third parties to conduct and support our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize verekitug or any other potential future product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

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

- Our success is largely based upon our intellectual property and proprietary technologies, and we may be unable to protect and/or enforce our intellectual property.

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

PART I

Item 1. Business.

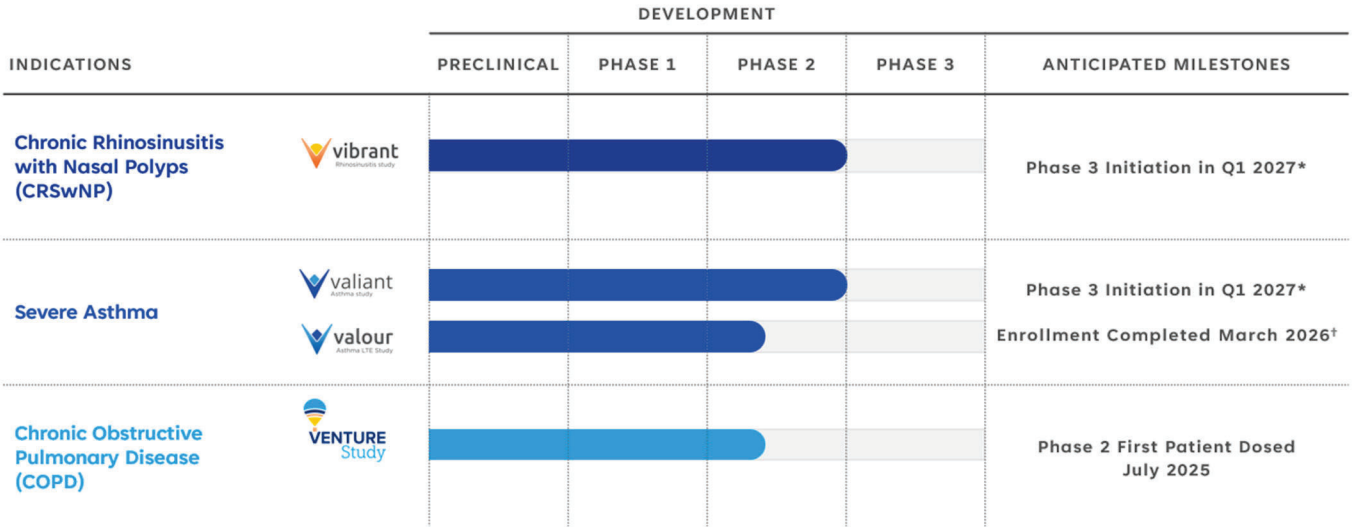
Overview

We are a clinical-stage biotechnology company developing treatments for inflammatory diseases, with an initial focus on severe respiratory disorders. We are developing verekitug, the only known antagonist currently in clinical development that targets the receptor for Thymic Stromal Lymphopoietin ("TSLP"), a cytokine which is a clinically validated driver of inflammatory response positioned upstream of multiple signaling cascades that affect a variety of immune mediated diseases. Preclinical and clinical data to date demonstrate verekitug's highly potent inhibition of the TSLP receptor, which we believe will translate to a differentiated product profile, including improved clinical outcomes, substantially extended dosing intervals and the potential to treat a broad spectrum of patients. We have advanced this highly potent monoclonal antibody into separate Phase 2 trials for the treatment of severe asthma, including a long-term safety and efficacy extension study ("Phase 2 LTE"), chronic rhinosinusitis with nasal polyps ("CRSwNP"), and chronic obstructive pulmonary disease ("COPD"). We reported positive top-line results in our CRSwNP Phase 2 trial in September 2025 and positive top-line results in our severe asthma Phase 2 trial in February 2026. We initiated our Phase 2 COPD trial in July 2025. We plan to initiate dosing in Phase 3 trials in both severe asthma and CRSwNP in the first quarter of 2027, prioritizing a Phase 3 development strategy that focuses on maximizing efficacy in both indications, without biomarker restriction, with quarterly at-home administration. Our experienced team is committed to maximizing verekitug's unique attributes to address the substantial unmet needs for patients underserved by today's standard of care.

There are seven biologics approved for the treatment of severe asthma; four of these biologics are also approved for CRSwNP, and two are also approved for the treatment of COPD. Total estimated biologics sales in 2023 for asthma in the United States, Europe and Japan markets were approximately $7.5 billion. In December 2021, tezepelumab (marketed as Tezspire by Amgen Inc. ("Amgen") and AstraZeneca PLC ("AstraZeneca")), a monoclonal antibody targeting the TSLP ligand, not the receptor, was approved by the U.S. Food and Drug Administration ("FDA") as an add-on maintenance treatment for patients with severe asthma. Tezepelumab is the first and only treatment for severe asthma without any phenotype or biomarker limitation, highlighting the benefit of blocking TSLP signaling early in the inflammatory cascade as compared to other biologics' mechanisms of action which are further downstream. Tezepelumab is projected to reach global annual sales of over $3.0 billion for severe asthma alone in 2032 and, according to Amgen, achieved more than 20% of new to brand share of prescriptions in the United States in its first commercial year. In May 2024, Amgen and AstraZeneca reported Phase 2a proof-of-concept data for tezepelumab for the treatment of moderate to very severe COPD at the American Thoracic Society ("ATS") International Conference. This trial reported a reduction in the frequency of COPD exacerbations that has supported advancement of tezepelumab into Phase 3 development for COPD. These clinical data further demonstrate the potential for a TSLP targeted therapy to treat a variety of inflammatory diseases. Tezepelumab is projected to reach global annual sales of over $5.0 billion for COPD alone in 2033, if approved in this indication. The projections for tezepelumab's global annual sales are not indicative of the potential market opportunity for verekitug and are subject to a number of assumptions, risks and uncertainties that could cause them to be smaller than currently estimated. Despite the availability of existing biologics for severe respiratory disease, there remains a high unmet need that limits the utilization of these therapies, including suboptimal symptom control and frequent dosing intervals.

Verekitug is, to our knowledge, the only monoclonal antibody currently in clinical development that targets and inhibits the TSLP receptor. In May 2024, we presented full proof-of-concept data from our multicenter, randomized, double-blind, placebo-controlled Phase 1b multiple ascending dose ("MAD") clinical trial in asthma patients demonstrating that dosing with verekitug led to rapid and complete TSLP receptor occupancy, and reductions in fractional exhaled nitric oxide ("FeNO," a disease-related biomarker) and blood eosinophil levels ("eos," a disease-related biomarker) that were rapid, substantial and sustained for up to 24 weeks after the last dose. This study also demonstrated that verekitug is approximately 300-fold more potent than tezepelumab (based on published tezepelumab data), which, combined with verekitug's pharmacokinetic ("PK") profile, enables an extended dosing interval of up to 24 weeks, compared to tezepelumab (four-week dosing interval). Furthermore, clinical data from our MAD trial indicate an approximately 50% greater effect on FeNO than has previously been reported for tezepelumab. We have not conducted head-to-head clinical studies of verekitug against tezepelumab, and note that ongoing and future clinical trials for verekitug may produce differing clinical activity and tolerability results. Three Phase 1 clinical trials have been completed for verekitug across a total of 120 participants, including 32 patients with asthma. In these trials, which were not designed to support formal statistical comparisons, verekitug was well tolerated, demonstrated no evidence of clinically meaningful anti-drug antibodies ("ADAs"), and showed a predictable and consistent PK profile with high subcutaneous bioavailability. In December 2025, the full manuscript from the MAD trial was published in *Clinical Pharmacology and Therapeutics*. Based on its extended dosing interval and effect on broadly accepted disease-associated biomarkers, we believe verekitug, if approved, will be the preferred biologic for the treatment of severe asthma, CRSwNP and COPD.

Our current clinical development pipeline for verekitug is summarized in the chart below. We conducted two separate multi-national, placebo-controlled, randomized Phase 2 clinical trials to investigate the efficacy of two extended dosing intervals of 12 and 24 weeks for patients with severe asthma and 12 weeks for patients with CRSwNP. These trials were designed using endpoints that, pending interactions with regulatory authorities, could allow data from these trials to support submissions for product approval. We announced data from the Phase 2 clinical trial in CRSwNP in September 2025 and data from the Phase 2 clinical trial in severe asthma in February 2026. We plan to initiate dosing in Phase 3 trials in both severe asthma and CRSwNP in the first quarter of 2027, prioritizing a Phase 3 development strategy that focuses on maximizing efficacy in both indications, without biomarker restriction, with quarterly at-home administration. Based on available data from Phase 1 clinical trials with verekitug, we initiated our Phase 2 clinical trial in COPD in July 2025. Beyond these indications, we believe verekitug has broad potential, and we intend to leverage its unique attributes to develop it as a potential therapy for numerous TSLP-driven diseases.



* Phase 3 preparation initiated in both CRSwNP and severe asthma.

† VALOUR is a Phase 2 long-term safety and efficacy study of verekitug in eligible participants with severe asthma who completed the Phase 2 VALIANT study.

Leveraging TSLP biology to address unmet needs in severe asthma, CRSwNP and COPD

TSLP overview

Verekitug is a monoclonal antibody that targets and inhibits the TSLP receptor. TSLP is a member of a class of epithelial cytokines, also including IL-25 and IL-33, commonly referred to as alarmins. TSLP is primarily produced by epithelial cells, especially in the lung, gastrointestinal tract and skin. Dendritic cells, basophils, mast cells, keratinocytes and fibroblasts also produce TSLP with appropriate stimulation. In response to various environmental triggers, including viruses, bacteria, allergens, chemical irritants and physical injury, TSLP can initiate and amplify a wide range of innate and adaptive immune responses, including supporting epithelial barrier function, dendritic cell activation, type 2 innate lymphoid cell activation and survival, immune cell recruitment, induction of type 2 responses and regulation of B cell function. Beyond type 2 inflammation, data also support a role for TSLP in propagating non-type 2 inflammatory processes, including IL-17 production, modulation of airway structural cells and the promotion of fibrosis. As such, TSLP signaling is a central instigator of multiple downstream biologic pathways relevant to human diseases that are characterized by epithelial inflammation, including asthma, CRSwNP and COPD.

The TSLP signaling pathway is well-understood as a contributor to disease-driving proinflammatory pathways and is a clinically and commercially validated target for therapeutic development. Historically, development of biologics for severe asthma and related conditions has focused on type 2 inflammatory cytokines that are activated downstream in the TSLP signaling pathway, for instance IL-4, IL-5 and IL-13. However, in addition to its effect on type 2 inflammation, emerging evidence indicates that TSLP also impacts non-type 2 inflammation, which may result in broader downregulation of pathways relevant to the pathogenesis of multiple inflammatory diseases. We believe verekitug has the potential, if approved, to address unmet needs in multiple diseases characterized by TSLP-driven pathobiology due to the high potency and potential for extended dosing intervals that we have observed in our preclinical and clinical development to date.

Only one drug targeting the TSLP pathway has been approved for the treatment of severe asthma. In December 2021, tezepelumab (marketed as Tezspire by Amgen and AstraZeneca), a monoclonal antibody targeting the TSLP ligand, not the

receptor, was approved by the FDA as an add-on maintenance treatment for patients with severe asthma. Tezepelumab is the first and only treatment for severe asthma without any phenotype or biomarker limitation, highlighting the benefit of blocking TSLP signaling early in the inflammatory cascade as compared to other biologics' mechanisms of action which are further downstream. In the Phase 3 clinical trial of tezepelumab in adults and adolescents with severe, uncontrolled asthma, patients who received tezepelumab had fewer exacerbations and better lung function, asthma control and health-related quality of life than those who received placebo. Based on pooled safety data from the clinical trials of tezepelumab, Tezspire's FDA approved label identifies hypersensitivity reactions following administration as a clinically significant adverse reaction, as well as pharyngitis, arthralgia and back pain as additional adverse reactions that occurred at an incidence of greater than or equal to 3% and more common than the placebo group. Furthermore, a Phase 2a clinical trial for tezepelumab in COPD patients, which demonstrated a clinically-significant reduction of COPD exacerbations, the most frequently reported adverse events for tezepelumab were worsening of COPD (12.1%) and incidents of COVID-19 infections (14.5%, trial commenced in July 2019), demonstrating a safety and tolerability profile consistent with that observed for tezepelumab in severe asthma. In October 2025, tezepelumab was approved in the U.S. for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled CRSwNP. This approval was based on the efficacy and safety data from its Phase 3 trial; in this study, tezepelumab demonstrated a reduction in nasal polyp severity and showed reduction for the need for surgery and systemic corticosteroid use versus placebo. These clinical data further demonstrate the potential for a TSLP targeted therapy to treat a variety of inflammatory diseases.

Severe asthma

Asthma is a common respiratory disease characterized by chronic airway inflammation that is often underdiagnosed and under-treated. For some people, asthma can simply be a nuisance, for others it can interfere with daily life and potentially even be life-threatening. Of the more than 25 million Americans living with asthma, it is estimated that 5% to 10% suffer from severe asthma. Severe asthma is defined as asthma that remains uncontrolled despite optimized treatment with high-dose inhaled corticosteroids or that requires high-dosed inhaled corticosteroids to prevent symptoms from becoming uncontrolled. It is estimated that approximately 90% of people with severe asthma are eligible for biologics, but only 440,000 patients are currently treated with biologics, suggesting more than 80% of eligible patients are not being optimally treated. In 2023, global sales of biologics for the treatment of severe asthma were approximately $7.5 billion.

These statistics show there is a large population of people living with uncontrolled symptoms of severe asthma. Key areas of unmet need for people living with severe asthma include improved control of exacerbations and symptoms and reduced treatment burden (e.g., need for frequent injections).

Chronic rhinosinusitis with nasal polyps (CRSwNP)

CRSwNP is an inflammatory disease of the upper airway, marked by chronic sinonasal inflammation and the presence of inflammatory polyps in the nasal passages and paranasal sinuses. It is estimated by Sanofi that approximately 900,000 patients in the United States and Europe suffer from CRSwNP. Nasal polyps are associated with significant morbidity and debilitating symptoms; it is estimated that more than 40% of people with severe asthma also have CRSwNP and that up to 70% of people with CRSwNP also have asthma, demonstrating a strong association between the two conditions.

The current treatment options for patients with CRSwNP are corticosteroids, surgery and, more recently, biologics. Although a treatment option, surgery does not guarantee symptom relief. Even with surgery, many people with CRSwNP remain symptomatic, with the recurrence rate of CRSwNP ranging from 20% to 60% within 18 months to four years and increasing to 79% after 12 years. Recurrence is particularly common for people with severe disease, including those also living with asthma or who have undergone prior surgeries. The recent FDA approvals of biologic treatments for CRSwNP have established a well-understood regulatory pathway and route to commercialization. It is estimated that approximately 300,000 adult patients in the United States are eligible for biologics.

Despite these available treatments, the quality of life ("QoL") studies and post-surgical recurrence rates clearly show that many people with CRSwNP have uncontrolled symptoms that are impacting their daily life and current treatments are not meeting their needs.

Chronic obstructive pulmonary disease (COPD)

Similar to asthma, COPD is a chronic inflammatory disease that obstructs airflow from the lungs. Chronic inflammation causes structural changes within the lungs, narrowing already small airways and damaging lung parenchyma which causes air sacs to lose functionality and decreases lung elasticity. It is typically caused by long-term exposure to irritants, most often cigarette

smoke. People with a history of asthma are also more likely to have COPD. Historically, COPD has been considered to have elements of both type 2 and non-type 2 immune responses.

COPD is the fourth leading cause of death worldwide, causing approximately 3.5 million deaths in 2021. Almost 14.2 million Americans, or 6.5% of the adult population, reported in one study that they have been diagnosed with COPD, yet the actual number is likely higher given that more than half of adults with low pulmonary function in another study reported that they were not aware that they had COPD.

Treatments for COPD are similar to those for asthma and CRSwNP, including inhaled steroids to reduce inflammation in the airways as well as bronchodilator inhalers to relax airways and improve airflow. Oxygen and surgery may also be used for people with severe COPD. Dupilumab (marketed as Dupixent by Sanofi and Regeneron Pharmaceuticals, Inc. ("Regeneron")), an interleukin ("IL")-4 receptor alpha antagonist ("IL-4Ra"), and mepolizumab (marketed as Nucala by GlaxoSmithKline ("GSK")), an IL-5 antagonist, are the only biologics approved for the treatment of COPD.

Despite available treatments, 60% of all COPD patients report some limitations in their daily activity, with 45% being unable to work and 75% complaining of difficulty climbing stairs. Given the high levels of morbidity and mortality associated with COPD, the currently available medicines are not sufficient to control symptoms or disease progression.

Verekitug: Inhibiting TSLP signaling in severe asthma, CRSwNP and COPD

Verekitug is a novel recombinant fully human immunoglobulin G1 ("IgG1") monoclonal antibody that binds to the TSLP receptor and inhibits its signaling. In 2021, we acquired verekitug from Astellas Pharma Inc. ("Astellas"). Astellas discovered the compound and completed preclinical studies and a Phase 1 single ascending dose ("SAD") trial, providing the early foundational work for our Phase 1b MAD trial. In those preclinical studies, which were not designed to support formal statistical comparisons, verekitug potently inhibited TSLP signaling. Additionally, verekitug inhibited cytokine production from CD4+ T cells, suggesting that it may be effective against type 2 and non-type 2 inflammation. In the Phase 1 SAD trial in healthy volunteers, verekitug demonstrated a favorable safety profile with no drug-related serious treatment-emergent adverse events, dose proportional pharmacokinetics and a pharmacodynamic effect consistent with TSLP antagonism.

We have conducted four additional clinical trials of verekitug: a Phase 1b MAD trial in patients with asthma, a Japanese ethnobridging study in healthy volunteers, a Phase 2 trial in patients with CRSwNP, and a Phase 2 trial in patients with severe asthma. Across the five clinical trials, we have treated approximately 500 participants with verekitug. In these trials, verekitug was well tolerated and showed a predictable and consistent PK profile with high subcutaneous bioavailability. Immunogenicity in Phase 2 trials was consistent with previous experience, and meaningful differences in either safety or efficacy were not observed in patients with anti-drug antibodies as compared to those without.

Our Phase 1b MAD clinical trial established clinical proof-of-concept for verekitug in asthma. In the trial, which was not designed to support formal statistical comparisons, verekitug demonstrated rapid, substantial and sustained target engagement and maintained maximal inhibition of disease-related biomarkers in patients with asthma for up to 24 weeks after the last study dose. Results of the Phase 1b study also demonstrated that verekitug is a potent inhibitor of the TSLP receptor and has the potential for an extending dosing interval compared to currently available treatments. Importantly, the PK/pharmacodynamic ("PD") modeling that was done based on the preclinical data aligned very closely with these early clinical results, strengthening our understanding of verekitug's attributes and behavior in humans.

We conducted two separate multi-national, placebo-controlled, randomized Phase 2 clinical trials to investigate the efficacy of two extended dosing intervals of 12 and 24 weeks for patients with severe asthma and 12 weeks for patients with CRSwNP. These trials were designed using endpoints that, pending interactions with regulatory authorities, could allow data from these trials to support submissions for product approval. We announced data from the Phase 2 trial in CRSwNP in September 2025 and data from the Phase 2 trial in severe asthma in February 2026. We plan to initiate dosing in Phase 3 trials in both severe asthma and CRSwNP in the first quarter of 2027, prioritizing a Phase 3 development strategy that focuses on maximizing efficacy in both indications, without biomarker restriction, with quarterly at-home administration. Based on available data from Phase 1 clinical trials with verekitug, we initiated our Phase 2 clinical trial in COPD in July 2025. Beyond these indications, we believe verekitug has broad potential, and we intend to leverage its unique attributes to develop it as a potential therapy for other TSLP-driven diseases.

Our team

We have built a team with deep experience and a strong track record of execution. Our leadership team, including our Chief Executive Officer E. Rand Sutherland, M.D., our Chief Medical Officer and Head of Research and Development Aaron Deykin, M.D., and our Chief Financial and Operating Officer Michael Paul Gray, M.B.A., and our board of directors have significant experience developing and commercializing innovative medicines, with deep expertise in severe asthma and other respiratory diseases.

Our strategy

Our mission is to develop verekitug to be the first approved antagonist of the TSLP receptor to benefit patients suffering from severe inflammatory diseases that are underserved by today's standard of care. The key components of our strategy to achieve this mission are:

- **Leverage verekitug's unique mechanism of action to improve the treatment options for millions of patients living with severe inflammatory diseases.** Preclinical and early clinical data demonstrate that verekitug is a highly potent inhibitor of the TSLP receptor. Verekitug is, to our knowledge, the only monoclonal antibody currently in clinical development that targets the TSLP receptor. We believe these characteristics will translate into a differentiated profile, including improved clinical outcomes, substantially extended dosing intervals, and the potential to treat for a broad spectrum of TSLP-driven inflammatory diseases.
- **Advance verekitug in severe asthma, CRSwNP and COPD.** We initiated a Phase 2 clinical trial to evaluate verekitug for the treatment of COPD in July 2025, reported positive top-line results in our CRSwNP Phase 2 trial in September 2025, and reported positive top-line results in our severe asthma Phase 2 trial in February 2026. We designed our trials to leverage established biomarkers, clinical trial paradigms and validated regulatory pathways to rapidly generate data to further establish the unique therapeutic profile of verekitug. In addition, these trials were designed using endpoints that, pending interactions with regulatory authorities, could allow data from these trials to support submissions for product approval.
- **Maximize the potential of verekitug by identifying additional TSLP-driven diseases with high unmet needs that could be addressed by our product candidate.** The TSLP signaling pathway is well understood to be either a risk factor for or a key driver of inflammatory diseases across multiple therapeutic areas, including respiratory, dermatology, gastroenterology, nephrology and allergy/immunology. Thus, we believe there is a significant opportunity to expand the impact of verekitug beyond our initial indications of focus in respiratory disease.

Overview of TSLP

TSLP is a member of a class of epithelial cytokines, also including IL-25 and IL-33, commonly referred to as alarmins. In response to various environmental triggers, including viruses, bacteria, allergens, chemical irritants and physical injury, TSLP is produced by the epithelium and can initiate and amplify a wide range of innate and adaptive immune responses including supporting epithelial barrier function, dendritic cell activation, type 2 innate lymphoid cell activation and survival, immune cell recruitment, induction of type 2 responses and regulation of B cell function. Beyond type 2 inflammation, data also support a role for TSLP in propagating non-type 2 inflammatory processes including IL-17 production, modulation of airway structural cells and the promotion of fibrosis. As such, TSLP signaling is a central instigator of multiple downstream biologic pathways relevant to human diseases that are characterized by epithelial inflammation, including asthma, CRSwNP and potentially COPD.

TSLP is primarily produced by epithelial cells, especially in the lung, gastrointestinal tract and skin. Dendritic cells, basophils, mast cells keratinocytes and fibroblasts also produce TSLP with appropriate stimulation. Relevant stimuli include mechanical injury, pro-inflammatory cytokines, allergen proteases and viral infections, among others. The breadth of TSLP effects suggests it is involved in tissue homeostasis and host defense and acts as an early alarm signal for the immune system. TSLP plays a critical role in many diseases, including asthma, allergic diseases and chronic inflammatory diseases.

In addition to type 2 mediators, TSLP has been shown to drive T helper ("Th") 17 cell polarization of naive CD4 helper cells. As severe asthma phenotypes have been associated with increased Th17 cells and neutrophilic inflammation, in addition to eosinophilic inflammation, interruption of TSLP signaling has the potential to provide benefit to patients whose disease is driven by both type 2 and non-type 2 inflammatory processes. Tezepelumab, an approved antibody against TSLP without restriction to patients with only type 2 inflammation, has been shown to have clinical benefits in patients with severe asthma who do not have elevated type 2 biomarkers as with all other approved therapies.

Beyond its role in inflammation, TSLP also acts on airway structural cells. Airway smooth muscle cells express TSLP receptor and when stimulated by TSLP, they increase production of IL-6 and IL-8. Bronchial fibroblasts also produce TSLP and express

TSLP receptor. With TSLP receptor signaling, the bronchial fibroblasts produce collagen, a smooth muscle actin, arginase 1 and transforming growth factor b1. Taken together, this indicates that TSLP plays a pivotal role in promoting structural changes in asthmatic airways. A summary of the TSLP signaling pathway is illustrated in Figure 1 below.

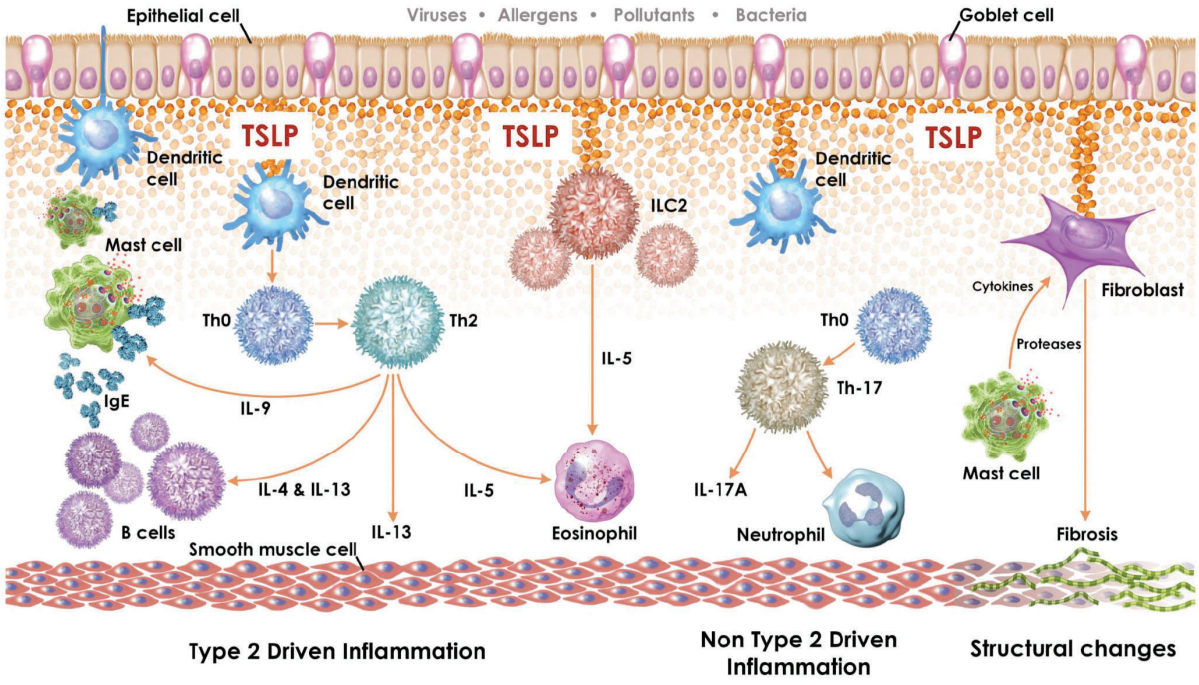


Figure 1: TSLP signaling pathway

TSLP initiates intracellular signaling through the binding of its TSLP receptor and the recruitment of the IL-7 receptor alpha-chain ("IL-7Ra"). TSLP receptor is expressed on many different cell types, including dendritic cells, T and B cells, natural killer T cells, eosinophils, basophils and epithelial cells. Once activated, the TSLP receptor complex then activates a signaling cascade that results in the production of type 2 pro-inflammatory cytokines, including IL-5, IL-9, IL-4 and IL-13. IL-5 is a key cytokine in eosinophilic inflammation. IL-9 is important in allergic inflammation, while IL-4 and IL-13 are both critical to type 2 inflammation.

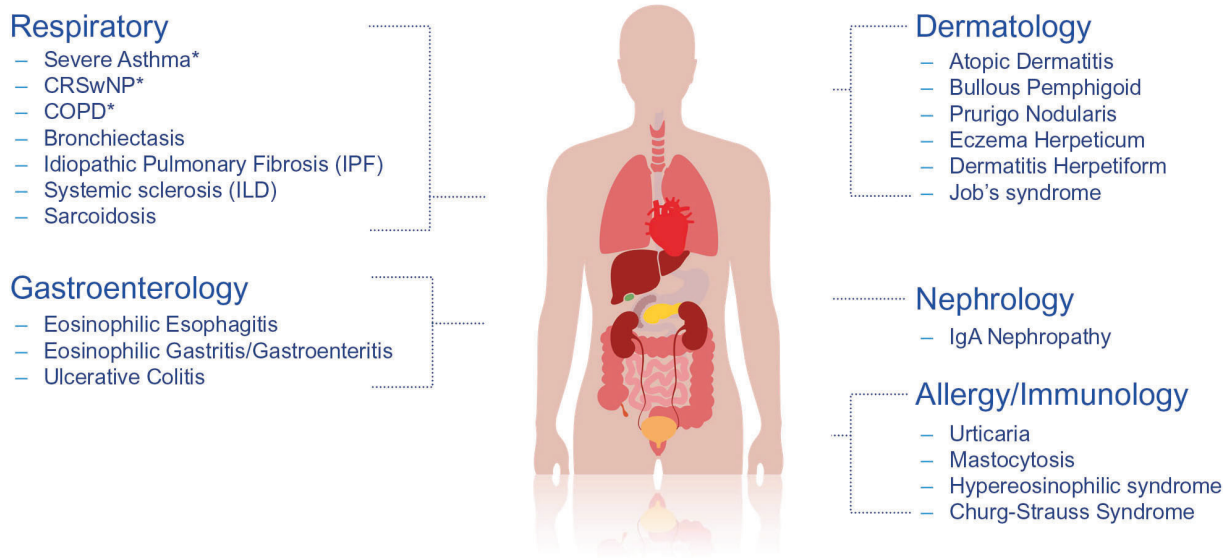
The role of TSLP in severe asthma, CRSwNP, COPD and related inflammatory diseases

Airway biopsies of people with asthma have shown overexpression of TSLP and type 2 cytokines, particularly in those with severe disease. Type 2 cytokines have enhanced release in the presence of TSLP and therefore are an additional indicator of TSLP expression. Blocking TSLP is expected to reduce type 2 cytokine production by Th2 memory cells, innate lymphoid type 2 cells and mast cells, all of which are involved in inflammation. Additionally, several single nucleotide polymorphisms at the TSLP genomic locus were associated with increased asthma susceptibility or protection.

TSLP may also play a role in the efficacy of corticosteroid treatments for people with asthma. In an animal model, the absence of TSLP signaling results in a significant increase in the anti-inflammatory effects of corticosteroids. These results appear to be relevant for people with asthma as well given that TSLP concentration in the bronchoalveolar lavage ("BAL") fluid from people with severe asthma were inversely correlated with corticosteroid-mediated inhibition of IL-5 production.

The therapeutic potential of inhibiting TSLP in people with asthma is supported by significant clinical data, including a Phase 3 trial of tezepelumab in adults and adolescents with severe, uncontrolled asthma. Tezepelumab is a fully human monoclonal antibody that binds to the TSLP ligand and prevents its interaction with the TSLP receptor. The study met its primary endpoint of reduction in rate of asthma exacerbations, including for those participants with low blood eos at baseline. The study also met several secondary endpoints showing improvements across multiple measures of disease, including lung function, asthma control and health-related quality of life.

TSLP has been implicated in many diseases beyond asthma as well, as shown in Figure 2 below. While the cause of CRSwNP is not fully understood, the role played by the immune system in the condition has been well studied. CRSwNP is predominantly a type 2 inflammatory response with elevated levels of TSLP. Lung epithelium and submucosa samples from people with COPD also contained a greater number of TSLP mRNA-positive cells and BAL samples from these patients had higher concentration of TSLP compared to healthy samples. TSLP has also been indicated as a driver of atopic dermatitis ("AD"), a chronic inflammatory disease of the skin. TSLP was found to be highly expressed in acute and chronic AD lesions but was undetectable in nonlesional skin. Figure 2 below shows many of the diseases in which TSLP has been implicated, including the three indications we are targeting, severe asthma, CRSwNP and COPD.



* Target indications for verekitug based on our current development strategy

Figure 2: Selected diseases in which TSLP has been shown to play a role

Overview of severe asthma

Disease overview

Asthma is a common disease of the lungs characterized by chronic airway inflammation that is often underdiagnosed and under-treated. With the narrowing of the bronchioles, people with asthma can experience edema or swelling due to fluid accumulation, hyperresponsiveness of the airway resulting in muscle contraction and excess mucus production. People living with asthma experience respiratory symptoms, such as wheeze, shortness of breath, chest tightness and cough, that vary over time and in intensity and also experience airflow limitations mostly with expiration. Asthma attacks can be triggered by infections or environmental irritants.

Approximately 350 million people live with asthma around the world, including more than 25 million Americans. For some people, asthma can simply be a nuisance, for others it can interfere with daily life and potentially even be life-threatening. Of the more than 25 million Americans living with asthma, it is estimated that 5% to 10% suffer from severe asthma. Severe asthma is defined as someone diagnosed with asthma who requires high-dose inhaled corticosteroids in order to control symptoms. Asthma is also considered severe when it is uncontrolled despite proper use of these medications. Individuals who suffer from severe uncontrolled asthma may experience symptoms throughout most days and every night. Their symptoms are also more intense and last for longer periods than with regular asthma. Severe asthma attacks can result in confusion or agitation, being unable to speak in full sentences, a bluish tint to the lips, face or fingernails, rapid breathing and having symptoms that don't improve after using a rescue inhaler. These attacks can last from hours to days, compared to mild asthma attacks which typically last only a few minutes. In rare instances, severe asthma attacks can result in death.

There are two main categories of severe asthma, type-2 inflammation and non-type-2 inflammation. Both types of asthma are assessed using eos and FeNO as common biomarkers. Type 2 inflammation refers to a specific type of immune response pattern where Th cells release cytokines such as IL-4, IL-5, IL-9 and IL-13 and also promote the formation of anti-immunoglobin E ("IgE") antibodies. Additionally, certain immune cells, specifically mast cells, basophils and eosinophils, become activated.

Collectively, these cells help to secrete mucus, promote swelling and contract smooth muscle cells, all of which are symptoms of asthma. A high eosinophil blood count is characteristic of type 2 inflammation and an important measure as eosinophils play a vital role in sustaining and enhancing chronic inflammatory asthmatic response. Elevated FeNO levels act as another important measure, as IL-13, mainly secreted by eosinophils, activates the expression of inducible nitric oxide synthase and increases the production of nitric oxide. It is estimated that 55% to 70% of people with severe asthma have type 2 inflammation as a major contributing cause. Understanding of the type 2 inflammation pathway has allowed for the development of targeted therapies for the treatment.

Non-type 2 inflammation asthma is assessed by a lower blood eosinophil count and lower exhaled nitric oxide. It is characterized by Th1 and/or Th17-cell mediated inflammation rather than the Th2-cell mediated inflammation seen in type 2 inflammation. People with non-type 2 asthma typically have poor steroid response and have historically not been candidates for biologic treatments. Recently tezepelumab was approved by the FDA for people with severe asthma irrespective of their blood eosinophil count given the results of the Phase 3 trial showed improvement in asthma symptoms for both type 2 and non-type 2 patient populations.

Overview of current asthma treatments

Asthma cannot be cured, but for many people it can be controlled. The long-term goals of asthma management from a clinical perspective are to achieve good control of symptoms to allow for normal daily activities and to minimize the risk of asthma-related deaths, exacerbations, persistent airflow limitations and side effects.

The standard of care for asthma includes three main categories of treatment:

- Controller medications, which contain inhaled corticosteroids (“ICS”), are used to reduce airway inflammation, control symptoms and reduce future risks of exacerbations and related decline in lung function. Patients with mild asthma can typically control symptoms as they occur with low-dose ICS. Patients with severe asthma require high doses of ICS and may not be able to control their symptoms even with proper use of inhaler. Importantly, people with non-type 2 inflammation asthma are not responsive to steroid treatment.
- Reliever medications are provided to all patients for as-needed relief of breakthrough symptoms. These treatments could be ICS-formoterol, ICS-long-acting beta-agonist (“LABA”) or as-needed short-acting beta2 agonist (“SABA”). Over-use of SABA can lead to an increased risk of asthma exacerbations and therefore reducing the need for reliever medications is an important goal in asthma treatment.
- Biologic therapies for patients with severe asthma whose persistent symptoms and exacerbations are not controlled with high dose controller medications. Add on therapies include biologics such as IgE, anti-IL-4, anti-IL5, anti-IL-13 and anti-TSLP; bronchodilators, such as long-acting muscarinic antagonists (“LAMA”); antibiotics, such as azithromycin; bronchial thermoplasty; and low dose oral corticosteroids. Similar to ICS, people with non-type 2 inflammation asthma do not respond well to most biologic therapies, with the exception of the only currently approved TSLP signaling inhibitor, tezepelumab.

Biologic therapies for severe asthma

In the past few years, several new biologics have been approved by the FDA for the treatment of severe asthma. Most of these therapies work by targeting specific cells or proteins in the body involved in the type 2 inflammatory response triggered with asthma, including eosinophils, IgE and several ILs or their receptors. In clinical trials, biologics have shown to reduce airway hyperactivity and the number of asthma attacks. They may allow for the reduction or even discontinuation of long-term oral steroid use.

Biologics are administered either subcutaneously or intravenously on a bi-weekly, monthly, bi-monthly, or bi-annual basis, depending on the specific product. Table 1 below identifies FDA-approved biologic treatments for asthma and each product’s

mechanism of action, specific asthma indication and dosing interval. Despite the efficacy shown in clinical trials, it is estimated that less than 25% of people with severe asthma receive biologic treatment.

FDA approved biologic treatments	Mechanism of action	Type of asthma	Dosing interval
Omalizumab / Xolair	Anti-IgE	Moderate to severe persistent allergic asthma	2 or 4 weeks
Dupilumab / Dupixent	Blocks IL-4 and IL-13	Moderate to severe eosinophilic asthma	2 weeks
Mepolizumab / Nucala	Blocks IL-5	Severe eosinophilic asthma	4 weeks
Reslizumab / Cinqair			4 weeks (IV)
Benralizumab / Fasenra			8 weeks
Depemokimab / Exdensur			26 weeks
Tezepelumab / Tezspire	Blocks TSLP	Severe asthma (without restriction to type 2 patients only)	4 weeks

Table 1: Overview of FDA approved biologic treatments for asthma

Tezepelumab is a human monoclonal antibody that binds to the TSLP ligand and prevents its interaction with the TSLP receptor. While tezepelumab has a different mechanism of action compared to verekitug, which inhibits the TSLP receptor itself, both antibodies work at the same point in the TSLP signaling pathway which is upstream of other competitor biologics currently approved for the treatment of asthma, CRSwNP and COPD. We believe the biologic validation for efficacy in patients with severe asthma without elevated type 2 markers as well as the clinical and regulatory progress of tezepelumab provide a strong rationale for our own development program.

In 2021, the results of a Phase 3 trial of tezepelumab in participants with severe, uncontrolled asthma were published in the *New England Journal of Medicine*. Participants were dosed every four weeks ("q4w") with tezepelumab or placebo. The trial met its primary endpoint of reduction in annualized asthma exacerbation rate ("AAER") with a 56% reduction in AAER over 52 weeks compared to placebo. Tezepelumab also achieved a statistically significant reduction in AAER in participants with low baseline eosinophil counts. In addition, the study included biomarker endpoints that have been found to be clinically relevant in asthma: change from baseline in eosinophil count and change in baseline in FeNO. Both endpoints showed a significant improvement in the biomarkers with a decrease of 150 cells/µl from baseline for the eosinophil count and a decrease of 17 parts per billion ("ppb") for baseline for FeNO. There were no clinically meaningful differences in safety results between the tezepelumab and placebo groups. The most frequently reported adverse events were nasopharyngitis, upper respiratory tract infection and headache. As reported in the *New England Journal of Medicine*, patients who received tezepelumab had fewer exacerbations and better lung function, asthma control and health-related quality of life than those who received placebo. Based on pooled safety data from the clinical trials of tezepelumab, the resulting FDA approved label for Tezspire identifies hypersensitivity reactions following administration as a clinically significant adverse reaction, as well as pharyngitis, arthralgia and back pain as additional adverse reactions that occurred at an incidence of greater than or equal to 3% and more common than the placebo group.

Dupilumab (q2w), mepolizumab (q4w), reslizumab (q4w), benralizumab (q8w), and depemokimab (q26w) are biologics that target cytokines acting downstream of the TSLP receptor. These treatments, which produce a 48% to 81% reduction in asthma exacerbation rates, have all been approved by the FDA for the treatment of asthma, but all have labels that are restricted to people with high eosinophilic levels, thereby limiting their use in a substantial portion of severe asthma patients. We believe this is due to their downstream mechanism which is restricted to the type 2 inflammation pathway.

The clinical program for tezepelumab and other biologics have established clinical endpoints that were found to be acceptable for approval by the FDA, providing a strong rationale for our own development program.

Unmet need for people living with severe asthma

While there are many approved asthma treatments, there remains a significant unmet need for people living with severe asthma. Despite the use of high dose medicines, avoiding triggers and following treatment plans, many people with severe asthma continue to have uncontrolled symptoms.

Severe asthma may impact normal daily activities, resulting in missing work or school and can directly impact a person's quality of life. People with severe asthma often demonstrate significant reduction of their lung function when tested by spirometry or a

pulmonary function test. Despite the fact that severe asthma accounts for a small percentage of people with asthma, half of all asthma-related healthcare costs are attributed to their treatment. In the United States, asthma is responsible for $80 billion in annual costs due to care, absenteeism and mortality. Asthma also results in over 1.0 million emergency department visits each year and over 3,500 deaths per year in the United States alone.

People living with uncontrolled symptoms despite compliance with their treatment plan are in need of options with greater efficacy than those that are currently available. This has the potential to not only better control symptoms and improve quality of life but to also reduce the burden on our healthcare system.

Even though increased medicine adherence leads to better symptoms control and health outcomes, complying with a treatment plan can be challenging for severe asthma patients. A recent study looked at compliance with biologic treatments using proportion days covered ("PDC") as a surrogate measure for adherence. The study authors set 0.75 as the mark of good adherence. In the first six months of being prescribed a biologic treatment for asthma, only 61% of people achieved a PDC of ≥0.75.

Our market research, conducted with healthcare providers, payers, and patients, consistently indicates that efficacy is the primary driver of clinical impact and commercial success in severe asthma and CRSwNP, that healthcare providers are unwilling to trade off any aspect of safety or efficacy for extended dosing, and that the majority of value generated by dosing convenience is captured by moving from every 2- or 4-week dosing to quarterly dosing. These findings support our development strategy focused on delivering high efficacy with quarterly dosing convenience.

Market research shows healthcare providers are not willing to trade off safety or efficacy for extended dosing interval. For instance, approximately 70% of healthcare providers reported that they would switch their asthma patients to another biologic if they observed waning efficacy of a q24w drug.

We believe that by reducing the frequency of dosing we can increase patient compliance with biologic treatments for severe asthma. Additionally, a less frequent dose interval may appeal to patients that are not satisfied with their current treatment plan or are unwilling to take current biologics due to the treatment burden that comes with frequent dosing.

There is also a subpopulation of patients that live with uncontrolled symptoms due to the limitation of currently available treatments. These patients often have an absence of biomarkers associated with type 2 inflammation and, perhaps unsurprisingly, do not respond to treatments that target molecules downstream in the type 2 inflammation pathway. These patients are in need of a highly effective treatment which has a broad impact on the inflammation pathway.

Market opportunity for severe asthma

Asthma is a large and growing market as new treatments become available and diagnoses continue to increase. In 2022, 13.5% of Americans had been diagnosed with asthma at one point in their lives, which is a 48% increase in total asthma diagnoses compared to 9.1% of Americans in 1999.

The major asthma markets, including the United States, France, Spain, Germany, Italy, the United Kingdom ("UK") and Japan, have estimated annual sales of approximately $7.5 billion for 2023 with a compound annual growth rate ("CAGR") of approximately 5.9% through 2032. The United States alone was estimated to have approximately $6.0 billion in asthma market sales for 2023.

Of the more than 50 million people diagnosed with asthma in these major markets, it is estimated that only 440,000 patients are treated with biologics currently, or less than 25% of eligible patients. This creates a significant opportunity for a biologic that meets patients' needs in terms of efficacy and the reduced burden of a longer dosing interval. We believe the longer dosing interval will increase adherence and potentially provide a treatment option for asthma sufferers who were unwilling to take treatments with more frequent dosing. Additionally, because severe asthma is typically treated by specialty care providers rather than primary care physicians, we believe that commercialization can be successfully executed with a focused strategy and sale force.

In the past several years, seven biologic treatments for asthma have been approved by the FDA and six of these have achieved or are projected to achieve greater than $1.0 billion in annual sales by 2026, underscoring the need for new treatments and the large size of the market. Tezepelumab is projected to reach peak global annual sales of over $3.0 billion for severe asthma alone in 2032, and had achieved more than 20% of new to brand share of prescriptions in the United States in its first commercial year.

Taken together, we believe the strength of the biologic market has demonstrated there is room for multiple entrants into the market and the opportunity for rapid acceleration for market share. The opportunity in asthma is shown in Figure 3, which summarizes 2023 estimates of biologics eligible patients and patients treated with biologics. We believe the potency and safety clinical data that we have generated for verekitug to date, along with the expected extended dosing interval, means we are well positioned to capitalize on this market opportunity.

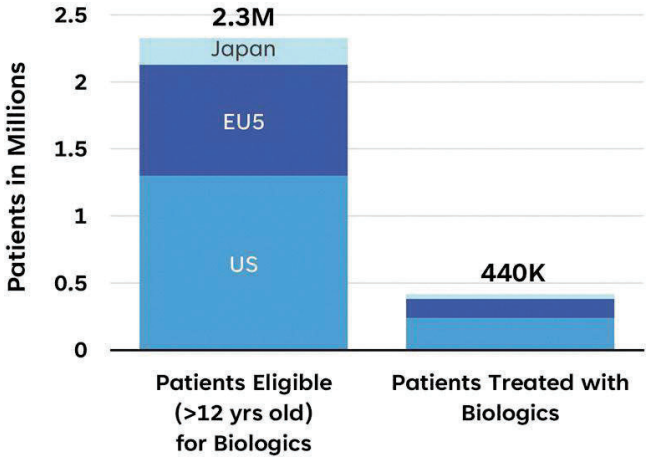


Figure 3: Biologics-eligible vs. currently-treated severe asthma patients

By acting upstream in the signaling pathway, we believe verekitug, similar to tezepelumab, has the potential to treat a broader asthma population than other available biologics. This would address a population that is refractory to existing treatments and in need of new therapies. We are confident in the ability of verekitug to gain market share if approved by regulatory agencies.

Overview of CRSwNP

Disease overview

CRSwNP is an inflammatory disease of the upper airway, marked by chronic sinonasal inflammation and the presence of inflammatory polyps in the nasal passages and paranasal sinuses. CRSwNP is associated with significant morbidity and debilitating symptoms, and it is estimated that approximately 900,000 patients in the United States and Europe suffer from this disease.

CRSwNP has four main symptoms: runny nose or postnasal drip, nasal congestion, facial pressure and/or pain and loss of smell and/or taste. Patients may also experience ear pain, sneezing, severe difficulty breathing through the nose and sleep disturbances. These symptoms can have a significant impact on quality of life. It is estimated that over 40% of people with severe asthma also have CRSwNP and that up to 70% of people with CRSwNP also have asthma, demonstrating a strong association between the two conditions and an increase in comorbid asthma severity.

The cause of CRSwNP is not fully understood although the role of the immune system in the condition has been well studied. CRSwNP is predominantly a type 2 inflammatory response with elevated levels of TSLP as well as IL-5, IL-13, eosinophilic granule proteins, eosinophil chemotactic proteins, basophils, innate type 2 lymphoid cells and mast cells. Additional studies have shown that certain populations lack increased eosinophils and have lower levels of IL-5, indicating a non-type 2 inflammatory response as well.

Overview of current CRSwNP treatments

Treatment for CRSwNP often begins with medical management, primarily involving topical corticosteroids and nasal saline irrigations. Intranasal corticosteroids have been shown to decrease nasal polyp size, lessen sinonasal symptoms and improve quality of life. Patients who are unable to manage their symptoms with medical management may undergo sinus surgery; however, polyps and symptoms can recur post-surgery. People with both asthma and CRSwNP are more likely to undergo sinus surgery than those with only CRSwNP.

Recently, biologics targeting the type 2 inflammation pathway have been approved by the FDA as treatments for CRSwNP. Similar to asthma, biologic treatments targeting IgE, IL-5, IL-4Ra, and TSLP have been approved for CRSwNP. Tezepelumab, the most recent of the FDA approvals in CRSwNP, showed reduction in nasal polyp severity, and reduction of the need for surgery and systemic corticosteroid use versus placebo. Omalizumab, an anti-IgE monoclonal antibody, was shown to reduce nasal polyp size and improve symptoms compared to placebo in CRSwNP. Mepolizumab, a humanized anti-IL5 antibody, was shown to reduce nasal polyps and improve sense of smell, post-nasal drip and nasal congestion compared to placebo for CRSwNP patients with severe nasal polyposis refractory to corticosteroid therapy. Dupilumab, a human monoclonal antibody that binds IL-4Ra and inhibits IL-4 and IL-13 signaling, reduced nasal polyp burden and improved nasal symptoms when used in conjunction with intranasal steroids in patients with refractory CRSwNP.

These FDA approvals have established a well-understood regulatory pathway and route to commercialization. The primary endpoints of the trials were similar as well, including reduction in nasal polyp score and nasal congestion/obstruction. The trials recruited a significant proportion of patients with comorbid asthma (58% to 71%) and with prior surgery (58% to 100%), highlighting the benefit that biologics can provide to a broad population of people with CRSwNP.

Unmet need for people living with CRSwNP

While there are several treatments available, there remains a significant disease and treatment burden for people living with CRSwNP. QoL studies show that the burden of living with CRSwNP is comparable to other chronic diseases such as COPD, asthma and diabetes. People with CRSwNP even had significantly worse social functioning scores than those with congestive heart failure. One of the most troublesome symptoms in terms of QoL for people with CRSwNP is loss of smell, which correlates with disease severity.

Beyond the burden of the disease, there are significant risks associated with current standard of care treatments for CRSwNP as well. Corticosteroid use, even in the short term, is associated with an increased risk of acute complications such as sepsis, venous thromboembolism and fracture.

People with serious CRSwNP requiring sinus surgery face an additional burden. While endoscopic sinonasal surgery is generally safe, risk exists with any surgical procedure. Minor complications are reported in 5% of routine endoscopic surgeries and major complications are reported in 0.5% to 1%. Even with a successful surgery, the recurrence rate of CRSwNP ranges from 20% to 60% within 18 months to four years and increases to 79% after 12 years. 37% of patients are found to have revision surgery over a 12-year period, and it is not uncommon for patients to have multiple surgeries. Recurrence is particularly common for people with severe disease, including those also living with asthma or who have undergone prior surgeries. Even with surgery, many people with CRSwNP remain symptomatic. One study reported that 23% of patients continued to have persistent symptoms post-surgery.

The recurrence of symptoms and need for multiple surgeries demonstrates that people living with CRSwNP do not have access to treatments that effectively manage their disease. A therapy with strong efficacy that provides better symptom control is a significant need for this patient population.

Our market research, conducted with healthcare providers, payers, and patients, consistently indicates that efficacy is the primary driver of clinical impact and commercial success in severe asthma and CRSwNP, that healthcare providers are unwilling to trade off any aspect of safety or efficacy for extended dosing, and that the majority of value generated by dosing convenience is captured by moving from every 2- or 4-week dosing to quarterly dosing. These findings support our development strategy focused on delivering high efficacy with quarterly dosing convenience.

Market opportunity for CRSwNP

In the major markets for CRSwNP, which include the United States, the five major European markets (France, Spain, Germany, Italy and the UK) and Japan, there are an estimated 900,000 people diagnosed with CRSwNP. Sales in these markets are expected to exceed $4.0 billion by 2030. Dupilumab alone has an annual global sales estimate for the treatment of CRSwNP of up to $1.5 billion by 2030 according to third-party research analyst reports.

Of the 900,000 people diagnosed with CRSwNP in the United States, major European markets and Japan, it is estimated that approximately 300,000 adults are eligible for biologics in the United States alone.

We believe there is a significant opportunity for additional biologic entrants into this market given the large unmet medical need that remains as many people with CRSwNP continue to live with uncontrolled symptoms despite surgery, and corticosteroid treatment.

Overview of COPD

Disease overview

Like asthma, COPD is a chronic inflammatory disease of the airways, associated with airflow worsening and episodic exacerbations that drive morbidity, mortality, and health care utilization. Chronic inflammation causes structural changes within the lungs, narrowing already small airways and damaging lung parenchyma which causes air sacs to lose functionality and decrease lung elasticity. It is typically caused by long-term exposure to irritants, most often cigarette smoke. Air pollution is also a major risk factor, primarily in lower and middle-income countries.

COPD is the fourth leading cause of death worldwide, causing approximately 3.5 million deaths in 2021. Almost 14.2 million Americans, or 6.5% of the adult population, reported in one study that they have been diagnosed with COPD, however, the true prevalence is likely higher given that more than half of adults with low pulmonary function in another study reported that they were not aware that they had COPD.

People living with COPD may experience daily cough, difficulty breathing, mucus production, chest tightness, wheezing, lack of energy and frequent respiratory infections. Symptoms often don't appear until significant lung damage has already occurred and will worsen over time. Despite the progressive nature of COPD, good symptom control can be achieved with proper treatment.

With moderate to severe COPD (stages 2 and 3) everyday activities may result in shortness of breath and frequent exacerbations, including increased and discolored phlegm. With very severe, or stage 4, COPD almost any activity results in shortness of breath, which limits mobility and may require supplemental oxygen. People with moderate to very severe COPD are also more likely to acquire lung infections like bronchitis and pneumonia.

Historically, COPD has been considered a disease driven by non-type 2 immune responses. Recently it has been shown that 20% to 40% of COPD patients also exhibit type 2 inflammation. Published research has shown that IL-4 and IL-13, cytokines in the type 2 inflammation pathway, may play a role in COPD pathogenesis. Elevated levels of TSLP have been found in the airways of people with COPD. In bronchial biopsies, TSLP receptor expression was highest in patients with severe COPD compared to healthy controls. Viral infection can also increase TSLP expression in epithelial cells, suggesting the potential role of TSLP in COPD exacerbations.

Overview of current COPD treatments

Currently available treatments for COPD include inhaled steroids to reduce airway inflammation and bronchodilator inhalers to improve airflow. Oxygen and surgery may also be used for some patients with severe COPD. Similar to asthma and CRSwNP, biologics are also being developed as new and potentially transformative treatments, and recently, dupilumab became the first biologic approved for the treatment of COPD.

In May 2023, Phase 3 clinical trial results in the *New England Journal of Medicine* showed that dupilumab, an anti-IL4Ra antibody, was the first biologic to demonstrate a significant reduction in moderate or severe acute exacerbations of COPD by 30%, when compared to placebo. Additionally, dupilumab also significantly improved lung function at 12 and 52 weeks. On the basis of these data, dupilumab was recently approved by the FDA as an add-on maintenance treatment of patients with inadequately controlled COPD and an eosinophilic phenotype. In May 2024, Phase 2a proof-of-concept data for tezepelumab for the treatment of moderate to very severe COPD were presented at the ATS International Conference. This trial reported a reduction in the frequency of COPD exacerbations that has supported advancement of tezepelumab into Phase 3 development in COPD. The most frequently reported adverse events for tezepelumab were worsening of COPD (12.1%) and incidents of COVID-19 infections (14.5%, trial commenced in July 2019), demonstrating a safety and tolerability profile consistent with that observed for tezepelumab in severe asthma. By contrast, previous trials of biologic agents targeting IL-5 or its receptors have shown mixed results with respect to clinical activity and adverse events. Taken together, these clinical trial data reinforce our plan to develop verekitug for the treatment of COPD.

Unmet need for people living with COPD

COPD is the fourth leading cause of death worldwide, causing approximately 3.5 million deaths in 2021 and is also associated with significant morbidity. Population studies have shown among patients hospitalized with COPD, 50% are readmitted in the future and approximately 13% will be hospitalized in a three-year period. In total, 60% of all COPD patients will report some limitations in their daily activity, with 45% being unable to work and 75% complaining of difficulty climbing stairs. These increases in hospitalizations and limitations to daily life are reported despite the currently available treatments. It is projected that there will be approximately 3.5 million COPD patients inadequately controlled on triple-therapy in the U.S. by 2033.

With the emerging data that type 2 inflammation plays a role in COPD, particularly exacerbations, for a portion of patients, there is a need to develop therapies that can address this patient population whose symptoms are inadequately managed with currently available therapies.

Market opportunity for COPD

Millions of people worldwide continue to suffer from COPD despite currently available treatments, underscoring the large need for more effective treatments for this patient population. Dupilumab and Mepolizumab are currently the only biologics approved for the treatment of COPD, and others are in late-stage clinical development.

Dupilumab is projected to reach peak sales of approximately $4.0 billion in COPD, while only penetrating 20% of the market, according to third-party research analyst reports. Tezepelumab, which shared positive Phase 2a data indicating it may be effective in patients with eosinophil counts at 150 or greater, is projected to have global annual sales of over $5.0 billion for COPD alone in 2033, if approved in this indication, given the broader patient population it may be able to address.

Given the size of the COPD patient population, high rates of morbidity and mortality despite currently available treatments, we believe COPD represents one of the largest unmet needs worldwide.

Verekitug, the only known antagonist of the TSLP receptor currently in clinical development

Our product candidate, verekitug, is a novel recombinant fully human IgG1 monoclonal antibody that we are developing as a potential treatment for multiple inflammation-related diseases across a broad spectrum of patients. Verekitug binds to the TSLP receptor and inhibits its signaling, and to our knowledge, it is the only monoclonal antibody that targets and inhibits the TSLP receptor currently in clinical development. TSLP is a cytokine which is a clinically validated driver of inflammatory response positioned upstream of multiple signaling cascades that affect a variety of immune mediated diseases. In preclinical studies, which were not designed to support formal statistical comparisons, verekitug demonstrated very high occupancy of the TSLP receptor and potent inhibition of TSLP signaling. Additionally, verekitug inhibited cytokine production from CD4+ T cells, suggesting that it may be effective against both type 2 and non-type 2 inflammation. Currently available biologics that target cytokines downstream of TSLP appear to only be effective against type 2 inflammation.

In May 2024, we presented full proof-of-concept data from our randomized, double-blind, placebo-controlled Phase 1b MAD clinical trial in asthma patients demonstrating that dosing with verekitug led to rapid and complete TSLP receptor occupancy, and reductions in disease-related biomarkers, FeNO and blood eos, that were rapid, substantial and sustained for up to 24 weeks after the last dose. This study also demonstrated that verekitug is significantly more potent than tezepelumab (based on published tezepelumab data), which, combined with verekitug's PK profile, enables an extended dosing interval of up to 24 weeks, compared to tezepelumab (four-week dosing interval). Furthermore, clinical data from our MAD trial indicate an approximately 50% greater effect on FeNO than has previously been reported for tezepelumab. We have not conducted head-to-head clinical studies of verekitug against tezepelumab, and note that ongoing and future clinical trials for verekitug may produce differing clinical activity and tolerability results. In the Phase 1 SAD trial in healthy volunteers, verekitug demonstrated a favorable tolerability profile with no drug-related serious treatment-emergent adverse events, dose proportional pharmacokinetics and a pharmacodynamic effect consistent with TSLP antagonism. We reported positive top-line results from our Phase 2 clinical trial in patients with CRSwNP in September 2025 and positive top-line results from our Phase 2 clinical trial in patients with severe asthma in February 2026. In both Phase 2 clinical trials, verekitug was generally well tolerated, demonstrating a favorable safety profile consistent with previous studies. Across our five Phase 1 and Phase 2 clinical trials, we have treated approximately 500 participants with verekitug.

Verekitug's preclinical and clinical data suggest:

1. Verekitug is an extremely potent inhibitor of TSLP signaling.

2. Verekitug's potency translates to a significant impact on biomarkers of severe asthma which are correlated with both disease severity and treatment response. Based on these clinical data verekitug's potency is more than 300-fold greater than that reported for tezepelumab.

3. Verekitug's potency enables an extended dosing interval of up to 24 weeks and is currently being investigated in our Phase 2 clinical trial in people with COPD.

Based on the consistency from preclinical to clinical results as well as the potent inhibition of TSLP signaling, we believe verekitug has the potential to be a best-in-class treatment for severe asthma, CRSwNP, COPD and other inflammatory diseases.

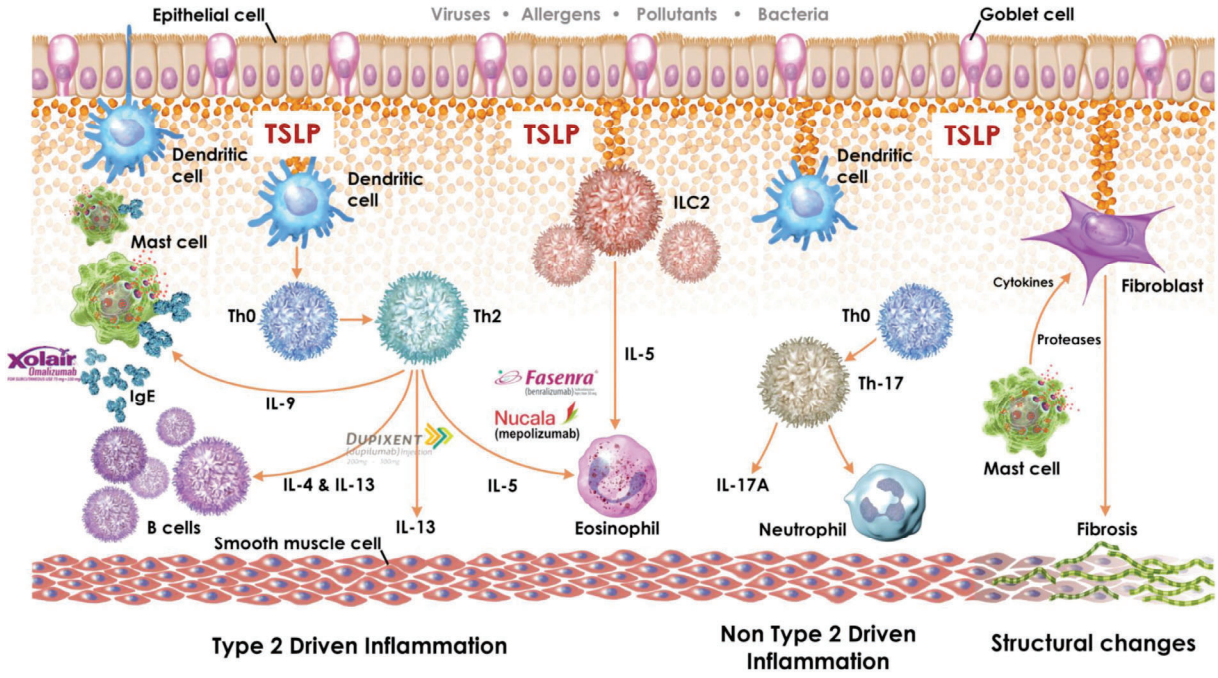


Figure 4: Verekitug neutralizes TSLP, a cytokine upstream of those targeted by existing biologics

Preclinical data

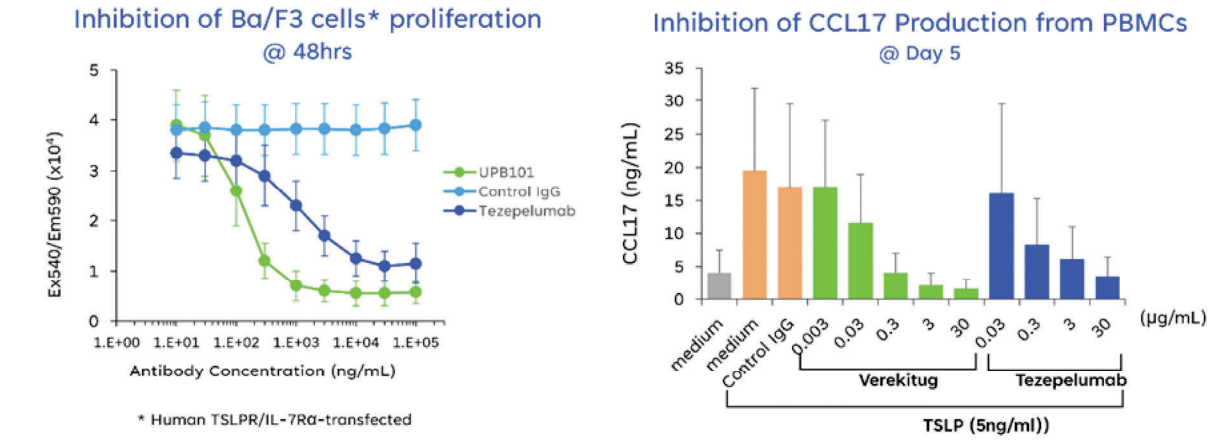
Target engagement and inhibition

In preclinical studies conducted by Astellas, which were not designed to support formal statistical comparisons, verekitug was able to efficiently bind and inhibit the TSLP receptor.

Verekitug inhibited the interaction between TSLP and TSLP receptor in a dose-dependent manner with a 50% inhibitory concentration ("IC_{50}") of 208 ng/mL and a 90% inhibitory concentration (IC_{90}) of 462 ng/mL. Verekitug also inhibited TSLP-induced proliferation of Ba/F3 cells (IC_{50} = 90.7 ng/mL, IC_{90} = 200 ng/mL). Studies also showed that verekitug inhibited TSLP-induced production of CCL-17 in a human cell line in a dose dependent manner.

These studies were conducted using tezepelumab as an active comparator. Across multiple experiments, verekitug was found to be at least more than four times more potent based on the IC_{50} and IC_{90} values for both the Ba/F3 cell proliferation and CCL17 production assays.

The IC_{90} values from the *in vitro* assays suggest a target trough concentration of approximately 0.3 µg/mL as an effective dose for verekitug. These results, as shown in Figure 5 below, underscore the potency of verekitug and the potential for sufficient efficacy even at low drug concentrations.



	IC50 (ng/mL)	IC90 (ng/mL)
Verekitug	90.7	200
Tezepelumab	518	15300

	IC50 (ng/mL)	IC90 (ng/mL)
Verekitug	16.1	163
Tezepelumab	67.0	855

Figure 5: Left panel: In a competitive ELISA study, verekitug was shown to inhibit the interaction between TSLP and TSLP receptor in a dose-dependent manner. Right panel: Ba/F3 cells were co-transfected with human IL-7Ra and TSLP receptor. When treated with verekitug, inhibition of TSLP-induced proliferation was seen.

Toxicology

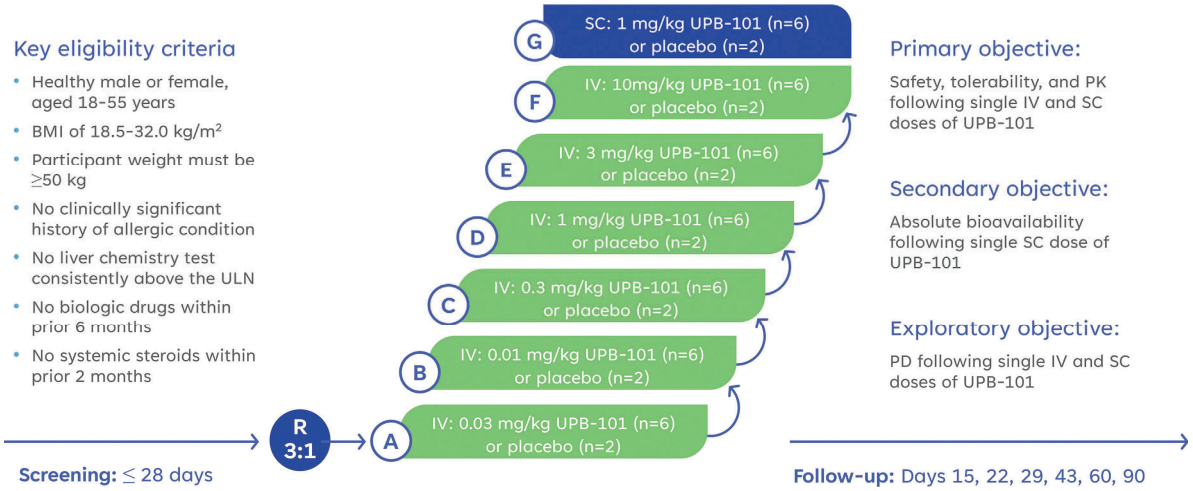
The safety of verekitug has been evaluated in multiple *in vitro* and *in vivo* studies conducted by Astellas. In single-dose toxicity studies, doses up to 50 mg/kg were not associated with system toxicity findings and verekitug showed no discernible subcutaneous irritation at the injection site in cynomolgus monkeys. Repeat-dose toxicology studies of 4-, 13- and 26-weeks duration were conducted in cynomolgus monkeys. In the 26-week study, dose levels of 25, 50 and 100 mg/kg once weekly were evaluated with no treatment-related findings seen for: clinical signs, body weight, food consumption, ophthalmology, electrocardiography, urinalysis, hematology, blood chemistry, gross pathology, organ weights or histopathology.

Phase 1 clinical trials

Phase 1 SAD clinical trial design

Verekitug was investigated in a Phase 1 SAD clinical trial conducted by Astellas, which enrolled 56 healthy volunteers aged 18 to 55. The primary objective of the study was safety, tolerability and PK following single intravenous ("IV") and subcutaneous ("SC") doses of verekitug. Secondary and exploratory objectives were absolute bioavailability following a single SC dose and PD following single IV and SC doses.

Participants were randomized three to one to verekitug or placebo. In the first six cohorts, verekitug was delivered via IV in ascending doses beginning at 0.03 mg/kg and ending at 10 mg/kg. The final cohort was a 1 mg/kg SC dose. Figure 6 below summarizes the Phase 1 SAD trial design.



BMI, body mass index; IV, intravenous; PD, pharmacodynamics; PK, pharmacokinetics; R, randomization; SC, subcutaneous; ULN, upper limit of normal.

Figure 6: Trial design schematic for Phase 1 SAD trial

Phase 1 SAD clinical trial safety and tolerability data

We presented the results from the Phase 1 SAD clinical trial of verekitug at the ATS International Conference in May 2023. The data showed a favorable tolerability profile at all dose levels in healthy participants.

As summarized in Figure 7 below, treatment-emergent adverse events ("TEAEs") were reported by 21 of 42 participants receiving verekitug (50%) and 3 of 14 (21%) participants receiving placebo. The majority of TEAEs were mild in severity and less than half of all reported TEAEs were considered to be related to the study drug. There was no clinically relevant increase in the frequency of TEAEs with the increase of dose. No drug-related serious TEAEs occurred during the study. One participant experienced a serious TEAE of nephrolithiasis which was deemed not related to the study drug by the investigator. The most frequently reported TEAEs were headache and dysmenorrhea (menstrual cramps).

No clinically relevant trends in clinical laboratory analyses, including hematology, biochemistry and urinalysis, were seen. Additionally, there were no clinically relevant trends in vital signs, physical assessments or electrocardiograms ("ECGs") detected. No injection site reactions were reported at the SC dose given in the final cohort.

ADAs were detected in 13 participants dosed with verekitug. Titers were low, less than 129, and the presence of ADAs did not significantly impact the serum PK profile in these individuals.

		verekitug, IV (each n=6)								
Parameter	Placebo IV (n=12)	Cohort A 0.03 mg/kg	Cohort B 0.1 mg/kg	Cohort C 0.3 mg/kg	Cohort D 1 mg/kg	Cohort E 3 mg/kg	Cohort F 10 mg/kg	Total (n=36)	Cohort G Placebo, SC (n=2)	Cohort G verekitug, SC 1 mg/kg (n=6)
Any TEAE[a], n(%)	3 (25.0)	3 (50.0)	4 (66.7)	2 (33.33)	3 (50.0)	3 (50.0)	1 (16.7)	16 (44.4)	0	5 (83.3)
Mild event (% of TEAEs)	15 (94.0)	5 (100)	2 (33.0)	1 (50.0)	2 (50.0)	4 (57.0)	1 (100)	15 (60.0)	0	6 (86.0)
Moderate event (% of TEAEs)	1 (6.0)	0	4 (67.0)	1 (50.0)	0	3 (43.0)	0	8 (32.0)	0	1 (14.0)
Severe event (% of TEAEs)	0	0	0	0	2 (50.0)	0	0	2 (8.0)	0	0
Drug-related TEAE[b], n(%)	2 (16.7)	2 (16.7)	3 (50.0)	0	0	1 (16.7)	0	5 (13.9)	0	3 (50.0)
Serious TEAE[c], n (%)	0	0	0	0	1 (16.7)	0	0	1 (2.8)	0	0
Nephrolithiasis, n (%)	0	0	0	0	1 (16.7)	0	0	1 (2.8)	0	0

Data indicated are number and percentage of subjects with specific TEAEs. Multiple occurrences of the same AE in the same subject are not reflected.

[a] Defined as any adverse event that started or worsened in severity after dose of study drug through end of study.

[b] Possible or probable, as assessed by the investigator or records where relationship was missing.

[c] Included serious adverse events upgraded by the sponsor based on review of the sponsor's list of Always Serious terms, if any upgrade was done.

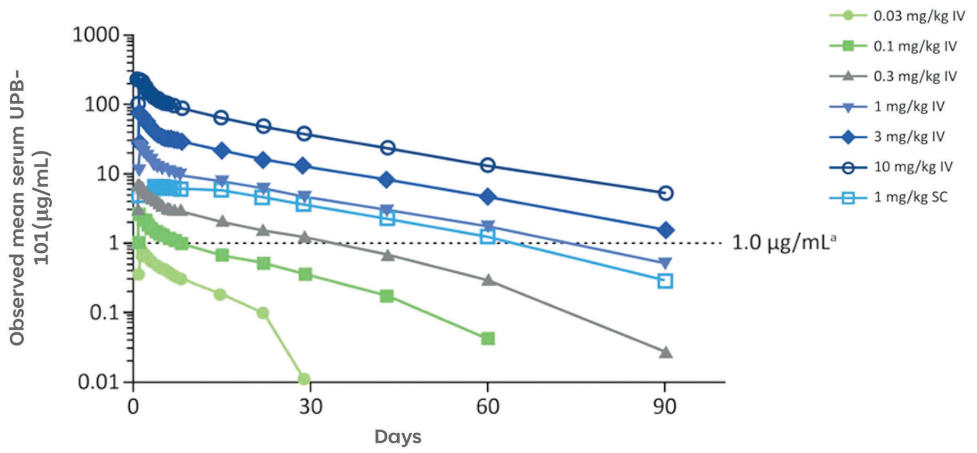
IV, intravenous; SC, subcutaneous; SOC, System Organ Class (per MedDRA v18.1); TEAE, treatment-emergent adverse event.

Figure 7: Incidence of treatment-emergent adverse events by cohort

Phase 1 SAD clinical trial PK data

In the six IV cohorts, there was a linear and dose-proportional increase in maximum serum concentration ("C_{max}") and total drug exposure over time (area under the curve) over the 0.1-10 mg/kg dose range. The mean terminal half-life was approximately 20 days for the 1, 3 and 10 mg/kg IV dose groups.

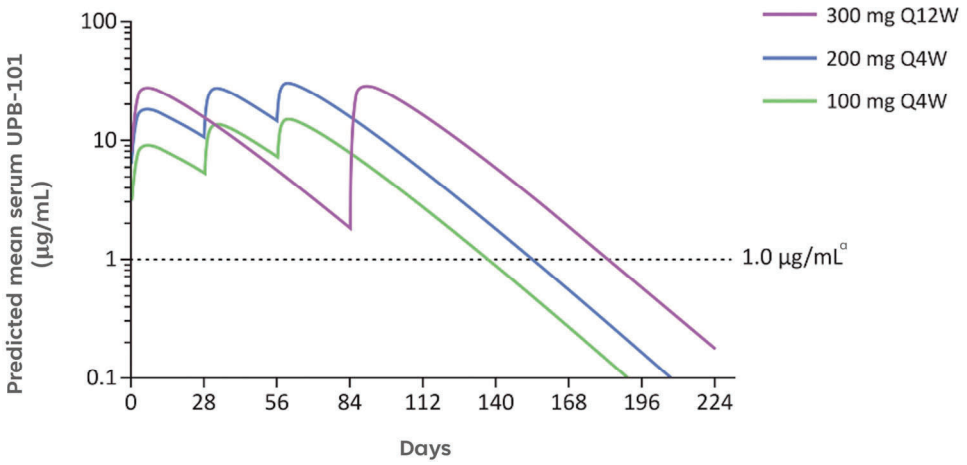
There was evidence of more rapid elimination of verekitug at serum concentrations below approximately 1.0 µg/mL, which may be attributed to target mediated drug disposition. Target-mediated drug disposition occurs when a drug binds with such high affinity to its pharmacological target site, in this case TSLP receptor, that it affects its PK characteristics. The PK profile of verekitug was linear and dose-proportional at concentrations exceeding the conservatively estimated therapeutic threshold (1.0 µg/mL). Figure 8 below illustrates the PK profiles for the six IV cohorts and one SC cohort in our Phase 1 SAD trial.



[a] Projected conservative therapeutic threshold at time of study

Figure 8: Single dose PK profiles for six IV cohorts and one SC cohort

Data from the SC cohort showed the absolute bioavailability after a dose of 1 mg/kg of verekitug was approximately 70%. A PK model fitted to the single dose SC PK data was used to predict the PK profiles after repeat SC administration at different dose levels and dose intervals, as illustrated in Figure 9 below. The then-anticipated therapeutic threshold concentration (1.0 µg/mL), conservatively estimated as a ½-log escalation from the 0.3 µg/mL concentration derived from *in vitro* pharmacology assays, was predicted to be maintained with a 12-week dosing interval.



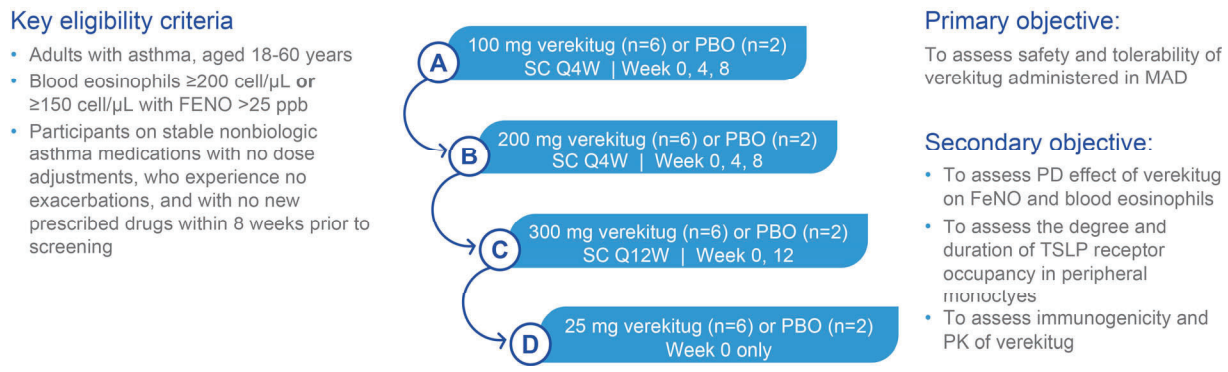
[a] Projected conservative therapeutic threshold at time of study

Figure 9: Simulated PK profiles for repeated SC administration based on Phase 1 SAD clinical trial data

Phase 1b MAD clinical trial design

We conducted a multicenter, randomized, double-blind, placebo-controlled Phase 1b MAD clinical trial of verekitug in asthma patients. The trial enrolled 32 adult participants aged 18 to 60 with mild to moderate asthma across four dosing cohorts. The primary objective of the study was to assess the safety and tolerability of verekitug. Secondary objectives included assessments of TSLP receptor occupancy, immunogenicity and PK, and exploratory objectives included assessments of PD.

Participants were randomized three to one verekitug to placebo. In the first two cohorts, participants were dosed subcutaneously every four weeks (q4w, three total doses) with 100 mg and 200 mg of verekitug, respectively. Participants in the third cohort were dosed subcutaneously with 300 mg every 12 weeks (q12w, two total doses). The final cohort was a single low dose of 25 mg subcutaneously. The 32-week trial included an observation period of up to 24 weeks after the last dose in the multi-dose cohorts. Figure 10 below summarizes this trial design.



PD, pharmacodynamics; PK, pharmacokinetics; SC, subcutaneous; PBO, placebo

Figure 10: Trial design schematic for Phase 1b MAD trial

Phase 1b MAD safety and tolerability data

Similar to the Phase 1 SAD clinical trial, the data from the Phase 1b MAD clinical trial showed a favorable tolerability profile for verekitug at all dose levels.

As summarized in Figure 11 below, TEAEs were reported by 21 of 24 (87.5%) participants receiving verekitug and 7 of 8 (87.5%) patients receiving placebo. TEAEs were mild to moderate in severity with no severe TEAEs reported. Over 90% of the TEAEs were deemed unrelated to study drug. There were no reported serious TEAEs and there were no withdrawals from the trial or treatment discontinuations due to TEAEs. The most frequently reported TEAE was headache. Several participants had mild, short-lived and self-limited injection site reactions; none were reported as an adverse event.

There were no clinically relevant trends observed in clinical laboratory analyses, including hematology, biochemistry and urinalysis. Additionally, there were no clinically relevant trends in vital signs, physical assessments or ECGs were observed. There was no clinically relevant immunogenicity observed in the trial.

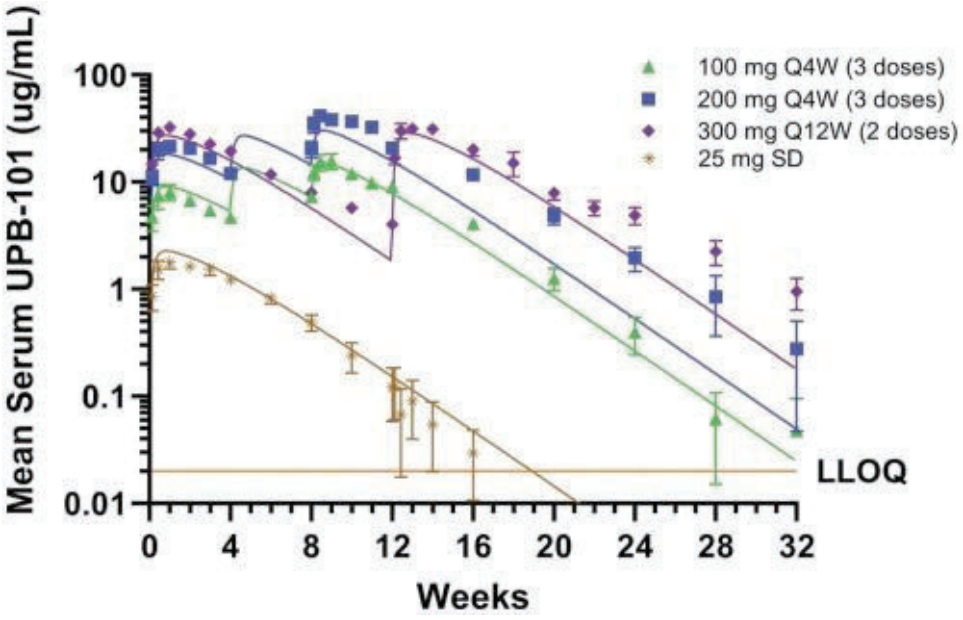
	100 mg Q4W (N=6)	200 mg Q4W (N=6)	300 mg Q12W (N=6)	25 mg X 1 (N=6)	Placebo (N=8)	Overall (N=32)
Number of TEAE	19	17	12	9	25	82
Number of Related TEAE	2	1	3	0	1	7
Subjects with any TEAE, n (%)	5 (83.3)	6 (100)	6 (100)	4 (66.7)	7 (87.5)	28 (87.5)
Mild, n (%)	1 (16.7)	4 (66.7)	5 (83.3)	0	3 (37.5)	13 (40.6)
Moderate, n (%)	4 (66.7)	2 (33.3)	1 (16.7)	4 (66.7)	4 (50.0)	15 (46.9)
Severe, n (%)	0	0	0	0	0	0
Subjects with any Related TEAE, n (%)	1 (16.7)	1 (16.7)	2 (33.3)	0	1 (12.5)	5 (15.6)
Subjects with any Serious TEAE, n	0	0	0	0	0	0
Subjects with any TEAE Leading to Withdrawal, n	0	0	0	0	0	0
Subjects with any TEAE Leading to Discontinuation of IMP, n	0	0	0	0	0	0

Figure 11: Treatment emergent adverse events observed in Phase 1b MAD clinical trial

PK/PD data demonstrated substantial and sustained receptor occupancy and biomarker suppression, supporting dosing intervals of up to q24w

We observed a desirable pharmacokinetics profile for verekitug that is supportive of extended dosing intervals up to every 24 weeks. In the first three cohorts, there was a dose-dependent increase in verekitug exposure with increasing dose levels across 100 mg q4w (three total doses), 200 mg dosed q4w (three total doses) and 300 mg dosed q12w (two total doses). However, given serum concentrations for the first three cohorts remained above the projected therapeutic threshold, a single dose administration (25 mg) cohort was included to generate data in support of PK/PD.

As shown in Figure 12, observed mean serum concentrations from the Phase 1b MAD study replicated the modeled PK from the Phase 1 SAD clinical trial in healthy volunteers.



Symbols: observed mean values from Phase 1b MAD study; Solid lines: predicted PK from Phase 1 SAD clinical trial in healthy volunteers; LLOQ: lower limit of PK quantification

Figure 12: Post-dose serum concentration of verekitug for each Phase 1b MAD cohort, overlayed with PK model based on Phase 1 SAD trial data

We demonstrated that dosing with verekitug led to rapid and complete TSLP receptor occupancy and reductions in FeNO and eos that were rapid, substantial and sustained for up to 24 weeks after last dose.

The pharmacodynamics of verekitug were assessed over the 32-week observation period by measuring TSLP receptor occupancy in CD14+ monocytes. As summarized in Figure 13 below, the first three cohorts (verekitug doses ≥100 mg) had substantial occupancy through the end of the observation period. The fourth single low dose cohort, added to interrogate the minimal concentration required to maintain full receptor saturation, produced substantial occupancy for 12 to 16 weeks supporting the high potency of verekitug at low doses. All cohorts demonstrated 100% TSLP receptor occupancy by verekitug within two weeks after first dose.

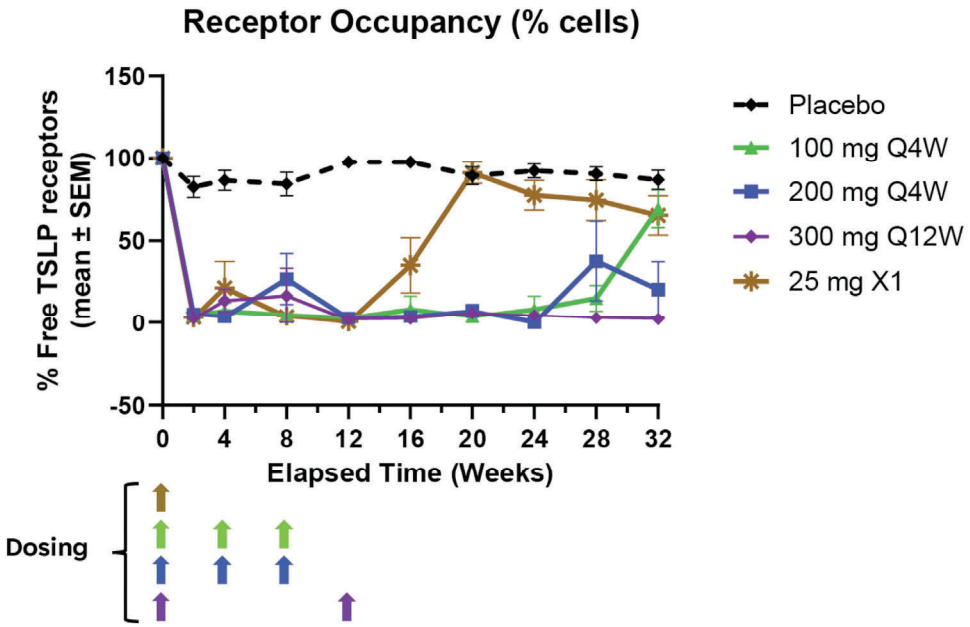


Figure 13: Percent of free TSLP receptors for each Phase 1b MAD cohort compared to placebo over 32 weeks

As shown in Figures 14 and 15 below, reductions in blood eos and FeNO levels were rapid, substantial and sustained. Additionally, these key disease-related biomarkers remained below baseline in all cohorts receiving ≥100 mg of verekitug through the 32-week observation period, up to 24 weeks past the last dose. In the single low dose cohort, blood eos and FeNO levels remained below baseline for 18 and 20 weeks of observation, respectively. The loss of the suppression of biomarkers in this cohort, which occurred shortly after the loss of receptor saturation, allowed determination of the minimal concentration required for the efficacy of verekitug.

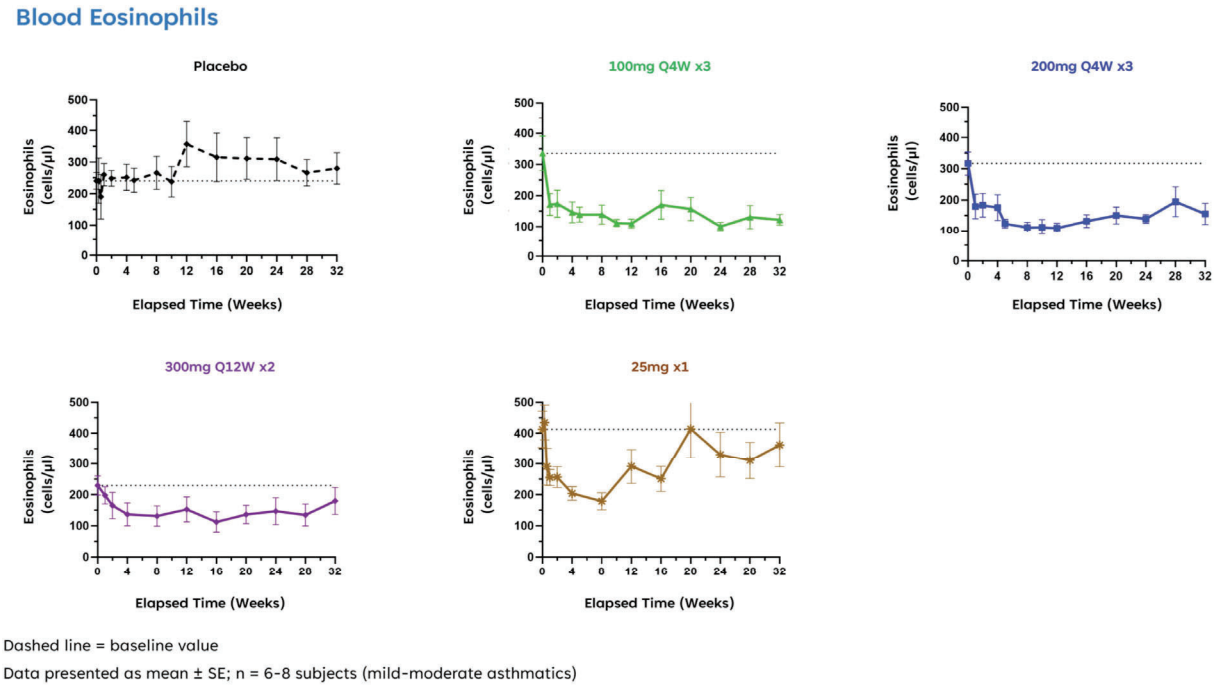


Figure 14: Levels of blood eosinophils compared to baseline for each cohort in Phase 1b MAD trial over 32 weeks

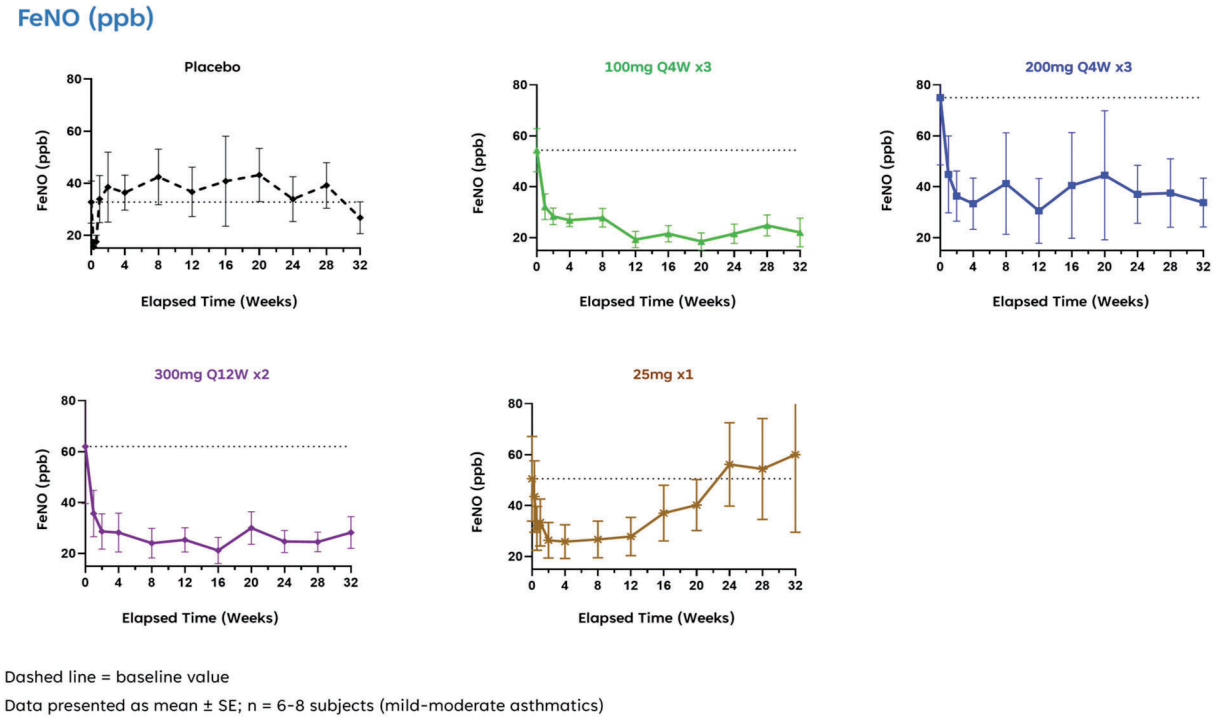
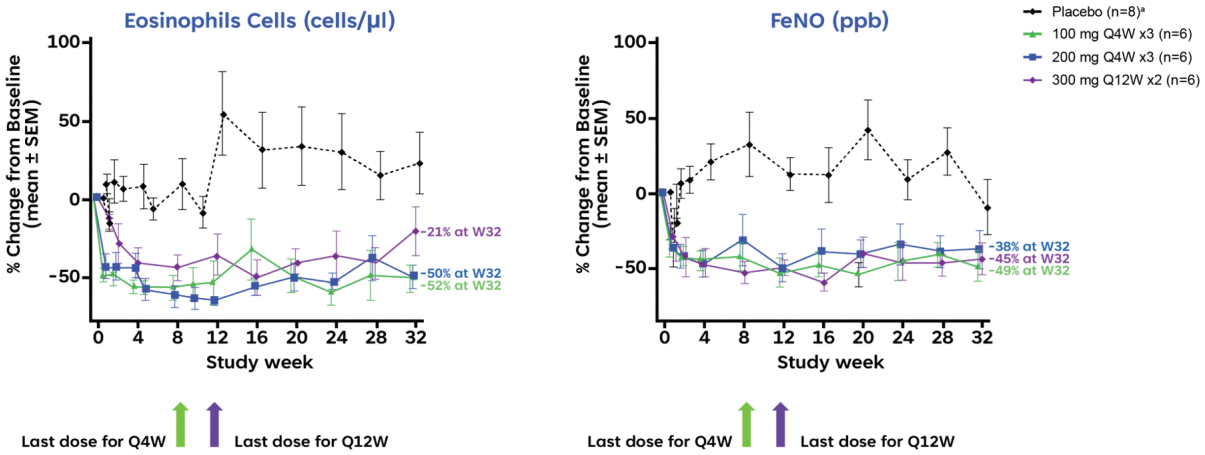


Figure 15: Levels of fraction of exhaled nitric oxide (right column) compared to baseline for each cohort in the Phase 1b MAD trial over 32 weeks

Patients receiving verekitug doses of 100 mg or greater experienced reductions in blood eos of up to 52% and FeNO reductions of up to 49% at 32 weeks. As seen in Figure 16 below, at week 12, the change from baseline in blood eos was -164 cells/µl for cohort 1, -204 cells/µl for cohort 2, and -77 cells/µl for cohort 3. Of note, cohort 3 had a lower baseline value for blood eos which may affect the absolute value change from baseline. For context, dupilumab has been observed to increase blood eos by approximately 30%, whereas mepolizumab (an eosinophil depleter) has been observed to reduce blood eos by 84%. In these same patients, the change from baseline in FeNO at week 12 was -28 ppb (a -54% change from baseline) for cohort 1, -47 ppb (a -51% change from baseline) for cohort 2 and -37 ppb (a -51% change from baseline) for cohort 3. The Phase 2 and 3 trials of tezepelumab in severe asthma reported a less substantial effect on FeNO, with a change from baseline in FeNO at week 12 of -17 ppb (a -25% change from baseline). Dupilumab's effect on FeNO was observed to be similar to that of tezepelumab, at an approximately -27% change from baseline, whereas mepolizumab was observed to have no effect on FeNO. These data are presented for reference purposes only and do not represent results of head-to-head comparative studies among these product candidates or relative to verekitug. Differences exist between trial designs, subject characteristics and timing of data, and caution should be exercised when comparing data across studies.



For the pharmacodynamic population, data collected after the dosing pause were excluded (n=2 in 100 mg cohort after Week 8 and n=2 mg cohort after Week 4).

[a] Data from the placebo groups in all cohorts were pooled for analysis.

FeNo, fractional exhaled nitric oxide; q4w, every 4 weeks; q12, every 12 weeks; SEM, standard error of mean.

Figure 16: Percent change from baseline through 32 weeks in eosinophils (left) and fraction of exhaled nitric oxide (right)

Our PK/PD modeling of the data generated in the Phase 1b MAD trial, as summarized in Figure 17 below, provides clinical proof-of-concept that verekitug has high potency in asthma patients. In particular, the potency of verekitug as assessed by suppression of FeNO is substantially greater than that reported for tezepelumab. Indeed, the half-maximal effective concentration ("EC_{50}") of verekitug, 0.008 µg/ml is 300-fold lower than that of tezepelumab, an anti-TSLP ligand antibody approved for use in severe asthma.

Verekitug			Tezepelumab[a]		
E_{MAX} (reduction from BL)	EC_{50} (µg/ml)	EC_{90} (µg/ml)	E_{MAX} (reduction from BL)	EC_{50} (µg/ml)	EC_{90} (µg/ml)
43.4 %; 95% CI [36.6-50.4]	0.008	0.07	27.8 %; 95% CI (23.1-32.2)	2.5	22.5

- >300-fold lower EC_{50} /EC_{90} compared to Tezepelumab
- ~1.5 times greater maximal reduction in PD (FeNO)

[a] No head-to-head clinical studies have been conducted. Differences exist between modeled data and trial design, and caution should be exercised when comparing data across studies.

Figure 17: Maximal, 50% and 90% effective concentrations of verekitug

Data from the Phase 1 SAD and Phase 1b MAD clinical trials enabled for further PK simulations of verekitug to determine the doses for a Phase 2 clinical trial, as shown in Figure 18 below. Doses of 100 mg q12w SC and 400 mg SC every 24 weeks (q24w) were projected to sustain serum concentrations of verekitug above the MAD-derived FeNO EC_{90} of 0.07 mg/L that was established in the MAD study for the entirely of the dosing interval, including at trough. For this reason, these doses were tested in our Phase 2 trial in severe asthma.

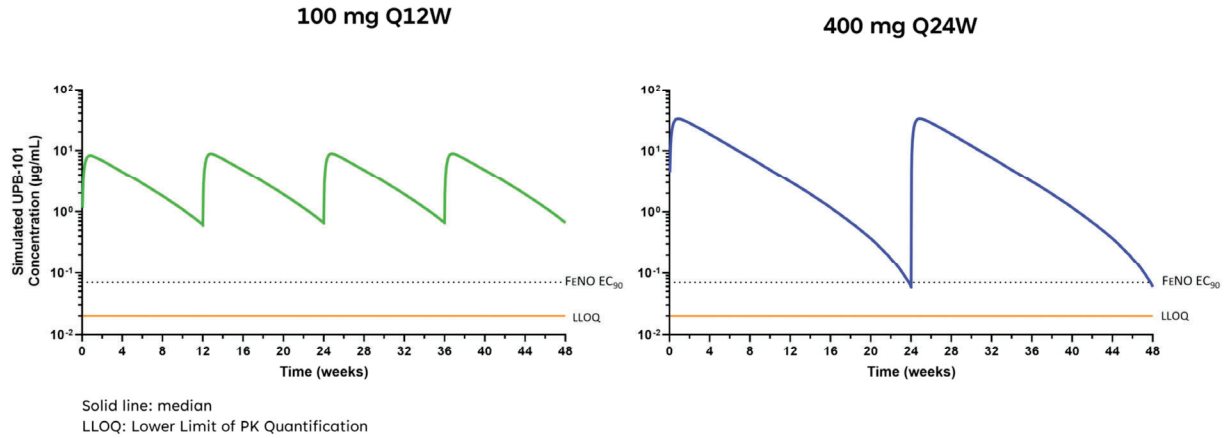


Figure 18: PK simulations of verekitug. Solid line = median, Shadow = 5-95 percentile prediction range

Japan PK trial

We also completed a third Phase 1 clinical trial of verekitug to support clinical development in Japan and other Asian countries. This study was an open-label, single dose, randomized PK and safety study to enable a comparison of verekitug's profile in Japanese vs. non-Japanese/non-East Asian participants. The study enrolled 32 healthy adult volunteers with eight participants in each of four treatment groups. Three cohorts (100 mg, 200 mg, 300 mg dose) were enrolled with Japanese participants and the fourth cohort enrolled solely non-Japanese/non-East Asian participants. The study showed a comparable verekitug PK profile between the two groups.

Summary of clinical results

To date, verekitug has demonstrated a favorable tolerability profile and unique pharmacology that is consistent across preclinical and clinical studies. The high potency seen in preclinical studies, which were not designed to support formal statistical comparisons, has accompanied clinical evidence of rapid and complete TSLP receptor occupancy, and reductions in disease-associated biomarkers, including FeNO and eos, that were rapid, substantial and sustained for up to 24 weeks after the last dose. These Phase 1 data underpinned our clinical development strategy for verekitug in severe asthma, CRSwNP, and COPD and supported our Phase 2 trial designs investigating 12- and 24-week dosing.

Phase 2 clinical trials

We have completed one Phase 2 clinical trial of verekitug for the treatment of CRSwNP (VIBRANT) and a separate Phase 2 clinical trial of verekitug for the treatment of severe asthma (VALIANT). In May 2025, we initiated a Phase 2 long-term extension study (VALOUR) in eligible participants with severe asthma who completed the VALIANT Phase 2 clinical trial, and in July 2025 we initiated a Phase 2 clinical trial of verekitug for the treatment of COPD (VENTURE). Based on available data from the VALIANT and VIBRANT Phase 2 trials and analysis from approximately 500 participants treated with verekitug across our five completed Phase 1 and 2 clinical trials, we plan to initiate dosing in Phase 3 trials in both severe asthma and CRSwNP in the first quarter of 2027, prioritizing a Phase 3 development strategy that focuses on maximizing efficacy in both indications, without biomarker restriction, and with quarterly at-home administration.

Severe asthma

In February 2026, we announced positive top-line data from the Phase 2 global, randomized, double-blind, placebo-controlled, dose-ranging, parallel group VALIANT clinical trial (NCT06196879) that evaluated the safety and efficacy of verekitug for up to 60 weeks, with a minimum of 24 weeks of treatment, in 478 adults with severe asthma. Participants were randomized into one of four groups, receiving either 100 mg of verekitug every 24 weeks (“q24w”), 400 mg of verekitug q24w, 100 mg of verekitug every 12 weeks (“q12w”), or placebo administered subcutaneously. The primary endpoint was a reduction of the AAER. Secondary endpoints included changes in air exhalation, nitric oxide exhalation, and a patient-reported assessment of asthma control, though these endpoints were not designed with sufficient power to detect statistically significant effects.

The trial met its primary endpoint of a statistically significant and clinically meaningful reduction in AAER with both q12w and q24w dosing, with verekitug demonstrating a reduction in AAER of 56% ($p<0.0003$) when dosed at 100 mg q12w and 39% ($p<0.02$) when dosed at 400 mg q24w, as compared with placebo.

Placebo-adjusted improvement in lung function, as measured by the forced expiratory volume in one second (“FEV1”), was 122 mL at week 60 with verekitug 100 mg q12w, and 139 mL at week 60 with 400 mg q24w. At week 60, verekitug also suppressed FeNO compared to placebo by 20.4 ppb ($p<0.0003$) when dosed at 100 mg q12w, and by 26.3 ppb ($p<0.0001$) when dosed at 400 mg q24w. These data represented a mean 43.5% ($p=0.03$) reduction from baseline in the 100 mg q12w group and a mean 44.9% ($p=0.03$) reduction from baseline in the 400mg q24w group. A third low-dose treatment group, 100 mg q24w, demonstrated a statistically significant effect on AAER, but did not provide consistent improvements in other endpoints.

Additional pre-specified analyses of secondary outcomes at week 24 revealed statistically significant placebo-adjusted improvements compared to baseline in both FEV1 and FeNO with the 100 mg q12w and 400 mg q24w dose regimens.

Verekitug was generally well tolerated across all active doses, demonstrating a favorable safety profile consistent with previous studies.

CRSwNP

In September 2025, we released top-line data from the Phase 2, global, randomized, double-blind, placebo-controlled, parallel group VIBRANT trial (NCT06164704) that evaluated the efficacy and safety of verekitug over 24 weeks in 81 adults with CRSwNP. Participants received either 100 mg of verekitug or placebo subcutaneously every 12 weeks for 24 weeks. The primary endpoint was change in endoscopic nasal polyp score at Week 24, a primary endpoint that has been used in several registrational trials for other biologic treatments for CRSwNP. Secondary endpoints included: nasal congestion score, sinus opacification, difficulty with sense of smell, total symptom score, percentage of participants requiring systemic corticosteroids or nasal polyp surgery, and time to first such interventions up to Week 24.

Over the 24-week treatment period, verekitug, dosed 100 mg every 12 weeks, met the primary endpoint and key secondary endpoints, demonstrating statistically significant and clinically meaningful reductions in both endoscopic nasal polyp score

("NPS") and nasal congestion score ("NCS"), with a generally well tolerated safety profile consistent with previous studies. Treatment with verekitug also resulted in a significant reduction in the need for surgery or systemic corticosteroids. The trial met its primary endpoint, demonstrating a statistically significant and clinically meaningful, placebo-adjusted reduction in NPS of -1.8 ($p<0.0001$) at Week 24 compared with baseline. The trial also showed a meaningful placebo-adjusted reduction from baseline in the patient-reported NCS, a key secondary endpoint, by -0.8 ($p=0.0003$).

Significant improvements were also observed in other key secondary endpoints, including sinus opacification as measured by the Lund-Mackay score, reduction in the need for either systemic corticosteroids or nasal polyp surgery, and total symptom score.

Verekitug was generally well tolerated, demonstrating a favorable safety profile consistent with previous studies, with no serious adverse events observed.

COPD

In July 2025, we announced dosing of the first patient in the Phase 2 multicenter, randomized, double-blind, placebo-controlled, parallel group VENTURE clinical trial (NCT06981078) designed to assess the efficacy and safety of verekitug in approximately 670 adults with moderate-to-severe COPD. Participants are randomized to receive verekitug at doses of 100 mg once every 12 weeks, 400 mg once every 24 weeks, or placebo, over treatment periods of between 60 weeks and up to 108 weeks. The primary analysis population includes patients with elevated eos. Subjects are randomized 1:1:1 to receive verekitug at doses of 100 mg q12w, 400 mg q24w and placebo administered SC. Given verekitug's potency, we are also enrolling a subset of patients without elevated eos at baseline to explore the potential for efficacy in this expanded population.

Aligned with recent registrational trials of biologics in this condition, the primary endpoint of the study is the annualized rate of moderate or severe COPD exacerbations. Secondary endpoints include changes in participants' day-to-day symptoms as well as measures of lung function, such as forced expiratory volume in one second. We have designed this trial using endpoints that, pending interactions with regulatory authorities, could allow data from this trial to support submissions for product approval.

Future opportunities

Research has shown TSLP to be either a risk factor for or a key driver of inflammatory diseases across several therapeutic areas, including respiratory, gastroenterology, dermatology, nephrology and allergy/immunology. Thus, we believe there is a significant opportunity to expand the impact of verekitug beyond severe respiratory diseases, including dermatology (e.g., atopic dermatitis) and gastroenterology. For example, other TSLP pathway-directed biologics are pursuing indications such as chronic urticaria, bullous pemphigoid, chronic pruritis and eosinophilic esophagitis. In parallel to conducting our own preclinical work in target indications, we will carefully monitor the results of these trials which have the potential to inform our selection of future indications for verekitug.

Manufacturing and supply

Our current strategy is to outsource all manufacturing of verekitug or any other potential future product candidates to third parties. We leverage third-party manufacturers to support the manufacturing of verekitug for clinical trials and, if we receive regulatory approval, we intend to rely on such third parties for commercial manufacture. We have manufactured sufficient supply for our ongoing Phase 2 COPD trial. We do not own or operate any manufacturing facilities for the production of clinical or commercial quantities of verekitug or any other potential future product candidates. We believe this strategy will enable us to maintain a nimble, efficient and effective working model without making significant internal capital investments. We currently obtain our supplies from these manufacturers on a purchase order basis and do not have any long-term supply agreements in place. In order to de-risk our supply chain, and as we advance toward potential commercialization, we intend to enter into long-term supply agreements as well as evaluate additional product manufacturing sources.

We rely, and expect to continue to rely, on third-party manufacturers to provide all of the active pharmaceutical ingredients and the final drug product formulation of verekitug that is being used in our clinical trials and preclinical studies in compliance with FDA and other foreign regulatory requirements, and on contract development and manufacturing organizations ("CDMOs") to manufacture and supply our preclinical and clinical materials. We have made technical development a major focus of our efforts and have worked to improve the formulation and manufacturing process in place at the time of our acquisition of verekitug in 2021. This effort has resulted in a greater than 6-fold improvement in the concentration of the formulation of verekitug, from 30 mg/mL to 200 mg/mL, which enabled the ability to employ both a 0.5mL (100 mg) and a 2.0mL (400 mg) SC injection in our severe asthma Phase 2 clinical trial. These 0.5mL and 2.0mL injection volumes are comparable to or smaller than those of other biologics approved for the treatment of severe asthma, including tezepelumab (1.91mL), dupilumab (2.0mL) and mepolizumab

(1.0mL). These process improvements have led to an approximately 35% increase in yield as well, while maintaining comparable product quality.

We have personnel with significant technical, manufacturing, analytical, quality, regulatory, including current Good Manufacturing Practices ("cGMP"), and project management experience to oversee our third-party manufacturers and to manage manufacturing and quality data and information for regulatory compliance purposes. At the appropriate time, we will determine whether to establish in-house manufacturing capabilities or continue to rely on third parties to manufacture commercial quantities for verekitug or any future products for which we may successfully develop and obtain regulatory approval.

Competition

The biopharmaceutical industry is characterized by rapid advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with verekitug. Verekitug and any future product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Our competitors include larger and better-funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities, governmental agencies and other public and private research institutions who may be active in research in our target indications and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, and our inability to compete successfully could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing intellectual property related to new product candidates, as well as entering into collaborations, joint ventures, license agreements and other similar arrangements. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Existing therapeutics for asthma include controller medications, reliever medications and more recently, biologics from Genentech, Inc. ("Genentech") and Novartis Pharmaceuticals Corporation ("Novartis") (Xolair), Sanofi and Regeneron (Dupixent), GSK (Nucala), GSK (Exdensur), AstraZeneca (Fasenra), and Amgen and AstraZeneca (Tezspire). Existing therapeutics for CRSwNP include topical corticosteroids, nasal saline irrigations and more recently, biologics from Genentech and Novartis (Xolair), Sanofi and Regeneron (Dupixent), GSK (Nucala), and Amgen and AstraZeneca (Tezspire). Existing therapeutics for COPD include inhaled steroids and bronchodilator inhalers and more recently, a biologic from Sanofi and Regeneron (Dupixent) and GSK (Nucala). A biologic targeting the TSLP ligand is also in development by Amgen and AstraZeneca (Tezspire) for COPD.

While there are numerous biologics approved for the treatment of severe asthma, tezepelumab, a monoclonal antibody targeting the TSLP ligand, is the first and only treatment for severe asthma without any biomarker limitation. To our knowledge, verekitug is the only monoclonal antibody currently in clinical development that targets and inhibits the TSLP receptor.

If we successfully obtain approval for verekitug and any future product candidates, we believe that the key competitive factors that will affect the success of these candidates will be efficacy, safety, tolerability, convenience, price, the level of generic competition and the availability of reimbursement from commercial, government and other third-party payors relative to such competing products. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are superior in one or more of these categories. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market.

Intellectual property

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

Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and trade secrets related to our business, defend and enforce our intellectual

property rights, particularly our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others.

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

Verekitug program

We own 6 patent families directed to verekitug. A first patent family is directed to compositions of matter of verekitug and methods of using the same for treating asthma and expire in 2034, without taking any potential patent term extension into account. As of March 20, 2026, this first patent family has two issued U.S. patents, 20 issued patents in foreign jurisdictions, including Argentina, Australia, Brazil, Canada, a European patent (validated in Albania, Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, Great Britain, Greece, Hungary, Croatia, Ireland, Iceland, Italy, Liechtenstein, Latvia, Lithuania, Luxembourg, Monaco, Malta, Macedonia, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Slovakia, and Turkey), Hong Kong, Indonesia, Israel, India, Japan, South Korea, Malaysia, Mexico, Philippines, Russia, Singapore, Taiwan, Ukraine, Vietnam and South Africa, and one pending application in Thailand. A second patent family is directed to certain pharmaceutical formulations comprising verekitug and methods of treating humans with asthma with such formulations, which expire in 2037, without taking any potential patent term extension into account. As of March 20, 2026, this second family includes three issued U.S. patents, one pending U.S. non-provisional application, 15 issued patents in foreign jurisdictions, including Canada, China, Hong Kong, Europe (validated in Switzerland, Germany, France, United Kingdom, and Ireland), two in Japan, South Korea, Macao, Mexico, Philippines, Russia, Singapore, two in Taiwan, Vietnam, and 3 pending applications in foreign jurisdictions, including in Indonesia, Singapore, and Thailand. The third patent family is directed to certain formulations that could be used with verekitug and methods of using the same and which expire in 2042, without taking any potential patent term extension into account. As of March 20, 2026, this third family has an issued U.S. patent, one pending U.S. non-provisional application, and 19 applications pending in foreign jurisdictions, including Argentina, Australia, Brazil, Canada, China, two in Hong Kong, Eurasia, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Singapore, Taiwan, Ukraine, and South Africa, of which Eurasia has been allowed. The other three patent families are directed to methods of using verekitug and comprise 5 pending U.S. provisional patent applications. Should any patents issue based on these other three patent families they would expire in 2046, without taking any potential patent term extension into account.

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

In the United States, the term of a patent covering an FDA-approved drug may be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years beyond the expiration of the patent, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended, and a given patent may only be extended once. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. If our product candidates receive FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved product candidates. We also intend to seek patent term extensions in any jurisdictions where they are available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

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

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

Asset purchase and license agreements

Asset acquisition from Astellas

In October 2021, we entered into an asset purchase agreement with Astellas Pharma, Inc. ("Astellas"), which we refer to as the "Astellas Asset Purchase Agreement." Pursuant to the Astellas Asset Purchase Agreement, we purchased from Astellas the compound designated by Astellas as ASP7266 (the "Compound"), the corresponding patent rights and any unregistered intellectual property rights, inventory related to the Compound, documents, data and copies of all filings and material correspondence with regulatory agencies (and the data included therein), and obtained an exclusive license under certain processes and methods of manufacture, testing, qualifying and use of the Compound to manufacture the Compound, with an upfront cash payment of $81.1 million. The Compound was renamed by us as verekitug (UPB-101). There are no future payments owed to Astellas under the Astellas Asset Purchase Agreement.

Related letter agreement with Astellas and Regeneron

In connection with the Astellas Asset Purchase Agreement, we concurrently entered into a letter agreement with Astellas and Regeneron Pharmaceuticals, Inc. ("Regeneron"), which we refer to as the "Regeneron Letter Agreement." The Regeneron Letter Agreement relates to a prior Non-Exclusive License and Material Transfer Agreement (the "Terminated Regeneron License Agreement") that Regeneron and Astellas entered into in March 2007, as amended in July 2010 and subsequently terminated in June 2018, subject to certain surviving rights and obligations of both Regeneron and Astellas. Under the Terminated Regeneron License Agreement, Astellas utilized Regeneron's human antibody technology in its internal research programs to discover certain product candidates, including the Compound, which it sold to us under the Astellas Asset Purchase Agreement.

Under the Regeneron Letter Agreement, Astellas assigned and transferred to us and we assumed and accepted certain of Astellas' surviving rights and obligations under the Terminated Regeneron License Agreement, including Astellas' royalty payment, reporting and indemnification obligations in connection with activities conducted by us or on our behalf with respect to the Compound. By assuming and accepting Astellas' surviving obligations under the Terminated Regeneron License Agreement, we are required to pay Regeneron mid-single-digit percentage royalties on aggregate worldwide net sales of any product developed by or on behalf of us that contains the Compound as an ingredient or component of the materials sold (a "Royalty Product") during the royalty term. The royalties are determined on a product-by-product and country-by-country basis and expire on the later of (i) a specified number of years after the launch of a given Royalty Product in a given country and (ii) the expiration of the last valid claim of royalty bearing company patent rights claiming or covering such Royalty Product in such country.

Exclusive license agreement with Maruho

In October 2021, we entered into a license agreement with Maruho Co., Ltd. ("Maruho"), as amended on May 30, 2023 (the "Maruho License Agreement"), under which we granted to Maruho an exclusive, irrevocable, perpetual, royalty-free, sublicensable (subject to our right of first negotiation as described below) license. The license was under certain intellectual property rights controlled by us or our affiliates to research, develop, manufacture via a third party contract manufacturer, sell and import any pharmaceutical, biologic or medical device product (or any combination thereof), which (i) was or is developed by or on behalf of us or our affiliates, and (ii) incorporates or uses the compound designated by Astellas as ASP7266 in Japan (collectively, the "Maruho License Product").

Pursuant to the Maruho License Agreement, we are responsible for and control the global research and development of the Maruho License Product, including in Japan. In addition, under the Maruho License Agreement, we granted Maruho a right of first negotiation, exercisable between the effective date of the Maruho License Agreement and the earlier of (a) October 11, 2027 and (b) the occurrence of a merger and acquisition of us by a third party, such that, in the event of our actual liquidation (not including deemed liquidation events such as a merger and acquisition by third parties), Maruho has the right to first negotiate to purchase all of our asset relating to the Maruho License Product. Maruho also granted us a right of first negotiation, exercisable between the effective date of the Maruho License Agreement and the earlier of (a) the fifth anniversary of such effective date and (b) a change of control of us, such that, in the event Maruho desires to sell, assign sublicense or otherwise transfer any or all of Maruho's rights under the Maruho License Agreement, we have a right to first negotiate to acquire such rights.

Both parties waive their right to termination of the Maruho License Agreement for any reason, except that Maruho has the right to terminate the Maruho License Agreement at any time by providing 60 days prior written notice to us.

License agreement with Lonza

In October 2021, in connection with the Astellas Asset Purchase Agreement, we entered into a license agreement with Lonza Sales AG ("Lonza"), as amended (the "Lonza License Agreement"), pursuant to which we obtained a worldwide, non-exclusive, sublicensable (subject to Lonza's right of pre-approval with respect to any sublicense of manufacturing activities) license to certain intellectual property rights owned by Lonza. The license allows us to use Lonza's glutamine synthetase gene expression system ("Lonza System") to develop, manufacture and commercialize the Compound, including any part of such system that is embodied within or otherwise used to create the cell lines expressing the Compound or a component thereof.

As consideration for the rights and licenses granted to us, we agreed to pay Lonza certain royalties and annual payments, in respect of the manufacturing and sale of the Compound, such amounts to be determined by the party manufacturing the Compound, and range from no annual payment to up to a mid-six-figure annual payment, and a less-than-one percent to a low-single-digit percentage royalty on net sales of the Compound.

Any royalties due under the Lonza License Agreement are payable on a country-by-country basis until ten years from the first commercial sale of the Compound in that particular country.

The Lonza License Agreement continues for an indefinite period of time unless otherwise terminated. We may terminate the agreement at any time upon prior written notice to Lonza. Furthermore, either party may terminate the agreement upon the occurrence of a material breach of such agreement by the other party that is irremediable or not remedied within a certain period of time, or the other party's failure to pay debts or entry into liquidation. Lonza also may terminate the Lonza License Agreement by providing written notice to us if we contest the secret or substantial nature of the know-how relating to the Lonza System that is licensed to us under the Lonza License Agreement.

Government regulation

Regulation of biological products in the United States

In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA"), and their implementing regulations. Biological products are also subject to other federal, state and local statutes and regulations. Verekitug is in clinical development and has not been approved by the FDA for marketing in the United States.

An applicant seeking approval to market and distribute a new biological product in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies performed in accordance with the FDA's Good Laboratory Practices ("GLP") regulations, as applicable;
- completion of the manufacture, under cGMP conditions, of the product candidate that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an Investigational New Drug application ("IND"), for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") representing each clinical trial site before each clinical trial site may be initiated;
- performance of adequate and well-controlled human clinical trials, in accordance with current Good Clinical Practices ("GCP") and any additional nonclinical studies required to establish the safety and effectiveness of the product candidate for each proposed indication;
- preparation and submission to the FDA of a biologics license application ("BLA"), as applicable, requesting approval to market the product candidate for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product and proposed labeling;
- review of the product by an FDA advisory committee, where appropriate and as applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

- satisfactory completion of any FDA audits of the preclinical studies and clinical trial sites to assure compliance with GLP, as applicable, and GCP, and the integrity of clinical data in support of the BLA;
- payment of user fees under the Prescription Drug User Fee Act ("PDUFA"), unless exempted;
- obtaining FDA approval, or licensure, of the BLA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS") and any post-approval studies or other post-marketing commitments required by the FDA.

The failure to comply with the applicable U.S. requirements at any time during the product development process, including preclinical testing, clinical testing, and the approval process, or the post-approval process, may subject an applicant to delays in development, regulatory review or approval and/or administrative or judicial sanctions. These sanctions may include, but are not limited to, the FDA's refusal to allow an applicant to proceed with clinical testing, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, issuance of warning or untitled letters, adverse publicity, product recalls, marketing restrictions, product seizures, import detentions and refusals, total or partial suspension of production or distribution, injunctions, fines and civil or criminal investigations and penalties brought by the FDA or the Department of Justice ("DOJ"), and other governmental entities, including state agencies.

Preclinical studies and investigational new drug application

Before testing any product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential for efficacy and toxicity in animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information, analytical data, and plans for the proposed clinical studies, are submitted to the FDA as part of an IND application. Some preclinical testing may continue after an IND is submitted.

An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product candidate or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and places the clinical trial on a partial or complete clinical hold. In that case, the IND sponsor and the FDA must resolve the clinical hold issues before the clinical trials can begin.

Clinical holds also may be imposed by the FDA after clinical trials have begun, including if there is concern for patient safety, as a result of new data, findings, or developments in clinical, preclinical and/or chemistry, manufacturing and controls, or where there is non-compliance with regulatory requirements. A separate submission to an existing IND must be made for each successive clinical trial conducted during development, and the FDA reviews such submissions before each clinical trial can begin.

Human clinical trials in support of a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease or condition to be treated under the supervision of qualified investigators in accordance with GCP requirements. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary. The GCP requirements encompass both ethical and data integrity standards for clinical trials. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data.

Further, each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects and the possible liability of the institution. An IRB must operate in compliance with

FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with GCP requirements or that the participants are being exposed to an unacceptable health risk.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board ("DSMB"), or data monitoring committee ("DMC"). This group may recommend continuation of the trial as planned, changes in trial conduct, or cessation of the trial at designated check points based on certain available data from the trial to which only the DSMB/DMC has access.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- Phase 1 clinical trials are initially conducted in a limited population of healthy subjects or disease-affected patients to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.
- Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.
- Phase 3 clinical trials typically proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are generally undertaken within an expanded patient population to provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites to provide a basis for physician labeling and for submitting a BLA to seek regulatory approval for a biological product.

In some cases, the FDA may approve a BLA but require the sponsor to conduct additional clinical trials to further assess the product's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of patients in the approved indication and, where applicable, to confirm a clinical benefit for products approved under accelerated approval. The failure to exercise due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

Information about applicable clinical trials must be submitted within specific timeframes to the National Institutes of Health ("NIH") for public dissemination on its ClinicalTrials.gov website.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human subjects and 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 seven calendar days after the sponsor's initial receipt of the information.

Under the Pediatric Research Equity Act, a BLA or supplement thereto must contain data that are adequate 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 FDCA requires that a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP") within 60 days of an end-of-phase 2 meeting or as may be agreed between the sponsor and FDA. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The sponsor and the FDA must reach agreement on the PSP. The FDA or the sponsor may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Compliance with cGMP requirements

Concurrent with clinical trials, companies must finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMP requirements. To help reduce the risk of introduction of adventitious agents with the use of biological products, the PHSA emphasizes the importance of manufacturing controls for products with attributes that cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality 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. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Noncompliance with such requirements can lead to adverse findings by the FDA during these inspections; in instances of significant or continued noncompliance, such adverse findings can serve as the basis for additional regulatory action by the FDA, including but not limited to warning letters, recalls, seizure, consent decrees, fines, and/or criminal penalties.

Review and approval of a BLA

The results of product candidate development, preclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more specified indications. The BLA must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee. Under federal law, the submission of most BLAs are subject to an application user fee. The sponsor of an approved BLA is also subject to an annual program fee. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether to accept it for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. If the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of the application. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process may be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional or clarifying information within the last three months before the PDUFA goal date.

The FDA reviews a BLA to determine, among other things, whether the product is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of preclinical and clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. If the application is not approved, the FDA will issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible, will outline recommended actions the sponsor might take to obtain approval of the application. The complete response letter may require additional clinical data and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the deficiencies identified by the FDA. The FDA will then re-review the application, taking into consideration the response, and determine whether the application meets the criteria for approval. The FDA will not approve an application until issues identified in any complete response letters have been addressed. Failure to respond to a complete response letter may be considered by the FDA as a request to withdraw the application.

The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Even if the FDA approves a new product, the approval may be limited to specific disease states, patient populations and dosages, or the indications for use may otherwise be limited. It may also require that contraindications, warnings, or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including phase 4 clinical trials, to further assess the product's efficacy and/or safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including a REMS, to help ensure that the benefits of the product outweigh the potential risks. A REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast track, breakthrough therapy and priority review designations

FDA provides programs intended to facilitate and expedite development and review of new products that are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast track designation, breakthrough therapy designation and priority review designation. These designations are not mutually exclusive, and a product candidate may qualify for one or more of these programs. While these programs are intended to expedite product development and approval, they do not alter the standards for FDA approval.

The FDA may designate a product for fast track designation if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For products with fast track designation, sponsors may have more frequent interactions with the FDA, the product is potentially eligible for accelerated approval and priority review, if relevant criteria are met, and the FDA may initiate review of sections of a product with fast track designation's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a product with fast track designation may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff managers in the review process; assigning a cross-disciplinary lead for the review team; and taking other steps to design the clinical trials in an efficient manner. Breakthrough designation may be rescinded if a product no longer meets the qualifying criteria.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes and evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months. Priority review designation may be rescinded if a product no longer meets the qualifying criteria.

Accelerated approval pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM"), and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, confirm a clinical benefit during post-marketing studies or dissemination of false or misleading promotional materials would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for therapeutic candidates approved under accelerated regulations are subject to prior review by the FDA.

Orphan drug designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for treatment of rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the biological product for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a sponsor for tax credits and the product for market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. After FDA grants orphan designation, the product must then go through the review and approval process like any other product.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same product for the same indication for seven years, except in certain limited circumstances. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity for that broader indication.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor, or the sponsor is unable to provide sufficient quantities.

Pediatric exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be safe and effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted and extends whatever statutory or regulatory periods of exclusivity that cover the product by six months.

U.S. patent term extension and marketing exclusivity

In the United States, a patent claiming a new biological product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. The extension period is typically one-half the time between the effective date of the IND and the submission date of the BLA, plus the time between the submission date of the BLA and the ultimate approval date, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Patent term extension cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The United States Patent and Trademark Office ("USPTO") reviews and approves the application for any patent term extension in consultation with the FDA.

Biosimilars and exclusivity

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") established a regulatory framework authorizing the FDA to approve biosimilars and interchangeable biosimilars. A biosimilar is a biological product that is highly similar to an already FDA-licensed biological product, called the "reference product." The FDA has issued multiple guidance documents outlining an approach to review and approval of biosimilars. Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a reference product. In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biosimilar product and the reference product may be switched without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products, which may be substituted by pharmacies for the reference product, subject to state pharmacy law.

Post-approval regulation

If regulatory approval for a product or new indication for an existing product is obtained, the sponsor will be required to comply with all generally applicable post-approval regulatory requirements as well as any specific post-approval requirements that the FDA may impose as part of the approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with advertising and promotional labeling requirements and record-keeping requirements. Manufacturers and certain of their subcontractors must register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort to maintain compliance with cGMP regulations and other regulatory requirements.

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

- restrictions on the marketing or manufacturing of the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product licenses;
- product recall, seizure or detention, or refusal to permit the import or export of products;
- withdrawal of the product from the market; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription biological products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the internet and social media. Promotional claims about a product's safety or effectiveness are prohibited before it is approved. After approval, a product generally may be promoted for uses or patient populations consistent with the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe products for uses that are not approved by the FDA (sometimes called "off-label use") because the FDA does not regulate the practice of medicine. However, FDA regulations restrict manufacturers' communications about off-label uses. Promotional materials for approved biological products generally must be submitted to the FDA in conjunction with their first use.

If a company, including any representative of the company or anyone speaking on behalf of the company, is found to have promoted off-label uses, the company may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the DOJ, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes its products.

Data privacy and security laws

In the ordinary course of business, we collect, receive, or otherwise process personal data, including information we may collect about participants in our clinical trials. Accordingly, we are, or may be become, subject to numerous data privacy and security obligations, including global, federal, state, and local laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations related to privacy and data security.

Under the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the U.S. Department of Health and Human Services ("HHS"), has issued regulations to protect the privacy and security of protected health information ("PHI"), used or disclosed by covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their regulations, including the final omnibus rule published on January 25, 2013, also imposes certain obligations on the business associates of covered entities and their subcontractors that obtain protected health information in providing services to or on behalf of covered entities. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that are applicable to our business. In addition to possible federal administrative, civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. Accordingly, state attorneys general have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. New laws and regulations governing privacy and security may be adopted in the future as well.

Additionally, numerous states have recently enacted consumer privacy laws that grant rights to data subjects and place increased privacy and security obligations on entities handling personal data of consumers or households. While we are not currently subject to laws such as the California Consumer Privacy Act ("CCPA"), some observers note that the CCPA and similar legislation could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business.

Because of the breadth of these laws and the narrowness of the statutory exceptions under such laws, it is possible that some of our current or future business activities, including certain clinical research, sales and marketing practices and the provision of certain items and services to our customers, could be subject to challenge under one or more of such privacy and data security laws. The heightening compliance environment and the need to build and maintain robust and secure systems to comply with different privacy compliance and/or reporting requirements in multiple jurisdictions could increase the possibility that we may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any applicable privacy or data security laws or regulations, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a consent decree or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. While there are some exemptions for certain data processed in the context of clinical trials, developments in data privacy and security laws may further complicate compliance efforts. The impact these increasingly stringent laws and evolving regulatory frameworks related to personal data processing may have on us is more fully discussed in the section titled "Risk factors" appearing elsewhere in this Annual Report.

Additionally, to the extent we collect personal data from individuals outside of the United States, through clinical trials or otherwise, we are, or may become, subject to foreign data privacy and security laws, such as the European Union's General Data Protection Regulation 2016/679 ("EU GDPR") and other national data protection legislation in force in relevant EEA Member States, and the EU GDPR as it forms part UK law by virtue of section 3 of the European Union (Withdrawal) Act 2018 ("UK GDPR"). Foreign privacy and data security laws impose significant and complex compliance obligations on entities that are subject to those laws, as more fully discussed in the section titled "Risk factors" appearing elsewhere in this Annual Report.

Regulation and procedures governing approval of medicinal products outside the United States

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. For example, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of a marketing authorization application ("MAA") and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

Clinical trial approval

In April 2014, the European Union adopted the Clinical Trials Regulation (EU) No 536/2014 ("CTR"), which entered into application on January 31, 2022 repealing and replacing the Clinical Trials Directive 2001/20/EC. The CTR is directly applicable in all European Union Member States meaning no national implementing legislation in each European Union Member State is required. The CTR aims at harmonizing and streamlining the approval of clinical trials in the European Union, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. For instance, the CTR provides for a streamlined application procedure via a single-entry point and strictly defined deadlines for the assessment of clinical trial applications. Sponsors conducting clinical trials must, as in the United States, post specified clinical trial information in the European Union on the Clinical Trials Information System.

PRIME designation in the European Union

The PRIority MEdicines ("PRIME"), scheme is intended to encourage product development in areas of unmet medical need and is intended to support development of products representing substantial innovation reviewed under the centralized procedure. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the European Union or, if there is, the new medicine will bring a major therapeutic advantage) and they

must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of therapeutic candidates with PRIME designation, including but not limited to early and proactive regulatory dialogue with the European Medicines Agency ("EMA"), frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated EMA contact and a rapporteur from the Committee for Medicinal Products for Human Use ("CHMP") are typically appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

Marketing authorization

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union Member States (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, an applicant must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan ("PIP"), covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver or a deferral for one or more of the measures included in the PIP. The Paediatric Committee of the EMA ("PDCO"), may grant deferrals for some medicines, allowing a company to delay development of the medicine for children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine for children is not needed or is not appropriate, such as for diseases that only affect the elderly population. The respective requirements for all marketing authorization procedures are laid down in Regulation (EC) No 1901/2006, the so-called Paediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP (even where such results are negative) are eligible for six months' supplementary protection certificate extension. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union Member States, as well as the countries of the EFTA Pillar of the European Economic Area (Norway, Iceland and Liechtenstein) ("EEA"). Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer, HIV, AIDS, 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 European Union, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union. Applicants must demonstrate the quality, safety and efficacy of their products to the EMA. The CHMP provides an opinion regarding the MAA. The European Commission grants or refuses a marketing authorization in light of the opinion delivered by the EMA.

Under the centralized procedure, the CHMP is responsible for conducting an initial assessment of a product. The maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who makes the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation.

Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

National marketing authorizations, which are issued by the competent authorities of the Member States of the European Union and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the European Union, this national authorization can be recognized in other Member States through the mutual recognition procedure. If the product has not received a national authorization in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure.

Regulatory data protection in the European Union

In the European Union, new active substances (including both small molecules and biological medicinal products) approved on the basis of a complete and independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Regulation (EC) No 726/2004, as amended, and Directive 2001/83/EC, as amended. Data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization, for a period of eight years from the date on which the reference product was first authorized in the European Union. During the additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced, but no medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new active substance so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on an MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Patent term extensions in the European Union and other jurisdictions

The European Union also provides for patent term extension through supplementary protection certificates ("SPCs"). The rules and requirements for obtaining an SPC are similar to those in the United States. An SPC may extend the term of a patent for up to five years after its originally scheduled expiration date and can provide up to a maximum of fifteen years of marketing exclusivity for a product. In certain circumstances, the period of SPC protection may be extended for six additional months if a product is granted a marketing authorization in the EU with the results of the pediatric clinical trials conducted in accordance with an agreed pediatric investigation plan (even where such results are negative). Although SPCs are available throughout the European Union, sponsors must apply on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the European Union.

Periods of authorization and renewals

A marketing authorization is valid for five years, in principle, and it may be renewed indefinitely after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing Member State. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the European Union market (in the case of the centralized procedure) or on the market of the authorizing Member State (in the case of a national procedure) within three years after authorization, or which is not placed on the market for a consecutive period of three years at any time during its authorization, ceases to be valid.

Regulatory requirements after marketing authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product, and must adhere in strict compliance with the applicable European Union laws, regulations and guidance, including Directive 2001/83/EC, Directive (EU) 2017/157, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's

GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of products to assure their safety and identity.

Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to induce or reward improper performance generally is usually governed by the national anti-bribery laws of European Union Member States and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the European Union.

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

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

Orphan designation and exclusivity

Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan product by the European Commission if its sponsor can establish that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition, where either (i) such condition affects not more than five in ten thousand persons in the European Union when the application is made, or (ii) without incentives it is unlikely that the marketing of the product in the European Union would generate sufficient return to justify the necessary investment in its development. For either of these conditions, the applicant must also demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the product will be of significant benefit to those affected by that condition.

An orphan designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized marketing authorization. Marketing authorization for an orphan product leads to a ten-year period of market exclusivity following marketing approval of the orphan product. During this market exclusivity period, the European Commission or the European Union Member States may only grant a marketing authorization to a "similar medicinal product" for the same therapeutic indication as an authorized orphan product if: (i) a second applicant can establish that its product, although similar to the authorized orphan product, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the authorized orphan product consents to a second application; or (iii) the marketing authorization holder for the authorized orphan product cannot supply enough orphan medicinal product. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, including if the product is sufficiently profitable not to justify market exclusivity. Orphan designation must be requested before submitting an application for marketing approval. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The aforementioned European Union rules are applicable in the EFTA Pillar of the EEA (Iceland, Liechtenstein and Norway).

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 European Union for all medicines (including those for rare diseases and for children). The European Commission provided the legislative proposals to the European Parliament and the Council of the European Union for their review and approval. 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 was 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 (the "UK") is not generally subject to EU laws in respect of medicines. The EU laws that have been transposed into UK law through secondary legislation remain applicable in the UK; however, new legislation such as the CTR is not applicable in the UK. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency (the "MHRA") became 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"), which continued to follow the EU regulatory regime for a period following Brexit. However, on January 1, 2025 a new arrangement called the Windsor Framework came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes and EU labeling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines. In particular, the MHRA is now responsible for approving medicinal products placed on the UK market (*i.e.*, Great Britain and Northern Ireland), and the EMA no longer has a role in UK marketing authorizations. A single UK-wide marketing authorization will be granted by the MHRA for all novel 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 all medicines placed on the UK market to be labelled “UK Only”, indicating they are not for sale in the EU. However, although a separate authorization is now required to market medicinal products in the UK, under an international recognition procedure which was put in place by the MHRA on January 1, 2024, the MHRA may take into account decisions on the approval of a marketing authorization from the EMA (and certain other regulators) when considering an application for a UK marketing authorization. The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the (now-repealed) EU Clinical Trials Directive, as implemented into UK national law through secondary legislation. In April 2025, the UK introduced the Medicines for Human Use (Clinical Trials) (Amendment) Regulations. These changes, which will take full effect from April 2026, aim to create a streamlined, risk-proportionate system that accelerates approvals while maintaining robust safety standards.

Coverage and reimbursement

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize verekitug and any potential future 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. 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. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (“CMS”), an agency within the HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;

- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for verekitug and any potential future product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Other healthcare laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Such laws include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil monetary penalties;
- the federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;
- HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any

healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties.

Finally, there are state and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018, governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and responsible individuals may be subject to imprisonment.

Healthcare reform

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as gene therapy and therapies addressing rare diseases such as those we are developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. For example, in the United States, in 2010 the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), was enacted, which, among other things, subjected

biologic products to potential competition by lower-cost biosimilars; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011 and subsequence legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2032. 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.
- On April 13, 2017, CMS, an agency within the HHS, published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap, set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for verekitug and any potential future product candidates for which we may obtain regulatory approval or the frequency with which verekitug or any potential future product candidates is prescribed or used.

Additionally, there has been increasing legislative and enforcement interest in the U.S. 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.

In August 2022, the Inflation Reduction Act of 2022 (the "IRA") was signed into law. The IRA includes several provisions that may impact our business, depending on how various aspects of the IRA are implemented. Provisions that may impact our business include a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on most drugs in Medicare Part D, permitting the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, requiring companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. Under the One Big Beautiful Bill Act of 2025, this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan drug designations or indications, are exempt from the Medicare drug price negotiation program. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

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

On April 15, 2025, the Trump Administration published Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the federal government to take measures to reduce drug prices, including eliminating the so-called "pill penalty" under the IRA that creates a distinction between small molecule and large molecule products for

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

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

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards ("PDABs") and similar entities. While many PDABs have been granted authority to promote drug price transparency and reporting, some states have granted PDABs more expansive authority, including to set Upper Payment Limits ("UPLs") on select, high price drugs. The adoption and implementation of UPLs may put downward pressure on drug prices and impact our company's future revenues. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

Employees and human capital resources

As of March 20, 2026, we had 75 full-time employees, 22 of which have M.D. or Ph.D. degrees, and seven full-time consultants. Within our workforce, 56 employees are engaged in research and development activities and 19 are engaged in business development, finance, legal, and general management and administration activities. Our human capital objectives include identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Facilities

Our corporate headquarters is presently located in Waltham, Massachusetts, where we lease and occupy 16,801 square feet of office space. The initial term of the lease expires on November 1, 2027, with an option to extend the lease for an additional three years thereafter.

We believe that our leased premises are sufficient for our needs. To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

Legal proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Corporate information

We were incorporated under the laws of the State of Delaware on April 21, 2021 under the name "Upstream Bio, Inc." Our principal corporate office is located at 890 Winter Street, Suite 200, Waltham, MA 02451, and our telephone number is (781) 208-2466. Our website address is www.upstreambio.com. We do not incorporate the information on or accessible through our website into this Annual Report, and you should not consider any information on, or that can be accessed through, our website as part of this Annual Report.

Available information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended, are available through the "Investors" page of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (the "SEC"). Information on our website is not part of this Annual Report or any of our other securities filings unless specifically incorporated herein by reference. In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Our code of business conduct and ethics, corporate governance guidelines and the charters of our Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee are available on our corporate website.

Item 1A. Risk Factors.

Our business involves significant risks. Investors should carefully consider the risks and uncertainties described below, as well as the other information in this Annual Report on Form 10-K (this "Annual Report") and in the other documents that we file with the Securities and Exchange Commission (the "SEC"). The risks described below are not the only ones facing us. The following risks, or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the trading price of our common stock could decline, and investors could lose all or part of their investment.

This Annual Report also contains forward-looking statements and estimates that involve risks and uncertainties not presently known to us or that we currently deem immaterial, which also may impair our business operations. See "Special Note Regarding Forward-Looking Statements" elsewhere in this Annual Report for more information. Our actual results could differ materially from those anticipated in our forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

Risks related to our limited operating history, financial condition and need for additional capital

We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future success and viability. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in April 2021 and our operations to date have been limited to pre-commercial activities. We have not yet demonstrated an ability to generate revenues, obtain regulatory approvals, manufacture any product on a commercial scale or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Our limited operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet

demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business will suffer.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. Verekitug is currently our only product candidate. We will continue to incur significant research and development and other expenses related to our preclinical and clinical development of verekitug and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net losses totaled $143.4 million and $62.8 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $334.2 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, verekitug in multiple indications.

We anticipate that our expenses will increase substantially if, and as, we:

- advance verekitug through clinical development;
- seek regulatory approvals for verekitug in indications for which clinical trials are successful;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support the ongoing development of verekitug;
- experience an increase in headcount as we expand our research and development organization and market development and pre-commercial planning activities;
- undertake any pre-commercial or commercial activities required to establish sales, marketing and distribution capabilities;
- seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- maintain, expand and protect our intellectual property portfolio;
- make milestone, royalty or other payments due under our license agreements and any potential future in-license or collaboration agreements; and
- make milestone, royalty, interest or other payments due under any potential future financing or other arrangements with third parties.

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

Additionally, our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA"), the European Commission, or other comparable foreign regulatory authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing or maintaining appropriate manufacturing arrangements for our clinical trials or in the development of verekitug or any potential future product candidates.

We will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek regulatory and marketing approval for, verekitug in multiple indications. Even if verekitug or our potential future product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. To date, we have funded our

operations principally through private financings, our initial public offering ("IPO"), which closed in October 2024. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the clinical development of verekitug, and commence additional clinical trials.

As of December 31, 2025, we had cash, cash equivalents and short-term investments in the amount of $341.5 million. Based upon our current operating plan, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our operating expenses and capital expenditure requirements through 2027. We have based this estimate on assumptions that may prove to be wrong, and we could expend our available capital resources sooner than we expect. We may also raise additional financing on an opportunistic basis in the future. For example, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop verekitug. Our future capital requirements will depend on many factors, including but not limited to:

- the scope, timing, progress, costs and results of the ongoing development of verekitug as well as for potential discovery, preclinical development and clinical trials for other potential future product candidates;
- the number of clinical trials required for regulatory approval of verekitug or our potential future product candidates;
- the costs, timing and outcome of regulatory review of verekitug or our potential future product candidates;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses;
- the cost of manufacturing clinical and commercial supplies of verekitug or our potential future product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the effectiveness of our approach to identifying target patient populations;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for verekitug or any other potential future product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of verekitug or any other potential future product candidates for which we receive marketing approval;
- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of macroeconomic trends including inflation and rising interest rates;
- addressing any potential supply chain interruptions or delays;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in business, products and technologies.

Because of the numerous risks and uncertainties associated with research and development of product candidates, we are unable to predict the timing or amount of our working capital requirements. In addition, if we obtain regulatory approval for verekitug or any other potential future product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution which make it difficult to predict when or if we will be able to achieve or maintain profitability. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to support our continuing operations. Our ability to raise additional funds will depend on financial, economic, political and market conditions and other factors, over which we may have no or limited control. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, future commercialization efforts or other operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to verekitug or any other potential future product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations with our existing cash, cash equivalents and short-term investments, any future equity or debt financings and upfront and milestone and royalties payments, if any, received under any future licenses or collaborations. If we raise additional capital through the sale of equity or convertible debt securities, or issue any equity or convertible debt securities in connection with a collaboration agreement or other contractual arrangement, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. In addition, the possibility of such issuance may cause the market price of our common stock to decline. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring, selling or licensing intellectual property rights or assets, which could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams or verekitug or any other potential future product candidates or grant licenses on terms that may not be favorable to us. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Risks related to our business

Verekitug is our only product candidate, and we are dependent on a third party having accurately generated, collected and reported data from certain preclinical studies that were previously conducted for verekitug.

We currently have a single product candidate, verekitug, which is in clinical development for the treatment of severe asthma, chronic rhinosinusitis with nasal polyps ("CRSwNP"), and chronic obstructive pulmonary disease ("COPD"). Our business presently depends entirely on our ability to successfully develop, obtain regulatory approval for, and commercialize verekitug for one or more of the indications that we are pursuing in a timely manner. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and may be able to better sustain the delay or failure of a lead product candidate.

In addition, our assumptions about verekitug's development potential are partially based on data generated from preclinical studies conducted by Astellas Pharma, Inc. ("Astellas"), which sold the rights to verekitug to us pursuant to an asset purchase agreement in October 2021. We are dependent on Astellas having conducted its research and development in accordance with the applicable protocols, informed consent, legal and regulatory requirements, and scientific standards; having accurately reported the results of all preclinical studies conducted with respect to verekitug and having correctly collected the data from these studies. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of verekitug will be adversely affected. Furthermore, we may observe materially and adversely different results as we continue to conduct our clinical trials. If we are unable to develop, receive marketing approval for and successfully commercialize verekitug, or if we experience delays as a result of any of the above factors or otherwise, our business would be significantly harmed.

If we are unable to advance verekitug in clinical development for one or more of the indications that we are pursuing, obtain regulatory approval and ultimately commercialize verekitug, or experience significant delays in doing so, our business will be materially harmed.

To date, as an organization, we have not completed the development of any product candidate, and verekitug remains in clinical development. Our future success and ability to generate revenue is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize verekitug or any other potential future product candidates. Verekitug and any other potential future product candidates will require substantial additional investment for clinical development, regulatory review and approval in one or more jurisdictions. If verekitug or any other potential future product candidates encounter safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed.

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

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

We are currently conducting, and may in the future conduct, clinical trials for verekitug or any other potential future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are currently conducting, and may in the future conduct, clinical trials for verekitug or any other potential future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials. We are currently conducting clinical trials outside the United States, including but not limited to in Canada, Japan, South Korea, South Africa, the United Kingdom ("UK") and countries in South America and the European Union, and we expect to continue to conduct trials internationally in the future. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or any other comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the U.S. population and U.S. medical practice, the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice ("GCP") regulations, and the FDA can validate the data through on-site inspections or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements, including in relation to the use of data from clinical trials conducted in foreign jurisdictions. In addition, such

foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. Additionally, recent policy proposals in the United States may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in verekitug or any other potential future product candidates that we may develop being delayed or not receiving approval for commercialization in the applicable jurisdiction.

The successful development of pharmaceutical products involves a lengthy and expensive process and is highly uncertain.

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

- clinical trial results may show product candidates to be less effective than expected (for example, a clinical trial could fail to meet its primary or key secondary endpoint(s)) or have an unacceptable safety or tolerability profile;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals, which, among other things, may be caused by patients who fail the trial screening process, slow enrollment in clinical trials, patients dropping out of trials, patients lost to follow-up, length of time to achieve trial endpoints, additional time requirements for data analysis or a Biologics License Application ("BLA") or similar foreign application preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data (such as long-term toxicology studies) or unexpected safety or manufacturing issues;
- preclinical study results may show verekitug or any other potential future product candidates to have harmful side effects;
- post-marketing approval requirements; or
- the proprietary rights of others and their competing products and technologies that may prevent verekitug or any other potential future product candidates from being commercialized.

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

Furthermore, any product candidate we develop and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for verekitug or any other potential future product candidates 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 verekitug or any of our other potential future product candidates will not ever obtain regulatory approval.

We have no experience as an organization in submitting and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations ("CROs") or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude its obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a

product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

In addition, if verekitug or any other potential future product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with current Good Manufacturing Practices ("cGMPs") and GCPs for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a regulatory authority or a third party might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with verekitug or any other potential future product candidates post-approval could adversely affect our business, financial condition, results of operations and growth prospects.

Certain estimates of market opportunity and forecasts may prove to be smaller than we believe.

The estimates of market opportunity and forecasts of market growth included in documents that we file with the SEC may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all. Our initial focus is on the development of verekitug for the treatment of severe respiratory disorders, including severe asthma, CRSwNP and COPD. Our projections of addressable patient populations within these indications are based on our estimates and independent market research, industry and general publications obtained from third parties. Market opportunity estimates and growth forecasts included in this Annual Report and the other documents that we file with the SEC are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these indications. Additionally, the potentially addressable patient population may not ultimately be amenable to treatment with our product candidate if we cannot achieve our intended dosing interval. Our market opportunity may also be limited by current and future products of our competitors that are already available in the market or may enter the market for such patients. If any of our estimates prove to be inaccurate, the market opportunity for verekitug could be significantly diminished and have an adverse material impact on our business.

Due to the significant resources required for drug development and depending on our ability to access capital, we must prioritize the development of verekitug. Moreover, we may fail to expend our limited resources on the development of verekitug for the treatment of additional indications or for the development of other potential future product candidates that may have been more profitable or for which there is a greater likelihood of success.

Our product candidate, verekitug, is in clinical development for the treatment of severe asthma, CRSwNP, and COPD. Our initial focus is on developing verekitug for the treatment of severe respiratory disorders.

Due to the significant resources required for the development of verekitug, we must decide which indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of verekitug or misread trends in the pharmaceutical industry, our business, financial condition, results of operations and growth prospects could be materially and adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities verekitug or any potential future product candidates with other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to verekitug through collaboration, licensing or royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

If we successfully commercialize verekitug, our results of operations will be affected by the level of royalty payments that we are required to pay to Regeneron.

In connection with our Asset Purchase Agreement with Astellas, we also entered into a letter agreement (the "Regeneron Letter Agreement") with Astellas and Regeneron Pharmaceuticals Inc. ("Regeneron"). Under the Regeneron Letter Agreement, we assumed from Astellas an obligation to make mid-single-digit percentage royalty payments to Regeneron upon the commercialization of products developed from materials originally licensed to Astellas. The payment of royalties may have a negative effect on our results of operations and our ability to reinvest capital generated from commercialization to develop verekitug in additional indications or grow our company. Furthermore, any failure on our part to pay royalties owed to Regeneron could impact our rights to verekitug, lead to the initiation of legal proceedings against us and thereby adversely affect our business.

We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties or other strategic alliances. The failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing clinician and patients' needs, competitive technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our existing products and technologies or expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products, employees or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- diversion of management's attention from our core business and disruption of ongoing operations;
- adverse effects on existing business relationships with suppliers, sales agents, healthcare facilities, surgeons and other healthcare professionals;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms, if at all, or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers, sales agent, healthcare facilities, physicians or other healthcare providers. Our ability to successfully grow through strategic transactions depends upon our ability to identify, negotiate, complete and integrate suitable target businesses, technologies or products and to obtain any necessary financing. These efforts could be expensive and time-consuming and may disrupt our ongoing business and prevent management from focusing on our operations.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our common stock as consideration. Additional funds may not be available on terms that are favorable to us, or at all.

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

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

The legislative and regulatory framework for the processing of personal data worldwide is rapidly evolving in a manner that is increasingly stringent and, globally, this legal and regulatory framework is likely to remain uncertain for the foreseeable future. In the United States, numerous federal, state and local laws and regulations, including federal health information privacy laws, state information security and data breach notification laws, federal consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), state consumer protection and privacy laws, and other similar laws (e.g., wiretapping and communications interception laws) govern the processing of health-related and other personal data.

At the state level, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording individuals certain rights concerning their personal data. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While existing state comprehensive privacy laws exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Certain states have passed laws regulating specific aspects of privacy. For example, a small number of states, such as Illinois and Texas, have enacted laws that specifically target the collection and use of biometric information. Additionally, we may be subject to new laws governing the privacy of consumer health data, such as Washington's My Health My Data Act. The My Health My Data Act 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 the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. The effects of state and federal privacy laws are potentially significant and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation. These various privacy and data security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Regulators and legislators in the U.S. 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 certain countries of concern, including China. The final rule also restricts certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. The final rule does not exempt key-coded or otherwise anonymized, pseudonymized, de-identified, or encrypted data. Actual or alleged violations of the final rule may be punishable by criminal and/or civil sanctions, and may result in exclusion from participation in federal and state programs.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern privacy, data security, and the transfer of personal data between jurisdictions. For example, the European Union's General Data Protection Regulation ("EU GDPR") and the United Kingdom's General Data Protection Regulation ("UK GDPR", together with the EU GDPR, "GDPR") impose strict requirements for processing personal data including relating to processing of sensitive data (such as health data), ensuring there is a legal basis or condition to justify the processing of personal data, where required requirements relating to obtaining consent of individuals, disclosures about how personal data is to be used, limitations on retention of information, implementing safeguards to protect the security and confidentiality of personal data, where required providing notification of data breaches, maintaining records of processing activities and documenting data protection impact assessments where there is high risk processing and taking certain measures when engaging third-party processors. Under GDPR, companies may face temporary or definitive bans on data processing and other corrective activities, fines of up to €20 million (£17.5 million GBP) or 4% of annual global revenues, whichever is greater, and private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Non-compliance could also result in a material adverse effect on our business, financial position and results of operations.

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

Although the UK is regarded as a third country under the EU GDPR, the European Commission adopted an adequacy decision in favor of the UK, a decision recognizing the UK as providing adequate protection under the EU GDPR and enabling data transfers from EU Member States to the UK without additional safeguards. In December 2025, the European Commission extended the validity of the UK adequacy decision for six years until December 2031, determining that the UK continues to offer a level of data protection that is "essentially equivalent" to the EU standards. This follows the UK's adoption of the Data (Use and Access) Act 2025 (the "DUAA") on 19 June 2025. The EU GDPR and the UK GDPR currently impose substantially similar obligations. However, it is possible that the respective provisions, interpretations and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties, leading to additional compliance costs and could increase our overall risk.

Additionally in the EEA, the NIS 2 Directive ("NIS 2") is replacing the cybersecurity legal framework under the current NIS framework, aiming to ensure a high level of cybersecurity in the region. NIS 2 brings new medium and large organizations providing services in the EEA within scope of the legal framework. It extends to additional sectors and expands the list of in-scope healthcare organizations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in-scope organization's compliance with NIS 2, requires covered organizations to put in place certain cyber risk management measures, strengthens incident reporting requirements and provides supervisory authorities with a greater oversight. EU Member States had until 17 October 2024 to transpose NIS 2 into national legislation, although some countries have still not completed the transposition. As such, the cybersecurity regulatory landscape in the EEA is currently fragmented and uncertain. To the extent we are subject to NIS 2, we will require additional investment of our resources in compliance programs. Under NIS 2 companies may be subject to administrative fines of up to the higher amount of €10 million or 2% of worldwide turnover.

In addition to privacy and data security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to privacy and data security, and our efforts to comply with such obligations may not be successful.

We publish privacy policies and other statements, such as compliance with certain certifications or self-regulatory principles, regarding privacy and data security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

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

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

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

Issues in the development and use of artificial intelligence ("AI"), combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. Development, use, and deployment of these technologies could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational, and other risks and challenges that could affect our business. Specifically, risks related to bias, AI hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks such as model poisoning or data poisoning, surveillance, data leakage, loss of consensus reality, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. In addition, AI technologies, including generative AI tools, may create content, analyses or recommendations without human intervention that take or suggest actions based on incomplete or inaccurate data, "hallucinatory" inferences, or flawed training inputs or contain copyrighted or other protected material, and if our customers or others use this flawed or protected content or materials to their detriment, we may be exposed to brand or reputational harm, competitive harm, and/or legal liability. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

A growing number of legislators and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of artificial intelligence, and use of such technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of artificial intelligence and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. For example, the EU's Artificial Intelligence Act ("AI Act") entered into force on August 1, 2024, with most provisions becoming effective on August 2, 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 artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. The 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 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. As a result, we may face a fragmented and evolving compliance landscape that

could increase operational complexity, regulatory scrutiny, and legal exposure associated with the use or development of AI technologies. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The FDA, for example, issued draft guidance on the use of AI in regulatory decision-making for drug and biological products that centers on the context of use while establishing a credibility assessment framework for establishing and evaluating AI model outputs intended to support regulatory decision-making.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our products and services 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. Additionally, our vendors may incorporate AI tools into their offerings without disclosing this use to us, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we develop or use AI systems governed by these laws or regulations, including as informed by regulatory guidance, we will need to meet higher standards of data quality, transparency, monitoring and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non-compliance.

Risks related to the discovery and development of verekitug or any other potential future product candidates

The regulatory approval processes of the FDA, the EMA, and the European Commission and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for verekitug or any other potential future product candidates, our business will be substantially harmed.

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

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. The general approach for FDA approval of a new drug has generally been dispositive data from two or more adequate and well-controlled clinical trials of the product candidate in the relevant patient population, although FDA leadership announced in February 2026 that the FDA will, going forward, adopt the default position that one adequate and well-controlled trial, combined with confirmatory evidence, can serve as the basis of approval for novel products. The FDA, the EMA, the European Commission, or other comparable foreign regulatory authorities may disagree with us about whether a clinical trial is adequate and well-controlled or may request that we conduct additional clinical trials prior to regulatory approval. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. In addition, there is no assurance that the doses, endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. The clinical development of verekitug or any other potential future product candidates is also susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if verekitug or any other potential future product candidates have a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that verekitug or any other potential future product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events or other adverse events, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

Verekitug or any other potential future product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- the FDA, the EMA, the competent authorities of individual EU Member States, or other comparable foreign regulatory authorities may disagree with the dosing regimen, design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA and the European Commission, or other comparable foreign regulatory authorities that a product candidate is safe and effective for any of its proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA and the European Commission, or other comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA or the European Commission, or other comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of verekitug or any other potential future product candidates may not be sufficient to support the submission of a BLA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the FDA, the EMA or other comparable foreign regulatory authorities may not file or accept our BLA or marketing application for substantive review;
- staffing changes and backlogs at the FDA, the EMA or other comparable foreign regulatory authorities may create unexpected delays in the review and approval of any applications we may submit;
- the FDA, the competent authorities of individual EU Member States or other comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, the EMA and the European Commission, or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

Verekitug represents a novel approach to the treatment of inflammatory diseases, which makes it difficult to predict its likelihood of success and the timing and cost of development and obtaining regulatory approval.

We have concentrated our research and development efforts to develop the only known antagonist currently in clinical development that targets the receptor for Thymic Stromal Lymphopoietin ("TSLP") and our future success depends on the successful development of this differentiated therapeutic approach. We are in the early stages of developing verekitug and there can be no assurance that any development problems we have experienced or may experience in the future will not cause significant delays or result in unforeseen issues or unanticipated costs, or that any such development problems or issues can be overcome. We may also experience delays or encounter difficulties in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our future clinical studies or commercializing our products on a timely or profitable basis, if at all. In addition, our expectations with regard to the advantages of inhibiting the TSLP receptor relative to the approach of other therapies may not materialize or materialize to the degree we anticipate. Further, our scalability and costs of manufacturing may vary significantly as we develop verekitug and understand these critical factors.

In addition, the clinical study requirements of the FDA, the EMA and the European Commission, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Approvals by the European Commission and FDA for existing biologic treatments for asthma, such as dupilumab and tezepelumab, as well as other pathways to approval, may not be indicative of what these regulators may require for approval of our therapy. More generally, approvals by any regulatory authority may not be indicative of what any other regulatory authority may require for approval or what such regulatory authorities may require for approval in connection with new product candidates.

Verekitug may also not perform successfully in clinical trials or may be associated with adverse events that distinguish it from previously approved therapies or those that may be approved in the future. Unexpected clinical outcomes could materially and adversely affect our business, results of operations and prospects.

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

The results observed from preclinical studies or early-stage clinical trials of verekitug or any other potential future product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from such preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. For instance, results seen in our Phase 2 clinical trials in patients with CRSwNP and patients with severe asthma may not translate to our planned Phase 3 trials. Furthermore, verekitug or any other potential future product candidates may not be able to demonstrate similar activity or adverse event profiles as other product candidates that we believe may have similar profiles. In addition, in our planned future clinical trials, we may utilize clinical trial designs or dosing regimens that have not been tested in prior clinical trials.

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

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

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, European Commission, or comparable foreign regulatory authority approval.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of verekitug or any other potential future product candidates, which could prevent us from achieving our projected development and commercialization goals in the timeframes we announce and expect, and harm our business and results of operations. Many of the factors that cause or lead to a delay in the initiation or completion of clinical trials may also lead to the denial of regulatory approval or limit market acceptance of verekitug or any other potential future product candidates.

We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an IND or similar foreign authorization, or not approving or delaying approval for any clinical trial grant or similar approval we need

to initiate a clinical trial. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize verekitug or any other potential future product candidates we develop, including:

- regulators, institutional review boards ("IRBs"), ethics committees, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site, or provide a related positive opinion permitting such activities;
- we may not reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;
- the number of subjects or patients required for clinical trials of verekitug or any other potential future product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing verekitug or any other potential future product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which may be required to resubmit to an IRB, ethics committee and regulatory authorities for re-examination;
- regulators or other reviewing bodies may find deficiencies with, fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of verekitug or any other potential future product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the potential for approval policies or regulations of the FDA, the EMA, and the European Commission, or the applicable regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval.

Regulators, IRBs, or ethics committees of the institutions in which clinical trials are being conducted may suspend, limit or terminate a clinical trial, or data monitoring committees may recommend that we suspend or terminate a clinical trial, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, the competent authorities of individual EU Member States, or other comparable foreign regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of verekitug or any other potential future product candidates in such other indications. We do not know whether any clinical trials that we conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market verekitug or any other potential future product candidates for the indications that we are pursuing. If later-stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for verekitug or any other potential future product candidates will be adversely impacted.

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;

- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other comparable foreign regulatory authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used to manufacture verekitug or any other potential future product candidates;
- the efforts of our collaborators with respect to the commercialization of verekitug or any other potential future product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the development and commercialization of verekitug or any other potential future product candidates may be delayed, and our business, financial condition, results of operations and growth prospects may be harmed.

Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market verekitug or any other potential future product candidates would also significantly harm our business. Our development costs will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. There can be no assurance that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize verekitug or any other potential future product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize verekitug or any other potential future product candidates, which may harm our business, financial condition, results of operations and growth prospects. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of verekitug or any other potential future product candidates.

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

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

Interim, initial, top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular preclinical study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participants enrollment continues and more participants' data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between interim data and final data could significantly harm our business prospects. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and could adversely affect the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and investors may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the

conclusions reached, our ability to obtain approval for, and commercialize, verekitug or any other potential future product candidates may be harmed, which could harm our business, financial condition, results of operations and growth prospects. Further, disclosure of interim, top-line or preliminary data by us or by our competitors could result in volatility in the price of our common stock. Furthermore, if we fail to replicate the positive results from our preclinical studies or clinical trials in our future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize verekitug or any other potential future product candidates.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with our protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. Patient enrollment is affected by many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the number and location of study sites and proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in our clinical trials will drop out of the trials before completion.

We may experience challenges in recruiting principal investigators and patients to participate in ongoing and future clinical trials for verekitug or any other potential future product candidates if we are unable to sufficiently demonstrate the potential of such product candidates. In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as verekitug or any other potential future product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Furthermore, if significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our trials and patients may drop out of our trials.

If we are unable to enroll a sufficient number of patients for our clinical trials, it would result in significant delays or might require us to abandon one or more clinical trials or our development efforts altogether. Delays in patient enrollment may result in increased costs, affect the timing or outcome of the planned clinical trials, product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of verekitug or any other potential future product candidates, cause the value of the company to decline and limit our ability to obtain additional financing if needed.

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

Undesirable side effects caused by verekitug or any other potential future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, European Commission, or other comparable foreign regulatory authorities. We may also observe additional safety or tolerability issues with verekitug or any other potential future product candidates in ongoing or future clinical trials.

Many compounds that initially showed promise in clinical or earlier-stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Results of ongoing or future clinical trials of

verekitug or any other potential future product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier-stage testing. In addition, although we believe that verekitug's mechanism of action may differentiate it from other products that address the TSLP signaling pathway, such as tezepelumab, adverse events observed in clinical studies or postmarket use of these products may also be observed with verekitug, which could impact our ability to recruit patients to our clinical trials and our clinical development strategy.

If unacceptable side effects arise in the development of verekitug or any other potential future product candidates, we, the FDA, competent authorities of individual EU Member States, or other comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA, competent authorities of individual EU Member States or other comparable foreign regulatory authorities could order us to cease clinical trials, or the FDA, the European Commission, or other comparable foreign regulatory authorities could deny approval of verekitug or any other potential future product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using verekitug or any other potential future product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of verekitug or any other potential future product candidates. Inadequate training in recognizing or managing the potential side effects of verekitug or any other potential future product candidates could result in harm to patients that are administered verekitug or any other potential future product candidates. Any of these occurrences may adversely affect our business, financial condition, results of operations and growth prospects significantly.

Moreover, clinical trials are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. With a limited number of patients and limited duration of exposure, rare and severe side effects of our current or future product candidates may only be uncovered with a larger number of patients exposed to the product candidate. It is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

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

Although the development and potential commercialization of verekitug in severe asthma, CRSwNP and COPD are our initial focus, as part of our longer-term growth strategy, we plan to initiate and advance development of verekitug in additional indications. Expansion into new indications will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA, the European Commission, and comparable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, there can be no assurance that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

Risks related to the commercialization of verekitug or any other potential future product candidates

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

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

recommend switching products or they are required to switch due to lack of coverage and adequate reimbursement. Even if we are able to demonstrate verekitug's or any other potential future product candidates' safety and efficacy to the FDA, the European Commission, and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of verekitug or any other potential future product candidates may require significant resources, including management time and financial resources, and may not be successful. If verekitug or any other potential future product candidates are approved but do not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of verekitug or any other potential future product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Any failure by verekitug or any other potential future product candidate that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects.

Competitive products may reduce or eliminate the commercial opportunity for verekitug or any other potential future product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize verekitug or any other potential future product candidates may be adversely affected.

The clinical and commercial landscapes for the treatment of inflammatory diseases are highly competitive and subject to rapid and significant technological change. We face competition with respect to our indications for verekitug and will face competition with respect to any other drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies, such as Sanofi, Regeneron, AstraZeneca and Amgen, that currently market and sell drugs or are pursuing the development of drug candidates for the treatment of the indications that we are pursuing. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We believe that a significant number of product candidates are currently under development for the same indications we are currently pursuing, and some or all may become commercially available in the future for the treatment of conditions for which we are trying or may try to develop product candidates. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. See the section titled "Business—Competition" for examples of the competition that verekitug faces.

In most cases, we do not currently plan to run head-to-head clinical trials evaluating verekitug or any other potential future product candidates against the current standards of care, which may make it more challenging for verekitug or any other potential future product candidates to compete against the current standards of care due to the lack of head-to-head clinical trial data.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than verekitug or any other potential future product candidates we may commercialize and may render our therapies obsolete or non-competitive before we can recover development and commercialization expenses. If verekitug or any other potential future product candidates are approved, it could compete with a range of therapeutic treatments that are in development. In addition, our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than verekitug or any other potential future product candidates, which could render verekitug or any other potential future product candidates obsolete and noncompetitive.

If we obtain approval for verekitug or any other potential future product candidates, we may face competition based on many different factors, including the efficacy, safety and tolerability of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Existing and future competing products could present superior treatment alternatives, including being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing verekitug or any other potential future product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

In addition, our competitors may obtain patent protection, regulatory exclusivities or FDA approval and commercialize products more rapidly than we do, which may impact future approvals or sales of verekitug or any other potential future product candidates that receive regulatory approval. If the FDA approves the commercial sale of verekitug or any other potential future product candidates, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if verekitug or any other potential future product candidates receives regulatory approval but cannot compete effectively in the marketplace.

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

If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing verekitug or any other potential future product candidates.

We currently have no marketing, sales or distribution capabilities. We intend to establish a sales and marketing organization, either on our own or in collaboration with third parties, with technical expertise and supporting distribution capabilities to commercialize verekitug or any other potential future product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of verekitug or any other potential future product candidates.

Factors that may inhibit our efforts to commercialize verekitug or any other potential future product candidates on our own include:

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

With respect to verekitug or any other potential future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold verekitug or any other potential future product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

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

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Risks related to employee matters and managing growth

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

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of regulatory affairs and sales, marketing and distribution, as well as to continue to support our public company operations. To manage these growth activities, we must continue to implement and improve our managerial, operational, quality and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of verekitug or any other potential future product candidates.

Our ability to develop verekitug or any other potential future product candidates and our future growth depends on attracting, hiring and retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management and scientific personnel, many of whom have been instrumental for us and have substantial experience with developing therapies, identifying potential product candidates and building the technologies related to the clinical development of verekitug or any other potential future product candidates. As we continue developing verekitug or any other potential future product candidates, we will require personnel with medical, scientific, or technical qualifications specific to each program. The loss of key personnel would delay our research and development activities. Despite our efforts to retain valuable employees, members of our team may terminate their employment with us on short notice. The competition for qualified personnel in the biotechnology and biopharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled scientific, technical and managerial

employees. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which would have a material adverse effect on our business.

In addition, our clinical operations and research and development programs depend on our ability to attract and retain highly skilled scientists, data scientists, and engineers, particularly in Massachusetts. There is powerful competition for skilled personnel in these geographical markets, and we have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we do, and any of our employees may terminate their employment with us at any time. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

Risks related to our dependence on third parties

We currently rely, and plan to rely in the future, on third parties to conduct and support our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize verekitug or any other potential future product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

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

We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, informed consent forms submitted to competent regulatory authorities, legal and regulatory requirements and scientific standards. Our failure or the failure of third parties to comply with the applicable protocol, informed consent forms, legal and regulatory requirements and scientific standards can result in rejection of our clinical trial data or other sanctions. If we or our third-party clinical trial providers or third-party CROs do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or be unsuccessful. Additionally, if we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving verekitug or any other potential future product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA or comparable foreign regulatory authorities will determine that any of our clinical trials comply with GCPs. We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Comparable transparency and publication requirements apply in foreign countries.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. Furthermore, at clinical trial sites, the availability of staff and trial participants has been limited due to a decrease in the number of clinical investigative sites across the globe. These contractors may also have

relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for verekitug or any other potential future product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize verekitug or any other potential future product candidates. In such an event, our financial results and the commercial prospects for verekitug or any other potential future product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

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

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

Our information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches, which could adversely affect our business.

Our information technology systems and data and those of our current or future contract research organizations or other contractors and consultants are vulnerable to compromise or damage from computer hacking, computer viruses, and malware (e.g., ransomware malicious software), business email compromises, data breaches, denial-of-service attacks, wrongful conduct by vendors, attacks enhanced or facilitated by AI, fraudulent activity, employee misconduct, human error, telecommunication and electrical failures, natural disasters, or other cybersecurity attacks or accidents. Future acquisitions could expose us to additional cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure. Cybersecurity attacks are increasing in frequency and sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, “hacktivists,” nation states, and others. As a result of a continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. Attempts to disrupt or gain unauthorized access to our and our third-party service providers’ information systems from malicious third parties or insider threats may incorporate widely varying and frequently changing tactics, which may be enhanced or facilitated by AI. Further, as a company with an increasingly global presence, our systems are subject to frequent attacks, which are becoming more commonplace in the industry, including attempted hacking, phishing attempts, such as cyber-related threats involving spoofed or manipulated electronic communications, which increasingly represent considerable risk. Due to the nature of some of the attacks described herein, there is a risk that an attack may remain undetected for a period of time. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. While we continue to make investments to improve the protection of data and information technology, including in the hiring of information technology (“IT”) personnel, periodic cyber security awareness trainings, improvements to IT infrastructure and controls, and conduct regular testing of our systems, there can be no assurance that our efforts will prevent service interruptions, security incidents, breaches in, or compromises of our systems or those of third-party CROs, vendors, contractors, consultants and/or third parties with whom we do business.

Like other companies in our industry, we and certain of our service providers have experienced cyberattack attempts or incidents and security incidents relating to our information technology systems and infrastructure. Any cybersecurity incident or data breach could adversely affect our business, by leading to, for example, the loss of trade secrets or other intellectual property, demands for ransom or other forms of blackmail, or the unauthorized disclosure of personal or other sensitive information of our employees, clinical trial patients, customers, and others. Although to our knowledge we have not experienced any significant

cybersecurity incident to date, if such an event were to occur, it could seriously harm our development programs and our business operations. We could be subject to breach notification requirements, regulatory actions taken by governmental authorities, litigation under laws that protect the privacy of personal information, or other forms of legal proceedings, which could result in significant liabilities or penalties, result in substantial costs and distract management. Further, a cybersecurity incident may disrupt our business or damage our reputation, which could have a material adverse effect on our business, financial condition, results of operations, growth prospects, share price and shareholder value. We could also incur substantial remediation costs, including the costs of investigating the incident, repairing or replacing damaged systems, restoring normal business operations, implementing increased cybersecurity protections, and paying increased insurance premiums. 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. Further, although we maintain cyber liability insurance, this insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or data breach.

For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in or denials of our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of clinical trial data or personal data, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media, and other parties pursuant to privacy and security laws. Likewise, we rely on our third-party research collaborators for research and development of verekitug and other third parties to conduct clinical trials, and similar events relating to their information technology systems could also seriously harm our business. Any security compromise affecting us, our collaborators or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures, and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of verekitug or any other potential future product candidates could be delayed, result in substantial costs and distract management.

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

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

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of verekitug or any other potential future product candidates from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA, the European Commission, or other comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for verekitug or any other potential future product candidates. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop verekitug or any other potential future product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of verekitug or any other potential future product candidates for which we are seeking to collaborate, reduce or delay its development program or one

or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

Our existing research and development arrangement as well as any future collaborations with third parties for the development and commercialization of verekitug or any other potential future product candidates may not be successful, which could adversely affect our ability to advance verekitug or any other potential future product candidates.

We have entered into a research and development arrangement and may in the future enter into collaborations for the development and commercialization of verekitug or any other potential future product candidates. Any collaborations may limit our control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of verekitug or any other potential future product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. For example, we granted Maruho Co., Ltd. ("Maruho") an exclusive, irrevocable, perpetual, royalty-free, sublicensable license for the development and commercialization of verekitug in Japan (the "Maruho License Agreement"). Under the Maruho License Agreement, we are responsible for and control the global research and development of verekitug in Japan. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Collaborations involving verekitug or any other potential future product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of verekitug or any other potential future product candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, which divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon verekitug or any other potential future product candidates, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with verekitug or any other potential future product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, including trade secrets and intellectual property rights, contract interpretation, or the preferred course of development might cause delays or termination of the research, development or commercialization of verekitug or any other potential future product candidates, might lead to additional responsibilities for us with respect to such product candidate, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidate.

Collaboration agreements may not lead to development or commercialization of verekitug or any other potential future product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of verekitug or any other potential future product candidates licensed to it by us.

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

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

We currently rely on and engage third-party manufacturers to provide all of the APIs and the final drug product formulation of verekitug that is being used in our clinical trials and preclinical studies, including WuXi Biologics (Hong Kong) Limited ("WuXi"). Legislative and regulatory actions have been taken that have the potential to negatively impact U.S. companies and institutions that accept U.S. funding for projects that utilize biotechnology equipment and services produced or provided by certain biotechnology providers having relationships with foreign adversaries and which pose a threat to national security. For example, in December 2025 the National Defense Authorization Act for Fiscal Year 2026 ("NDAA") was enacted, which includes Section 851 (commonly referred to as the "BIOSECURE Act"). The BIOSECURE Act restricts U.S. government agencies from procuring certain biotechnology equipment or services from, or entering into contracts with, entities that use biotechnology equipment or services from designated "biotechnology companies of concern" ("BCCS") and from expending certain federal loan or grant funds for such equipment or services. While WuXi is not currently listed as a BCC, earlier legislative drafts of the BIOSECURE Act explicitly identified WuXi as a BCC; and also on December 18, 2025, the chairmen of multiple Senate and House committees, including the House Select Committee on China, sent a letter to the Department of Defense recommending that WuXi be added to the Department of Defense's 1260H list, which would result in WuXi being designated as a BCC.

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

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

In addition, we typically order raw materials, APIs and drug product and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. We may not be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of verekitug or any other potential future product candidates or, to commercialize them, if approved. We may be unable to conclude agreements for commercial supply with third-party manufacturers or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of verekitug or any other potential future product candidates, and the costs of manufacturing could be prohibitive.

If our manufacturers have difficulty or suffer delays in successfully manufacturing material that meets our specifications, it may limit supply of verekitug or any other potential future product candidates and could delay our clinical trials. For example, during routine evaluation of drug samples as part of stability testing of material produced by a previous manufacturing process, particles were observed. This resulted in a brief pause in dosing in our Phase 1b MAD clinical trial of verekitug for the treatment of asthma while a standard investigation was conducted, after which dosing resumed. There can be no assurance that similar or longer delays will not be necessary in the future.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third-party manufacturer to comply with applicable regulatory requirements and reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;

- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over verekitug or any other potential future product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- the possible breach of manufacturing agreements by third parties because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

If we are unable to maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for verekitug or any other potential future product candidates. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and comparable foreign regulatory authorities.

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

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

Some of our manufacturers are located outside of the United States. There is currently significant uncertainty about the future relationship between the United States and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs. It is possible further tariffs may be imposed that could affect imports of APIs used in verekitug or any other potential future product candidates, or our business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to such raw materials used in verekitug or any other potential future product candidates. Given the unpredictable regulatory environment in China and the United States and uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements and policies, further governmental action related to tariffs, additional taxes, contracting matters, regulatory changes or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business, financial condition, results of operations and growth prospects.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including shutdown of the third-party vendor or rejection of drug product lots or processes, clinical holds, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or voluntary recalls of product candidates or drugs if approved, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of verekitug or any other potential future product candidates. The facilities used by our contract

manufacturers to manufacture verekitug or any other potential future product candidates must be evaluated by the FDA and comparable foreign regulatory authorities. We have limited control over the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the European Union, or other comparable foreign regulatory authorities, we may not be able to secure and/or maintain regulatory approval for verekitug or any other potential future product candidates manufactured at these facilities. In addition, we limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies or does not approve these facilities for the manufacture of verekitug or any other potential future product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market verekitug or any other potential future product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, European Union, and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop, and if approved, market verekitug or any other potential future product candidates.

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

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

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of verekitug or any other potential future product candidates, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of verekitug or any other potential future product candidates. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for verekitug or any other potential future product candidates, or if they are unable to produce increased amounts of verekitug or any other potential future product candidates while maintaining the same quality then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operations.

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

As verekitug or any other potential future product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause verekitug or any other potential future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, notification or approval by the FDA, or comparable foreign regulatory authorities. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of verekitug or any other potential future product candidates and jeopardize our ability to commence sales and generate revenue.

Risks related to government regulation

Obtaining and maintaining regulatory approval of verekitug or any other potential future product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval in other jurisdictions.

Obtaining and maintaining regulatory approval of verekitug or any other potential future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, the European Commission, or other comparable foreign regulatory authorities must also approve the manufacturing and marketing of the product candidate in those territories. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United

States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of verekitug or any other potential future product candidates will be harmed.

Even if we receive regulatory approval of verekitug or any other potential future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with verekitug or any other potential future product candidates.

If verekitug or any other potential future product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

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

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

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

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension, variation or withdrawal of approvals;

- product seizure or detention or refusal to permit the import or export of verekitug or any other potential future product candidates;
- total or partial suspension of production, distribution, manufacturing or clinical trials;
- operating restrictions;
- suspension of licenses; and
- injunctions, fines or the imposition of civil or criminal penalties.

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

The policies of the FDA, the EMA, and the European Commission, and comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of verekitug or any other potential future product candidates. In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For more information, see the section titled "Business—Government regulation".

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

Verekitug or any other potential future product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2010 (the "BPCIA") created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

We believe any of our potential future product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider verekitug or any other potential future product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

In the European Union, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

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

The FDA and comparable foreign regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review. However, there can be no assurance that we will successfully obtain such designations for verekitug or any other potential future product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for verekitug or any other potential future product candidates, there can be no assurance that we will realize their intended benefits.

For example, we may seek a Fast Track Designation for verekitug or any other potential future product candidates we develop. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development activities.

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

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

Even in the absence of obtaining fast track and/or breakthrough therapy designations, a sponsor can seek priority review at the time of submitting a marketing application. The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months. Priority review designation may be rescinded if a product no longer meets the qualifying criteria.

We may be unsuccessful in obtaining or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user fee waivers.

Similarly, in the EU, a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition. In the EU, orphan medicinal product designation entitles a party to incentives such as reduction of fees or fee waivers protocol assistance, and access to the centralized marketing authorization procedure.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same product and indication for that time period, except in limited circumstances. In the EU, marketing exclusivity prevents the EMA and competent authorities in the EU from accepting another application for marketing authorization for a similar medicinal product in the same therapeutic indication as the authorized orphan product. The applicable period is seven years in the U.S. and ten years in the EU. The EU exclusivity period may also be extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan. However, the EU exclusivity period can be reduced to six years, if at the end of the fifth, it is established that a product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that the product is sufficiently profitable so that market exclusivity is no longer justified or where the prevalence of the condition has increased above the threshold.

Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the designated drug from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or the European Commission can subsequently approve the same drug for the same condition if the FDA or the European Commission concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Where appropriate, we may secure approval from the FDA, the European Commission or other comparable foreign regulatory authorities through the use of expedited approval pathways, such as accelerated approval or comparable foreign abbreviated pathways. If we are unable to obtain such approvals, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA or approval following comparable foreign abbreviated pathways by foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or such comparable foreign regulatory authorities may seek to withdraw the accelerated approval.

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

verify the drug's predicted clinical benefit. The FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress.

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

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

The ability of the FDA and other comparable regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, availability of personnel and other resources, the FDA's or other comparable regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's or other comparable regulatory authorities' ability to perform routine functions. Average review times at the FDA and other comparable regulatory authorities have fluctuated in recent years and may continue to fluctuate as a result. In addition, government funding of the SEC and other U.S. government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, including executive and congressional priorities, which is inherently fluid and unpredictable.

Disruptions at the FDA, the SEC, other U.S. government agencies or comparable foreign regulatory authorities, including as a result of substantial leadership departures, personnel cuts, and policy changes, may also slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. Changes and cuts in FDA staffing have been reported by some within the pharmaceutical industry as creating instances of delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. For example, over the last several years, the U.S. government has shut down several times, including most recently a shutdown for a 43-day period from October 1, 2025 through November 12, 2025, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs again, such as the one that occurred in October 2025, or if global health concerns, funding shortages or staffing limitations hinder or prevent the FDA, the SEC or other regulatory authorities from conducting their regulatory inspections, reviews or other regulatory activities, including formal or informal interactions with product developers, it could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, government shutdowns and/or substantial leadership, personnel, and policy changes at the SEC could impact our business by delaying review of our public filings, which in turn could delay or frustrate our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations or delay the review or effectiveness of required regulatory or securities filings.

Since the change in the U.S. presidential administration in 2025, there continues to be substantial uncertainty as to how and to what extent the leadership of the FDA and the Trump Administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our product candidates. Additionally, the new administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates.

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

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. Healthcare professionals, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and would sell, market and distribute our products. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, supranational, national, federal and state healthcare laws and regulations that may affect our ability to operate may apply. For more information on healthcare laws and regulations that may impact our company, see the section titled "Business—Government regulation—Other healthcare laws".

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

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

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

The success of verekitug or any other potential future product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

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

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors, and the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for verekitug or any other potential future product candidates. Even if we do receive a favorable coverage determination for our products by third-party payors, coverage policies and third-party payor reimbursement rates may change at any time.

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

Moreover, increasing efforts by governmental and other third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for verekitug or any other potential future product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

In addition, in some foreign countries, the proposed pricing for a product must be approved before it may be lawfully marketed. The requirements governing product pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for verekitug or any other potential future product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

For more information on the laws and regulations that may impact coverage and reimbursement of verekitug or any other potential future product candidates, see the section titled "Business—Government regulation—Coverage and reimbursement".

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

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, (1) changes to our manufacturing arrangements, (2) additions or modifications to product labeling, (3) the recall or discontinuation of our products or (4) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. See the sections titled "Business—Government regulation—Coverage and reimbursement" and "—Healthcare reform".

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

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

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

The One Big Beautiful Bill Act (the "OBBBA") also included significant reforms to Medicaid, including an estimated $1 trillion in reduced federal Medicaid spending from 2025 through 2034, the imposition of work requirements for certain adult enrollees, more frequent eligibility redeterminations, and increased cost-sharing for beneficiaries. These changes are expected to reduce overall Medicaid enrollment and access to care. Although the effect on our business is currently unknown, any decrease in the number of insured patients or reimbursement levels for our products could adversely affect our revenue and commercial prospects.

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

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

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

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

Our employees, independent contractors, consultants, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our current and any future employees, independent contractors, consultants, contract manufacturing organizations, CROs and vendors. Misconduct by these parties could include intentional, reckless, and/or negligent conduct that fails to comply with FDA or other regulations, provide true, complete and accurate information to the FDA, the national competent authorities of individual EU Member States, and other comparable foreign regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. If we obtain FDA approval of verekitug or any other potential future product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and growth prospects.

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

If verekitug or any other potential future product candidates are approved by the FDA, we may only promote or market them in a manner consistent with their FDA-approved labeling. We will train our marketing and sales force against promoting verekitug or any other potential future product candidates for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from verekitug or any other potential future product candidates off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. Furthermore, the use of verekitug or any other potential future product candidates for indications other than those approved by the FDA may not effectively treat such conditions. Further, FDA's Office of Prescription Drug Promotion ("OPDP") actively scrutinizes promotional communications, including digital and social media; any materials that are false, misleading or promote unapproved uses can lead to enforcement actions and could necessitate corrective communications. Any such off-label use of verekitug or any other potential future product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use verekitug or any other potential future product candidates for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation. Similar requirements and considerations apply abroad.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the EU Member States.

We intend to seek approval to market verekitug or any other potential future product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for verekitug or any other potential future

product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of verekitug or any other potential future product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of verekitug or any other potential future product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for them and may be affected by existing and future healthcare reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians and other healthcare professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. Interactions between pharmaceutical companies and healthcare professionals, including the provision of benefits or advantages, are governed by strict laws, such as national anti-bribery laws of individual EU Member States and the Bribery Act 2010 in the UK, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians and other healthcare professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often may require prior notification or approval by the healthcare professional's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in some foreign countries, including some countries in the European Union, the proposed pricing for a product must be approved before it may be lawfully marketed. The requirements governing product pricing and reimbursement vary widely from country to country. The European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the individual EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This HTA of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU Member States, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of verekitug or any other potential future product candidates in those countries would be negatively affected.

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

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control. Export controls and trade sanctions laws and regulations may restrict or prohibit altogether the

provision, sale, or supply of our products to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions or an embargo. We are also subject to anti-corruption and anti-bribery laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, and other state and national anti-bribery laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

If we or any third-party manufacturer we engage now or in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could have a material adverse effect on our business.

We and third-party manufacturers we engage now are, and any third-party manufacturer we may engage in the future will be, subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

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

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

Risks related to our intellectual property

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

Our success depends, in large part, on our ability to obtain and maintain patent protection and trade secret protection for verekitug or any other potential future product candidates and their formulations and uses, as well as successfully enforcing our patents against third-party infringers and/or defending these patents against third-party challenges. If we (or our licensees should such licensees be granted the right to prosecute or enforce certain patents within our portfolio) fail to appropriately prosecute or are unable to obtain and maintain patent protection for verekitug or any other potential future product candidates (or aspects thereof), our ability to develop, license and/or commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using, selling or importing competing products. This failure or inability to properly or adequately protect the intellectual property rights relating to these product candidates could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

- patent applications may not result in any patent being issued;
- patents that may be issued may not include claims that cover a broad enough scope to prevent design around solutions by competitors;
- patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide adequate barriers to entry or any competitive advantage;
- because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a potential product can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization, reducing, or eliminating any advantage of the patent;
- our competitors, many of which have substantially greater resources than us or our partners do, and many of which have made significant investments in competing technologies, may seek, or may already have sought or obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products;
- there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop, and market competing products; and
- we may be involved in lawsuits to protect or enforce our patents or the patents we have rights to enforce, which could be expensive, time consuming and/or unsuccessful.

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

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

We may be forced to litigate to enforce or defend our intellectual property rights against infringement by competitors, and to protect our trade secrets against unauthorized use. In so doing, we may place our intellectual property at risk of being invalidated, rendered unenforceable, or limited or narrowed in scope such that we may no longer be used to adequately prevent the manufacture, sale or import of competitive product. Further, an adverse result in any litigation or other proceedings before government agencies such as the United States Patent and Trademark Office (the "USPTO"), may place pending applications at risk of non-issuance or limitations in scope. Further, derivation proceedings, entitlement proceedings, ex parte reexamination, inter partes review, post grant review, and opposition proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be used to challenge the inventorship, ownership, claim scope, or validity of our patents. Additionally, because of the substantial amount of discovery typically required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information or trade secrets could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the value of the company. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and

continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we enter into future arrangements involving government funding, and we make inventions as a result of such funding, our intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh Dole Act of 1980. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh Dole Act may similarly apply. Any exercise by the government of certain of our rights could harm our competitive position, business, financial condition, results of operations and growth prospects.

If we or our partners are sued for infringing or misappropriating the intellectual property rights of third parties, it could be costly and time consuming, and an unfavorable outcome in any such litigation could have a material adverse effect on our business.

Our success also depends upon our ability and the ability of us any of our future partners to develop, manufacture, market and sell verekitug or any other potential future product candidates without infringing on the proprietary rights of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, now unknown to us, which may later result in issued patents that verekitug or any other potential future product candidates or proprietary technologies may be alleged to infringe upon. Similarly, there may be issued patents relevant to verekitug or any other potential future product candidates of which we are not aware.

In addition, third parties may sue us alleging that we infringe, or have infringed, on their patents. Even if we are successful in defending any claims of infringement, the defense of such claims may be costly and present a time consuming distraction. In the event of a successful claim of infringement against us, we may be required to:

- pay substantial damages and/or ongoing royalty payments;
- stop using some or all of our technologies and methods;
- stop certain research and development efforts;
- develop non infringing products or methods (i.e., develop or design around); and/or
- obtain one or more licenses from third parties for an upfront lump sum, an ongoing royalty, or a combination thereof.

If required, there can be no assurance that we will be able to obtain such licenses on acceptable terms, or at all. If we are sued for infringement, we could encounter substantial delays in the development, manufacture, and commercialization of verekitug or any other potential future product candidates. Any litigation, whether to enforce our patent rights or to defend against allegations that we allegedly infringe on third-party rights, could be costly, time consuming, and may distract management from other important tasks.

As is commonplace 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. To the extent our employees are involved in research endeavors that are similar to those which they were involved in at their former place of employment, we may be subject to claims that such employees and/or we have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of such former employers. Litigation may be necessary to defend against such claims, which could result in substantial costs, be a distraction to management and ultimately have a material adverse effect on us, even if we are successful in defending such claims.

The biotechnology and pharmaceutical industries have experienced substantial litigation and other proceedings concerning intellectual property rights, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which could be uncertain and may prevent, delay, or otherwise interfere with our product discovery and development efforts. Our commercial success depends upon our ability or may depend on the ability of future collaborators to develop, manufacture, market, and sell our products. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights as well as administrative proceedings for challenging patents, including derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be subject to, and may in the future become party to, or threatened with, adversarial proceedings or litigation concerning intellectual property rights with respect to verekitug or any other potential future product candidates we may develop, including

interference proceedings, post grant review, inter partes review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office. Numerous United States and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing verekitug or any other potential future product candidates and infringement claims may be asserted against us or our partners based on existing patents or patents that may be granted in the future, regardless of their merit.

It is not always clear to industry participants, including us, which patents cover various types of therapies, products or their methods of use or manufacture. Moreover, as with many technology-based products, there may be third-party patent applications that, if issued, may include the claims that could be or are construed to cover components of verekitug or any other potential future product candidates. There may also be third-party patents of which we are currently unaware with claims to our technologies, compositions, methods of manufacture or methods of use.

Our ability to commercialize verekitug or any other potential future product candidates in the United States and abroad may be adversely affected if we cannot successfully defend against infringement claims or obtain a license on commercially reasonable terms to relevant third-party patents that cover verekitug or any other potential future product candidates. Even if we have a strong defense and/or believe that third-party intellectual property claims are without merit, there can be no assurance that a court would find in our favor on questions of infringement, validity, enforceability, and/or priority. A court of competent jurisdiction could hold that these third-party patents are valid and enforceable and have been infringed upon, which could materially and adversely affect our ability to commercialize verekitug or any other potential future product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claims, there is no assurance that a court of competent jurisdiction would invalidate the asserted claims of any such U.S. patent. If we are found to be infringing on a third party's intellectual property rights, and we are unsuccessful in demonstrating that any such patents are invalid or unenforceable, we could be required to pay damages and/or an ongoing royalty or obtain a license from such third party to continue developing, manufacturing, and marketing verekitug or any other potential future product candidates and our technologies. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to it, and it could require us to pay substantial licensing fees and/or make ongoing royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize verekitug or any other potential future product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. While less likely given the high bar required for injunction, we also could be temporarily or permanently forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed on a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and growth prospects.

The defense of third-party claims of alleged infringement or misappropriation of a third party's intellectual property rights often involves substantial litigation expense and could also be a substantial diversion of management and employee time and resources from our business. Some third parties may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and growth prospects. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications are due to be paid to the USPTO and foreign patent agencies outside of the United States over the lifetime of our patents and applications. If, in the future, we in-license patent rights, in the case of any in-licensed patent rights, we generally rely on our licensors to pay these fees due to U.S. and non U.S. patent agencies. For patent rights we own, we may rely on our outside patent counsel and/or annuity services in the United States and foreign countries to monitor these deadlines and to pay these fees when so instructed by us.

The USPTO and foreign patent agencies require compliance with procedural, documentary, fee payment, and other similar provisions, such as the requirement to disclose known prior art, during the patent application process. In the case of any in-licensed patent rights, we will generally depend on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property, and for our owned patent applications, we engage counsel and other professionals to help us comply with these requirements. While certain inadvertent lapses can be cured by payment of a late fee, by petition, or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in a partial or complete loss of patent rights in the relevant jurisdiction. In the unlikely event that a non-compliance event were to occur, our competitors might be able to enter the market with similar or identical products or technology given our partial or complete loss of patent rights, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Patent terms may be inadequate to protect our competitive position on verekitug or any other potential future product candidates for an adequate amount of time.

Patents have a limited lifespan. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from the earliest non provisional filing date in the applicable country. However, the actual protection afforded by a patent varies from country to country, and also depends upon many factors, including the type of patent, the scope of coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent, and whether a portion of the patent term has been terminally disclaimed based on other patents. Various extensions including patent term extension and patent term adjustment may be available, but the lives of such extensions, and the protections they afford, are limited. Even if patents covering verekitug or any other potential future product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting verekitug or any other potential future product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours for an adequate time period.

If we do not obtain sufficient patent term protections for verekitug or any other potential future product candidates, our business may be materially harmed.

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Additional patent terms may be available through a patent term adjustment process, resulting from USPTO delays during prosecution. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering verekitug or any other potential future product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from generics or biosimilars.

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

Despite the possibility of an extension, we may not be granted an extension for which it applies in the United States or any other jurisdiction because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time or the scope of patent protection afforded could be less than we request.

If we are unable to obtain patent term extension or restoration, or the foreign equivalent, or the term of any such extension is less than we request, our competitors or other third parties may obtain approval of competing drugs following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors or other third parties may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their drug

earlier than might otherwise be the case. Any of the foregoing could materially harm our business, financial condition, results of operations and growth prospects.

Changes in patent law in the United States and in non U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our technologies and verekitug or any other potential future product candidates.

As is the case with other biotech and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and are therefore costly, time consuming and inherently uncertain. Recent rulings from the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have narrowed the scope of patent protection available in specified circumstances and weakened the rights of patent owners in specified situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

In addition, U.S. Supreme Court rulings over the past decade have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of issued patents. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce and/or defend our existing patents and patents that we might obtain in the future.

The USPTO has issued subject matter eligibility guidance instructing USPTO examiners on the ramifications of the Supreme Court rulings in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Association for Molecular Pathology v. Myriad Genetics, Inc.*, and applied the *Myriad* ruling to natural products and principles including all naturally occurring molecules. In addition, the USPTO continues to provide updates to its guidance continues to be a developing area. The USPTO guidance may make it impossible for us to obtain similar patent claims in future patent applications. Currently, our patent portfolio contains claims of various types and scope, including methods of medical treatment. The presence of varying types of claims in our patent portfolio significantly reduces, but may not eliminate, our exposure to potential validity challenges.

On May 10, 2024, the USPTO issued a proposed rule to change terminal disclaimer practice to add a new requirement for terminal disclaimers filed to obviate (overcome) nonstatutory double patenting. Under the proposed rule, to overcome double patenting a patentee would need to agree that a patent with a terminal disclaimer will be enforceable only if the patent is not tied and has never been tied through one or more terminal disclaimers to a patent in which any claim has been finally held unpatentable or invalid over prior art. If this proposed rule becomes a final rule, it could significantly limit our patent rights and the ability to enforce them.

For our U.S. patent applications, which contain claims entitled to priority after March 16, 2013, there is a greater level of uncertainty due to the Leahy-Smith Act. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has promulgated regulations and developed procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not come into effect until March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

Among some of the other changes introduced by the Leahy-Smith Act are changes that limit where a patentee may file a patent infringement suit and new procedures providing opportunities for third parties to challenge any issued patent in the USPTO. Included in these new procedures is a process known as Inter Partes Review ("IPR"), which has been generally used by many third parties since the enactment of the Leahy-Smith Act to invalidate patents. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Additionally, the rights of review and appeal for IPR decisions is an area of law that is still developing.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing its inventions in Russia or from selling or importing products made using its inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and growth prospects may be adversely affected.

In addition, a European Unified Patent Court ("UPC") came into force on June 1, 2023. The UPC will be a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of a European patent in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Although we do not currently own any European patents, if we obtain such patents and applications in the future, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time and may adversely affect our ability to enforce or defend the validity of any European patents obtained. We may decide to opt out from the UPC for any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

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

In addition to seeking patents for our technologies and verekitug or any other potential future product candidates, we also rely on trade secret protection, as well as confidentiality agreements, non-disclosure agreements and assignment agreements with our employees, consultants and third parties, to protect our know-how and other confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable.

It is our policy to require our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements generally provide that all confidential information concerning our business or financial affairs developed by or made known to an individual or entity during the course of that party's relationship with us are to be kept confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements also provide that all inventions conceived by the individual, and that are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In the case of consultants and other third-party service providers, the agreements provide us with certain rights to all inventions arising from the services provided to us by those individuals or entities. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technologies and processes. Additionally, the assignment of intellectual property rights may not be self-executing, or assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. We may not be able to obtain

adequate remedies for any breaches of such agreements. Ultimately, enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time consuming, and the outcome is unpredictable.

In addition to contractual measures, we protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect despite these precautions. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. In addition, our trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any of that information was independently developed by a competitor, our competitive position could be harmed.

If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. In addition, courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets. Even if we are successful, these types of lawsuits may consume, in addition to substantial costs, significant amounts of our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Third parties may assert that our employees, consultants, or advisors have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals that are currently or were previously employed at universities, research institutions or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we employ measures to ensure that our employees, consultants, and advisors 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 inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We may then be directly or indirectly involved in litigation proceedings to defend against these claims. If we fail in defending against any such claims, in addition to potentially paying monetary damages, we may lose valuable intellectual property rights and/or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish verekitug or any other potential future product candidates that are approved for marketing from the products of our competitors. However, our trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we benefit from to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties 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 allegations of trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversions of resources and could adversely affect our business, financial condition, results of operations and growth prospects.

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

Intellectual property rights do not necessarily address all potential threats.

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

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

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

Risks related to ownership of our common stock

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

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

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

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

- the commencement, enrollment, completion or results of our current or future preclinical and clinical trials for verekitug or any other potential future product candidates;
- any delay in identifying and advancing a clinical candidate for our other programs;
- any delay in our regulatory filings for verekitug or any other potential future product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays, suspensions or terminations in future preclinical studies or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of verekitug or any other potential future product candidates or the failure of a regulatory authority to accept data from preclinical studies or clinical trials conducted in other countries;
- changes in laws or regulations applicable to verekitug or any other potential future product candidates, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize verekitug or any other potential future product candidates, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to verekitug or any other potential future product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly and annual operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or verekitug or any other potential future product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;

- changes in the structure of the healthcare payment systems;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices, such as the adoption of a new accounting standard;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general geopolitical, industry and macroeconomic conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, tariffs (including tariffs that have been or may in the future be imposed by the United States or other countries), sanctions, trade protection measures or other trade barriers (including further legislation or actions taken by the United States or other countries that restrict trade), social, political and economic risks and military acts of war or terrorism; and
- other events or factors, many of which are beyond our control.

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

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

Our quarterly and annual operating results may fluctuate significantly, due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and, if approved, commercialization activities relating to verekitug or any other potential future product candidates, which may change from time to time;
- the timing and status of enrollment for clinical trials;
- the cost of manufacturing verekitug or any other potential future product candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- timing and amount of any milestone, royalty or other payments due under any collaboration or license agreement;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and clinical trials for verekitug or any other potential future product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the timing of receipt of approvals for verekitug or any other potential future product candidates from regulatory authorities in the United States and internationally;
- exchange rate fluctuations;
- coverage and reimbursement policies with respect to verekitug or any other potential future product candidates, if approved, and potential future drugs that compete with our products; and
- the level of demand for verekitug or any other potential future product candidates, if approved, which may vary significantly over time.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our future revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if any forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. Similarly, if one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Our executive officers, directors, principal stockholders and their respective affiliates own a significant percentage of our common stock and have the ability to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates collectively own a significant percentage of our outstanding common stock. As a result, these stockholders, if acting together, have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with the interests of our other stockholders. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

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

Additionally, certain holders of our common stock have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 under the Securities Act or until the rights terminate pursuant to the terms of the stockholder agreements between us and such holders. We have registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans, and those shares are available for sale in the open market, unless such shares are subject to vesting restrictions with us or lock-up restrictions. Once we register the offer and sale of shares for the holders of registration rights, they can be freely sold in the public market upon issuance, subject to the lock-up agreements.

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

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies,

products or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

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

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value for our common stock, which is not certain.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Our third amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of not less than two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our third amended and restated certificate of incorporation or amended and restated bylaws.

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

Our second amended and restated bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our second amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our third amended and restated certificate of incorporation or our second amended and restated bylaws (including the interpretation, validity or enforceability thereof), or (iv) any action asserting a claim that is governed by the internal affairs doctrine (the "Delaware Forum Provision"). The Delaware Forum

Provision does not apply to any causes of action arising under the Securities Act or the Exchange Act. Our second amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act or the Exchange Act (the "Federal Forum Provision"). In addition, our second amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

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

We may not be able to continue to satisfy the listing requirements of Nasdaq.

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

Other general risks

Unfavorable global economic and market volatility resulting from geopolitical conditions, including those affecting the financial services industry, could adversely affect our business, financial condition, stock price, and results of operations.

Our business could be adversely affected by unstable economic and political conditions within the United States and foreign jurisdictions, including as a result of an economic downturn and geopolitical events, such as changes in or disruptions of U.S. governmental agencies, whether from a prolonged U.S. federal government shutdown or reduced resources, disruptions in capital markets, the potential for significant changes in U.S. federal policies or regulatory environment that affect the geopolitical landscape. Changes to U.S. policy implemented by the U.S. Congress or U.S. presidential administrations have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Since the start of the most recent U.S. presidential administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. For example, the implementation of tariffs by the U.S. government has led to increased trade and political tensions, between not only the U.S. and China, but also between the U.S. and other countries in the international community. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Additionally, in September 2025, the current administration also announced a 100% tariff on brand-name or patented drugs unless pharmaceutical companies expand their manufacturing operations in the U.S., and may impose more restrictions on goods. Although the pharmaceutical tariff is currently on hold, this could have a material adverse effect on our supply chain and business prospects as well as the larger biopharmaceutical industry. While certain tariffs have subsequently been suspended, modified or temporarily reduced, we cannot predict the results of the U.S. government's trade negotiations or the outcome of ongoing legal challenges to specific tariff policies. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Additionally, severe or prolonged economic downturn or additional global financial crises could result in a variety of risks to our business, including weakened demand for any product candidates we develop or our ability to raise additional capital when needed on acceptable terms, if at all. For example, on October 1, 2025, the U.S. federal government shut down through November 12, 2025, suspending services deemed non-essential as a result of the failure by Congress to enact regular appropriations for the 2026 fiscal year. If we experience another prolonged government shutdown, it could result in increased uncertainty and volatility in the global economy and financial markets which could have a material adverse effect on our business. Weak economic conditions or significant uncertainty regarding the stability of financial markets related to stock market volatility, inflation, recession, changes in tariffs or other trade restrictions, trade agreements, trade wars or governmental fiscal, monetary and tax policies, among others, could adversely impact our business, financial condition and operating results.

The global credit and financial markets have also generally experienced extreme volatility and disruptions (including as a result of actual or perceived changes in interest rates, inflation and macroeconomic uncertainties), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, global supply chain disruptions, and increases in unemployment rates. The financial markets and the global economy may also be adversely affected by military conflict, including the ongoing conflicts between Russia and Ukraine, and Israel and Hamas, terrorism, or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for verekitug or any other potential future product candidates and in our ability to raise additional capital when needed on acceptable terms, if at all.

In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at certain of these institutions may exceed insured limits. Market conditions and changes in financial regulations and policies can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. In addition, changes in regulations governing financial institutions are beyond our control and difficult to predict;

consequently, the impact of such changes on our business and results of operations is difficult to predict and may have an adverse effect on us.

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

Natural disasters or public health crises could severely disrupt our operations, and have a material adverse impact on our business, financial condition, results of operations and growth prospects. If a natural disaster, power outage, public health crisis or other event occurred that prevented us from conducting our clinical trials, releasing clinical trial results or delaying our ability to obtain regulatory approval for verekitug or any other potential future product candidates, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

We are eligible to be treated as an "emerging growth company" and a "smaller reporting company" and our election of reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

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

- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements;
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved;
- an exemption from compliance with the auditor attestation requirements of Section 404 in the assessment of our internal control over financial reporting; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.235 billion; (ii) December 31, 2029; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during any three-year period before that time; or (iv) the date on which we are deemed to be a "large accelerated filer", which would occur if the aggregate market value of our equity securities held by non-affiliates exceeds $700.0 million as of the last business day of our most recently completed second fiscal quarter. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies.

In addition, the JOBS Act provides that an emerging growth company can also take advantage of an extended transition period for complying with new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we are not subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

Even after we no longer qualify as an emerging growth company, we could still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements and reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

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

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect

to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), as well as rules subsequently adopted by the SEC and The Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act") was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period lasting up to five years after completion of a company's IPO. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have substantially increased, and will continue to increase, our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. These increased costs will continue to decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be reevaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We have begun the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which requires an annual management assessment of the effectiveness of our internal control over financial reporting. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company or a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We could be an emerging growth company for up to five years following the completion of our IPO. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

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

We are subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can

be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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

As of December 31, 2025, we had federal and state net operating loss ("NOLs") carryforwards of $66.9 million and $92.9 million, respectively. The federal NOLs are not subject to expiration and are limited in utilization to 80% of our taxable income and the state NOLs begin to expire in 2041. As of December 31, 2025, we had federal and state research and development credits of $5.7 million and $1.2 million, respectively, which will, if not utilized, begin to expire in 2043 and 2037, respectively. Our ability to utilize these NOLs to offset future tax liabilities depends on the successful development of our product candidates and future financial performance.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by "5 percent shareholders" over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. A corporation that experiences an ownership change will generally be subject to an annual limitation on the use of its pre-ownership change NOLs equal to the value of the corporation immediately before the ownership change, multiplied by the long-term tax-exempt rate (subject to certain adjustments). We may have experienced ownership changes in the past and may experience ownership changes in the future. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs by federal or state taxing authorities or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities. As a result, our ability to use our pre-change NOLs and tax credits to offset future taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. For example, the OBBBA was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. Under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development performed outside the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and development performed in the U.S. may, at the taxpayer's election, be immediately deducted or capitalized and amortized. In addition, the OBBBA provides that for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the U.S. in such taxable years by filing amended tax returns for such taxable years, and all other taxpayers that are not eligible to make such an election and that amortized expenses for research and development performed in the U.S. in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the two-taxable year period beginning with the first taxable year beginning after December 31, 2024. In recent years, many changes to tax laws have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to 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 become involved in securities class action litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

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

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cyber Risk Management and Strategy

We have adopted processes for assessing, identifying, and managing cybersecurity risks, that are integrated into our overall enterprise management framework, built into our information technology function and are designed to help protect our information assets and operations from internal and external cybersecurity threats, protect employee and clinical trial information from unauthorized access or attack, as well as secure our networks and systems. Such processes include physical, procedural, and technical safeguards, and periodic review of our procedures in an effort to identify risks and refine our practices. To support our internal resources, we leverage external tools and resources, including a managed service provider that provides ongoing support for the protection of our information technology infrastructure.

We have an employee security awareness program, required upon onboarding and on an annual basis thereafter, that is designed to raise awareness of cybersecurity threats across functions. As part of this employee training program, we periodically conduct phishing tests. We have also implemented a process to assess and review the cybersecurity practices of certain third-party vendors and service providers that may be critical to the operations of our business and who have access to our information systems including, as appropriate, through the inclusion of cybersecurity requirements in our contracts.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition; however, like other companies in our industry, we and our third-party vendors may, from time to time, experience threats and security incidents relating to our and our third-party vendors' information systems. For more information, see "*Risk Factors–Risks related to our dependence on third parties–Our information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches, which could adversely affect our business.*"

Governance Related to Cybersecurity Risks

Our audit committee of the board of directors, (the "Audit Committee"), is responsible for overseeing cybersecurity risk, pursuant to the Audit Committee charter, and periodically updates our board of directors on such matters. The Audit Committee receives periodic updates from management regarding cybersecurity matters, and we have a process for the Audit Committee to be notified between such updates in the event of any significant new cybersecurity threats or incidents.

Management is responsible for the operational oversight of company-wide cybersecurity strategy, policy, and standards across relevant departments to assess and help prepare us to address cybersecurity risks. Our Senior Manager of Information Technology reports to our Chief Financial and Operating Officer and oversees the day-to-day implementation and management of our cybersecurity program. Our Senior Manager of Information Technology has approximately 20 years of experience in information technology and regularly reports to executive management, the company's disclosure committee, and the Audit Committee on cyber matters, as appropriate.

Item 2. Properties.

Our corporate headquarters is presently located in Waltham, Massachusetts, where we lease and occupy 16,801 square feet of office space. The initial term of the lease expires on November 1, 2027, with an option to extend the lease for an additional three years thereafter.

We believe that our leased premises will be sufficient for our needs for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

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 has traded on the Nasdaq Global Select Market under the symbol "UPB" since October 11, 2024. Prior to that date, there was no public trading market for our common stock.

Holders

As of March 20, 2026, we had three holders of record of our common stock. The actual number of stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We do not intend to pay cash dividends to our stockholders in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

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

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated by reference herein to Part III, Item 12 of this Annual Report on Form 10-K.

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds

On October 10, 2024, our Registration Statement on Form S-1 (No. 333-282197) for our initial public offering ("IPO") was declared effective by the Securities and Exchange Commission (the "SEC").

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on October 11, 2024 (File No. 333-282197).

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. [Reserved]

Not applicable.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K (this "Annual Report"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review "Item 1A, Risk Factors" of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Please also see the section titled "Special note regarding forward-looking statements" included elsewhere in this Annual Report.

Overview

We are a clinical-stage biotechnology company developing treatments for inflammatory diseases, with an initial focus on severe respiratory disorders. We are developing verekitug, the only known antagonist currently in clinical development that targets the receptor for Thymic Stromal Lymphopoietin ("TSLP"), a cytokine which is a clinically validated driver of inflammatory response positioned upstream of multiple signaling cascades that affect a variety of immune mediated diseases. Preclinical and clinical data to date demonstrate verekitug's highly potent inhibition of the TSLP receptor, which we believe will translate to a differentiated product profile, including improved clinical outcomes, substantially extended dosing intervals and the potential to treat a broad spectrum of patients. We have advanced this highly potent monoclonal antibody into separate Phase 2 trials for the treatment of severe asthma, including a long-term safety and efficacy extension study ("Phase 2 LTE"), chronic rhinosinusitis with nasal polyps ("CRSwNP"), and chronic obstructive pulmonary disease ("COPD"). We reported positive top-line results in our CRSwNP Phase 2 trial in September 2025 and positive top-line results in our severe asthma Phase 2 trial in February 2026. We initiated our Phase 2 COPD trial in July 2025. We plan to initiate dosing in Phase 3 trials in both severe asthma and CRSwNP in the first quarter of 2027, prioritizing a Phase 3 development strategy that focuses on maximizing efficacy in both indications, without biomarker restriction, with quarterly at-home administration. Our experienced team is committed to maximizing verekitug's unique attributes to address the substantial unmet needs for patients underserved by today's standard of care.

Since our inception, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, establishing licensing, building our proprietary platform technologies, developing verekitug, establishing our intellectual property portfolio, conducting research, preclinical studies, and clinical trials, establishing arrangements with third parties for the manufacture of verekitug and related raw materials, and providing general and administrative support for these operations. To date, we have financed our operations primarily through the issuance and sale of our redeemable convertible preferred stock and proceeds from our initial public offering ("IPO"). As of December 31, 2025, we have received total gross proceeds of $400.0 million from the issuance and sale of our redeemable convertible preferred stock. In October 2024, we completed our IPO in which we issued and sold 17,250,000 shares of our common stock, including 2,250,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $17.00 per share. As a result of the IPO, we received $268.8 million in net proceeds, after deducting $20.5 million in underwriting discounts and commissions, and $3.9 million in other offering costs.

We have incurred significant net operating losses and negative cash flows since our inception. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful development, regulatory approval and eventual commercialization of verekitug and any other potential future product candidates, which we expect will take a number of years. For the years ended December 31, 2025 and 2024, we reported net losses of $143.4 million and $62.8 million, respectively. Our net losses have resulted principally from costs incurred in our research and development activities. As of December 31, 2025, we had an accumulated deficit of $334.2 million, and we had cash, cash equivalents and short-term investments of $341.5 million. Based on our current operating plan, we believe that our existing cash and cash equivalents and short-term investments will be sufficient to fund our operating expenses and capital expenditure requirements through 2027.

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

- continue to conduct our ongoing clinical trials of verekitug, including our global Phase 2 clinical trials, as well as initiate and complete additional clinical trials of verekitug in new indications or patient populations;
- conduct larger-scale clinical trials for verekitug or any potential future product candidates;
- manufacture, or have manufactured, clinical and commercial supplies of verekitug;

- seek regulatory approvals, prepare for and, if approved, proceed to commercialization for verekitug in current or new indications or any potential future product candidates;
- attract, hire and retain additional clinical, scientific, and management personnel;
- implement operational, financial, and management information systems;
- add quality control, quality assurance, legal, compliance, and other groups to support our operations;
- obtain, maintain, protect, expand and enforce our intellectual property portfolio, including intellectual property obtained through license agreements;
- defend against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- make royalty, milestone or other payments under current, and any future, license or collaboration agreements;
- establish a sales, marketing and distribution infrastructure, either ourselves or in partnership with others, to commercialize verekitug, if approved;
- potentially experience any delays, challenges, or other issues associated with the clinical development of verekitug and any potential future product candidates, including with respect to our regulatory strategies; and
- incur additional legal, accounting, investor relations and other general and administrative expenses associated with operating as a public company.

Our net operating losses may fluctuate significantly from period to period, depending upon the timing of our expenditures on research and development activities. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses and other current liabilities.

As a result, we will need additional financing to support our continuing operations. To date, we have funded our operations primarily with the sale of our redeemable convertible preferred stock and the proceeds from our IPO. We do not have any products approved for sale and have not generated any revenue from product sales since our inception. We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates and commercialize our products or enter into collaboration arrangements with third parties. Until we can generate sufficient product revenue to finance our cash requirements, if ever, we expect to fund our operations through equity offerings or debt financings, credit or loan facilities, potentially other capital resources, or a combination of one or more of these funding sources. We may be unable to raise additional funds or enter into other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back, or discontinue the development or commercialization of verekitug and one or more potential future product candidates, which could have a material adverse effect on our business, results of operations or financial condition.

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

Asset purchase and license agreements

Below is a summary of the key terms for certain of our asset purchase and license agreements. For a more detailed description of these agreements, see the section titled "Business—Asset purchase and license agreements" included elsewhere in this Annual Report.

Asset purchase agreement with Astellas and related letter agreement with Astellas and Regeneron

In October 2021, we entered into an asset purchase agreement (the "Astellas Asset Purchase Agreement") with Astellas Pharma, Inc. ("Astellas"). Pursuant to the Astellas Asset Purchase Agreement, we purchased from Astellas the compound designated by Astellas as ASP7266 (the "Compound," which was subsequently renamed by us as verekitug). There are no future payments owed to Astellas under the Astellas Asset Purchase Agreement.

In connection with the Astellas Asset Purchase Agreement, we concurrently entered into a letter agreement (the "Regeneron Letter Agreement") with Astellas and Regeneron Pharmaceuticals, Inc. ("Regeneron").

The Regeneron Letter Agreement relates to a prior Non-Exclusive License and Material Transfer Agreement (the "Terminated Regeneron License Agreement") that Regeneron and Astellas entered into in March 2007, as amended in July 2010 and subsequently terminated in June 2018, subject to certain surviving rights and obligations of both Regeneron and Astellas. Under the Terminated Regeneron License Agreement, Astellas utilized Regeneron's human antibody technology in its internal research programs to discover certain product candidates, including the Compound, which it sold to us under the Astellas Asset Purchase Agreement.

Under the Regeneron Letter Agreement, Astellas assigned and transferred to us and we assumed and accepted certain of Astellas' surviving rights and obligations under the Terminated Regeneron License Agreement, including Astellas' royalty payment, reporting and indemnification obligations in connection with activities conducted by us or on our behalf with respect to the Compound. By assuming and accepting Astellas' surviving obligations under the Terminated Regeneron License Agreement, we are required to pay Regeneron mid-single-digit percentage royalties on aggregate worldwide net sales of any product developed by or on behalf of us that contains the Compound as an ingredient or component of the materials sold (a "Royalty Product") during the royalty term. The royalties are determined on a product-by-product and country-by-country basis and expire on the later of (i) a specified number of years after the launch of a given Royalty Product in a given country and (ii) the expiration of the last valid claim of royalty bearing company patent rights claiming or covering such Royalty Product in such country. To date, we have not made any royalty payments to Regeneron under the Regeneron Letter Agreement.

Exclusive license agreement with Maruho

In October 2021, we entered into a license agreement with Maruho (as amended, the "Maruho License Agreement"), under which we granted Maruho an exclusive, irrevocable, perpetual, royalty-free, sublicensable (subject to our right of first negotiation) license. Under the Maruho License Agreement, Maruho is responsible for and controls, at its sole expense, (i) the preparation, filing, prosecution, obtaining and maintaining all regulatory approvals in Japan and (ii) the promotion, marketing, sale and commercialization in Japan.

Pursuant to the Maruho License Agreement, we maintain our responsibility for and control the global research and development of the Maruho license product, including in Japan. We will conduct specified clinical trial activities for Japan as part of our global research and development plan. Maruho will reimburse us for the costs of these research and development activities, including the cost of drug supply. Apart from reimbursement of qualifying research and development expenses, Maruho is not obligated to make any future payments under the Maruho License Agreement.

During the years ended December 31, 2025 and 2024, we received payments from Maruho in the amount of $2.8 million and $1.9 million, respectively.

License agreement with Lonza

In October 2021, in connection with the Astellas Asset Purchase Agreement, we entered into a license agreement with Lonza Sales AG ("Lonza") (as amended, the "Lonza License Agreement"). Pursuant to the Lonza License Agreement, we obtained a worldwide, non-exclusive, sublicensable (subject to Lonza's right of pre-approval with respect to any sublicense of manufacturing activities) license to certain intellectual property rights owned by Lonza. Lonza was the originator of the master cell bank for the Compound developed by Astellas. As consideration for the rights and licenses granted to us under the Lonza License Agreement, we agreed to pay Lonza certain royalties and annual payments, both payable in Swiss francs, in respect of the manufacturing and sale of the Compound, such amounts to be determined by the party manufacturing the Compound, and range from no annual payment to up to a mid-six figure annual payment, and a less-than-one percent to a low-single-digit percentage royalty on net sales of the Compound. In accordance with the Lonza License Agreement, we entered into a sublicense with Wuxi Biologics (Hong Kong) Limited to manufacture the Compound, requiring us to pay a mid-six-figure annual fee to Lonza pursuant to this provision. Any royalties due under the Lonza License Agreement are payable on a country-by-country basis until ten years from the first commercial sale of the Compound in that particular country. The Lonza agreement continues for an indefinite period of time unless otherwise terminated. We have the right to terminate the Lonza License Agreement at any time by providing prior written notice to Lonza. During each of the years ended December 31, 2025 and 2024, we made an annual payment to Lonza in the amount of $0.5 million pursuant to the Lonza License Agreement. These payments are recognized as research and development expense in the consolidated statements of operations and comprehensive loss. To date, we have not made any royalty payments to Lonza under the Lonza License Agreement.

Components of our results of operations

Collaboration revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales in the foreseeable future. All of our collaboration revenue has been derived from the Maruho License Agreement. If our development efforts for verekitug or any potential future product candidates are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales, royalties or payments from such collaboration or license agreements, or a combination of product sales and payments from such agreements.

Operating expenses

Research and development expenses

Research and development expenses consist primarily of costs incurred for our preclinical research and clinical development of verekitug, which include:

- expenses incurred under agreements with third parties, including contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and investigative sites that conduct clinical trials on our behalf, and costs related to the Maruho License Agreement;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions and costs related to the Maruho License Agreement;
- costs of outside consultants, including their fees and related travel expenses; and
- costs associated with license agreements to support the development of our technology.

We expense all research and development expenses in the periods in which they are incurred. Our direct research and development expenses are tracked on an indication-by-indication basis and consist of costs that include CROs and investigative sites that conduct clinical trials on our behalf, third party vendors that conduct research and preclinical studies on our behalf and outside consulting costs directly allocable to an indication. We do not allocate costs related to CMOs that manufacture verekitug for use in our preclinical studies and clinical trials as they are not distinguishable by indication but support all current and potential indications under our verekitug program. Additionally, we do not allocate costs for employee costs, including stock-based compensation, consulting, or other indirect costs that cannot be directly allocated to a specific indication.

We expect that our research and development expenses will increase in the future as we advance verekitug through clinical trials and any potential future product candidates that we may develop through preclinical studies and clinical trials, in pursuit of regulatory approval. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of verekitug and any potential future product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales or licensing of verekitug or any potential future product candidates. This is due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- the scope, timing, progress, costs and results of the ongoing development of verekitug as well as for potential discovery, preclinical development and clinical trials for other potential future product candidates;
- the number of clinical trials required for regulatory approval of verekitug or our potential future product candidates;
- the costs, timing and outcome of regulatory review of verekitug or our potential future product candidates;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses;
- the cost of manufacturing clinical supplies of verekitug or our potential future product candidates;
- the costs associated with hiring additional clinical, quality control, medical, scientific and other technical personnel to support the ongoing development of verekitug;

- the costs associated with increasing our headcount as we expand our research and development organization and market development and pre-commercial planning activities;
- the effectiveness of our approach to identifying target patient populations;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the effect of macroeconomic trends including inflation and rising interest rates; and
- addressing any potential supply chain interruptions or delays.

A change in the outcome of any of these factors or underlying variables with respect to the development of a product candidate could significantly change the costs and timing associated with the development of that product candidate.

General and administrative expenses

General and administrative expenses consist primarily of salaries and benefits, including stock-based compensation expense, for personnel in executive, finance, accounting, legal, human resources, business development, information technology, and other administrative functions. General and administrative expenses also include legal fees relating to patents and corporate matters; professional fees for accounting, auditing, tax, and consulting services; insurance costs; travel expenses; and facility-related expenses, which include depreciation costs and expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our headcount and expand our infrastructure to support the continued research and development of our programs and the growth of our business. We also expect to incur increased expenses associated with operating as a public company, including costs of accounting, audit, legal, regulatory, tax-related services, compliance with SEC rules and regulations and listing requirements, director and officer insurance premiums and investor relations costs.

Other income (expense)

Change in fair value of preferred stock tranche right liability

In connection with our Series B redeemable convertible preferred stock ("Series B Preferred Stock") financing, we issued shares under a stock purchase agreement that provided an obligation for us to issue additional Series B Preferred Stock in subsequent closings upon the satisfaction of certain conditions. The Series B tranche right liability was settled in April 2024 upon the satisfaction of relevant conditions. We classified the preferred stock tranche right as a liability on our consolidated balance sheets and initially recorded it at fair value upon the issuance date of the right. We remeasured the tranche right liability to fair value at each reporting date and immediately prior to being settled, and recognized changes in the fair value of the preferred stock tranche right liability as a component of other income (expense) in our consolidated statements of operations and comprehensive loss. Upon settlement of the tranche right, we derecognized the related liability, and stopped recognizing changes in the fair value of the preferred stock tranche right liability.

Interest income

Interest income consists of interest earned on money market funds, U.S. treasury bills and U.S. government agency bond investments.

Other income (expense), net

Other income (expense), net consists of miscellaneous income and expense unrelated to our core operations.

Income taxes

We recorded a full valuation allowance of our deferred tax asset position as of December 31, 2025 and 2024 as we believe it was more likely than not that we would not be able to utilize our deferred tax assets.

As of December 31, 2025, we had federal and state net operating losses ("NOLs") carryforwards of $66.9 million and $92.9 million, respectively. The federal NOLs are not subject to expiration and are limited in utilization to 80% of taxable income and

the state NOLs begin to expire in 2041. As of December 31, 2025, we had federal and state research and development credits of $5.7 million and $1.2 million, respectively, which will, if not utilized, begin to expire in 2043 and 2037, respectively.

On July 4, 2025, new U.S. tax legislation was signed into law (known as the "One Big Beautiful Bill Act" or "OBBBA") which makes permanent many of the tax provisions enacted in 2017 as part of the Tax Cuts and Jobs Act that were set to expire at the end of 2025. In addition, the OBBBA makes changes to certain U.S. corporate tax provisions, but many are generally not effective until 2026. The impacts of the OBBBA were not material to the 2025 consolidated financial statements; however, we will continue to evaluate impacts to future periods.

Results of operations

Comparison of the years ended December 31, 2025 and 2024

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

	Year Ended December 31,		
	2025	2024	Change
		(in thousands)	
Collaboration revenue	$ 2,854	$ 2,370	$ 484
Operating expenses:			
Research and development	136,806	62,966	73,840
General and administrative	26,409	17,168	9,241
Total operating expenses	163,215	80,134	83,081
Loss from operations	(160,361)	(77,764)	(82,597)
Other income (expense):			
Change in fair value of preferred stock tranche right liability	—	2,859	(2,859)
Interest income	16,933	12,123	4,810
Other expense, net	(15)	(24)	9
Total other income, net	16,918	14,958	1,960
Net loss	$ (143,443)	$ (62,806)	$ (80,637)

Collaboration revenue

Collaboration revenue was $2.9 million and $2.4 million for the years ended December 31, 2025 and 2024. Revenue during each of the years ended December 31, 2025 and 2024 was primarily related to the work performed associated with our Phase 2 clinical trial in patients with severe asthma under the Maruho License Agreement.

Research and development expenses

	Year Ended December 31,		
	2025	2024	Change
		(in thousands)	
Direct research and development expenses by program:			
Verekitug program:			
Asthma indication	$ 47,694	$ 28,069	$ 19,625
COPD indication	34,562	3,115	31,447
CRSwNP indication	7,564	10,524	(2,960)
Unallocated research and development expense:			
Manufacturing costs	23,013	6,580	16,433
Personnel expenses (including stock-based compensation)	18,343	9,911	8,432
Professional fees	2,940	2,062	878
Other unallocated expenses	2,690	2,705	(15)
Total research and development expense	$ 136,806	$ 62,966	$ 73,840

Research and development expenses were $136.8 million for the year ended December 31, 2025 compared to $63.0 million for the year ended December 31, 2024. The increase of $73.8 million was primarily driven by an increase of $48.1 million in expenses directly related to our verekitug program and $25.7 million of unallocated research and development expenses.

The increase in direct costs of $31.5 million related to the COPD indication was due to the costs associated with the initiation of our COPD Phase 2 clinical trial for which there were no comparable expenses during the same period in 2024. The increase in direct costs of $19.6 million related to the asthma indication was primarily due to the continued progress associated with our Phase 2 clinical trial and Phase 2 LTE study during the year ended December 31, 2025, compared to the same period in 2024. The decrease in direct costs of $3.0 million related to the CRSwNP indication was primarily due to wind down activities associated with our Phase 2 clinical trial during the year ended December 31, 2025 compared to the same period in 2024.

The increase in manufacturing costs of $16.4 million was primarily attributable to an increase in CMO costs for the development of Phase 3 clinical material, partially offset by a decrease in CMO costs for the development of Phase 2 clinical material during the year ended December 31, 2025, compared to the same period in 2024. The increase in personnel expenses of $8.4 million was primarily due to increased headcount in our research and development functions. Personnel expenses for the years ended December 31, 2025 and 2024 included stock-based compensation expense of $2.9 million and $1.2 million, respectively. The increase of $0.9 million in professional fees was related to consulting services to support our verekitug program.

We begin to separately track program expenses at development candidate nomination. Through December 31, 2025, we have incurred approximately $98.7 million, $37.7 million and $21.5 million in direct external expenses for the development of verekitug for severe asthma, COPD and CRSwNP, respectively, since their development candidate nominations.

General and administrative expenses

	Year Ended December 31,		
	2025	2024	Change
		(in thousands)	
Personnel expenses (including stock-based compensation)	$ 15,188	$ 10,842	$ 4,346
Professional fees	6,718	4,349	2,369
Other	4,503	1,977	2,526
Total general and administrative expense	$ 26,409	$ 17,168	$ 9,241

General and administrative expenses were $26.4 million for the year ended December 31, 2025 compared to $17.2 million for the year ended December 31, 2024. The increase of $9.2 million was primarily driven by an increase in personnel expenses of $4.3 million due to increased headcount in our general and administrative functions. Personnel expenses for the years ended December 31, 2025 and 2024 included stock-based compensation expense of $7.5 million and $4.8 million, respectively. Additionally, there was an increase of $2.4 million in professional fees primarily due to increased market research, recruiting, legal and consulting costs. Other expenses increased by $2.5 million primarily due to an increase in corporate insurance, taxes and occupancy costs.

Other income (expense)

Change in fair value of preferred stock tranche right liability

We recorded other income for the change in the fair value of the preferred stock tranche right liability of $2.9 million for the year ended December 31, 2024 related to the Series B Preferred Stock tranche right liability, for which there was no comparable income during the year ended December 31, 2025 as the Series B tranche right liability was settled in April 2024. The change in fair value of the Series B Preferred Stock tranche right liability was due to changes in the assumptions used in the valuation model during the period, including the estimated fair value of the Series B Preferred Stock, volatility and estimated time to the tranche closing.

Interest income

Interest income was $16.9 million and $12.1 million for the years ended December 31, 2025 and 2024, respectively, representing an increase of $4.8 million. The increase in interest income was due to increased balances in our money market funds, U.S. treasury bills and U.S. government agency bonds held during the year ended December 31, 2025, as compared to the year ended December 31, 2024.

Liquidity and capital resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized verekitug and we do not expect to generate revenue from product sales of verekitug for the next several years, if at all. To date, we have funded our operations primarily with the sale of our redeemable convertible preferred stock and the proceeds from our IPO. Through December 31, 2025, we have received gross proceeds of $400.0 million from the issuance and sale of our redeemable convertible preferred stock and $268.8 million in net proceeds from our IPO. As of December 31, 2025, we had cash, cash equivalents and short-term investments of $341.5 million.

Cash flows

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

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Net cash used in operating activities	$ (133,275)	$ (59,172)
Net cash used in investing activities	(93,480)	(59,485)
Net cash provided by financing activities	2,441	418,910
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (224,314)	$ 300,253

Operating activities

During the year ended December 31, 2025, operating activities used $133.3 million of cash, resulting primarily from our net loss of $143.4 million and non-cash amortization of premiums and accretion of discounts on short-term investments of $1.5 million, partially offset by non-cash stock-based compensation expense of $10.3 million and changes in operating assets and liabilities of $0.6 million. Net cash provided by changes in operating assets and liabilities was primarily driven by a $4.0 million increase in accrued expenses and other current liabilities, partially offset by a $1.5 million increase in prepaid expenses and other current assets due to upfront payments to CROs for activities associated with our COPD Phase 2 trial and our Phase 2 LTE study in patients with severe asthma, a $1.3 million decrease in accounts payable and a $0.6 million decrease in operating lease liabilities.

During the year ended December 31, 2024, operating activities used $59.2 million of cash, resulting primarily from our net loss of $62.8 million, non-cash changes in fair value of the preferred stock tranche right liability of $2.9 million and non-cash amortization of premiums and accretion of discounts on short-term investments of $1.7 million, partially offset by changes in operating assets and liabilities of $1.9 million and non-cash stock-based compensation expense of $6.0 million. Net cash provided by changes in operating assets and liabilities was primarily driven by a $2.0 million increase in accounts payable and a $1.5 million increase in accrued expenses and other current liabilities, partially offset by a $1.0 million increase in prepaid expenses and other current assets and a $0.5 million increase in accounts receivable. The increase in accounts receivable resulted primarily from the timing of revenue recognition compared to the timing of payments from Maruho for qualifying reimbursable expenses related to the Maruho License Agreement.

For all periods presented, changes in prepaid expenses and other assets, accounts payable and accrued expenses and other current liabilities not described above were generally due to the growth in our business, the advancement of our clinical programs, and the timing of vendor invoicing and payments.

Investing activities

During the year ended December 31, 2025, net cash used in investing activities was $93.5 million, consisting primarily of purchases of short-term investments of $385.9 million, net of maturities of short-term investments of $292.6 million.

During the year ended December 31, 2024, net cash used in investing activities was $59.5 million, consisting primarily of purchases of short-term investments of $290.6 million, net of maturities of short-term investments of $231.6 million and purchases of property and equipment of $0.5 million.

Financing activities

During the year ended December 31, 2025, net cash provided by financing activities was $2.4 million, consisting primarily of proceeds from the exercise of stock options.

During the year ended December 31, 2024, net cash provided by financing activities was $418.9 million, consisting of $268.8 million in net proceeds from our IPO after deducting underwriters discounts and commissions, and offering costs, $149.9 million in net proceeds from the issuance of Series B Preferred Stock and $0.2 million in proceeds from the exercise of stock options.

Funding requirements

We expect our research and development and general and administrative expenses and our operating losses will increase in the future as we advance verekitug through clinical trials and any potential future product candidates that we may develop through preclinical studies and clinical trials, in pursuit of regulatory approval. Due to the numerous risks and uncertainties associated with research, development and commercialization of product candidates, changes in the outcome of any factors 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. In addition, we expect to incur increased expenses associated with operating as a public company. Our future capital requirements, both short- and long-term, will depend on a variety of factors, including, but not limited to:

- the rate of progress in the development of verekitug and our potential future product candidates, if any;
- the scope, progress, results and costs of non-clinical studies, preclinical development, laboratory testing and clinical trials for verekitug and any potential future product candidates and associated development programs;
- the number and scope of preclinical studies and clinical trials that we pursue;
- the costs, timing, and outcomes of seeking and obtaining approvals by the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more preclinical studies or clinical trials than those that we currently expect or for such authorities to change their requirements on studies that had previously been agreed to;
- our ability to establish licensing or collaboration agreements or other strategic agreements;
- the achievement of milestones or other developments under any licensing or collaboration agreements;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under any license or collaboration agreements;
- the costs to establish, maintain, expand, enforce, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the costs associated with successfully defending against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- the costs of acquiring, licensing, or investing in additional businesses, products, product candidates, and technologies that we may identify;
- the costs to manufacture or to have manufactured sufficient, reliable, timely, and affordable supply of materials including commercial-grade product formulations that can be used in clinical trials and for commercial launch;
- the costs of commercializing product candidates, if approved, whether alone or in collaboration with others;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of building or contracting sales, marketing, and/or distribution capabilities, systems, and internal infrastructure for any product candidate that receives marketing approval;
- the impact of competitors' product candidates and technological advances and other market developments;
- the expenses needed to attract and retain skilled personnel; and
- the size of the markets and degree of market acceptance of any product candidates in territories in which we receive regulatory approval, including product pricing, product coverage, and the adequacy of reimbursement by third-party payors.

Our business plans may change in the future and we will continue to require additional capital to meet the needs of our operating expenses. See the section titled "Risk factors—Risks related to our limited operating history, financial condition and need for additional capital" included elsewhere in this Annual Report.

We believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our operating expenses and capital expenditure requirements through 2027. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we would be required to delay, scale back or discontinue our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and other commitments

Asset acquisition from Astellas and related letter agreement with Astellas and Regeneron

In October 2021, we entered into the Astellas Asset Purchase Agreement with Astellas, and concurrently entered into the Regeneron Letter Agreement with Astellas and Regeneron.

Under the Regeneron Letter Agreement, Astellas assigned and transferred to us and we assumed and accepted certain of Astellas' surviving rights and obligations under the Terminated Regeneron License Agreement. By assuming and accepting Astellas' surviving obligations under the Terminated Regeneron License Agreement, we are required to pay Regeneron mid-single-digit percentage royalties on aggregate worldwide net sales of a Royalty Product during the royalty term.

The royalties are determined on a product-by-product and country-by-country basis and expire on the later of (i) a specified number of years after the launch of a given Royalty Product in a given country and (ii) the expiration of the last valid claim of royalty bearing company patent rights claiming or covering such Royalty Product in such country.

To date, we have not made any royalty payments to Regeneron under the Regeneron Letter Agreement.

License agreement with Lonza

As consideration for the rights and licenses granted to us under the Lonza License Agreement, we agreed to pay Lonza certain royalties and annual payments, both payable in Swiss francs, in respect of the manufacturing and sale of the Compound, such amounts to be determined by the party manufacturing the Compound, and range from no annual payment to up to a mid-six figure annual payment, and a less-than-one percent to a low-single-digit percentage royalty on net sales of the Compound. In accordance with the Lonza License Agreement, we entered into a sublicense with Wuxi Biologics (Hong Kong) Limited to manufacture the Compound, requiring us to pay a mid-six-figure annual fee to Lonza pursuant to this provision.

Any royalties due under the Lonza License Agreement are payable on a country-by-country basis until ten years from the first commercial sale of the Compound in that particular country.

During the years ended December 31, 2025 and 2024, we did not make any royalty payments to Lonza under the Lonza License Agreement. The Lonza agreement continues for an indefinite period of time unless otherwise terminated. We have the right to terminate the Lonza License Agreement at any time by providing prior written notice to Lonza.

During the years ended December 31, 2025 and 2024, we made an annual payment to Lonza in the amount of $0.5 million pursuant to the Lonza License Agreement. These payments were recognized as research and development expense in the consolidated statements of operations and comprehensive loss.

Lease agreement

In July 2024, we entered into a three-year agreement for office space located at 890 Winter Street in Waltham, Massachusetts. We began paying monthly rent starting one month after lease commencement. Initial base rent was approximately $0.7 million for the first year and approximately $0.8 million for the second and third year. The lease commenced in September 2024.

Research and development

We enter into contracts in the normal course of business with CROs and investigator sites that conduct clinical trials on our behalf, CMOs that manufacture product candidates for use in our preclinical studies and clinical trials, and third-party vendors, including CROs, that conduct research and preclinical studies on our behalf. Prepayments under these arrangements can generally be repurposed or the services themselves cancelable upon prior written notice, though cancellation fees are likely. Payments due upon cancellation consist only of payments for services provided and expenses incurred up to the date of cancellation.

Critical accounting estimates and significant judgments

Our management's discussion and analysis of 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 ("U.S. GAAP"). The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and revenues and expenses that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

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

Prepaid and accrued research and development expenses

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

- expenses incurred under agreements with third parties, including CROs and investigative sites that conduct research, preclinical studies and clinical trials on our behalf, and in connection with the Maruho License Agreement;
- expenses incurred under agreements with third parties, including CMOs, that develop and manufacture our product candidate for use in our preclinical studies and clinical trials; and
- other providers and vendors in connection with research and development activities.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs, investigative sites, CMOs, and third-party vendors that conduct research, preclinical studies, and conduct clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense.

Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated, and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Although

we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

We also record advance payments to service providers as prepaid expenses and other current assets, which are expensed as the contracted services are performed. If the actual timing of the performance of services varies from the estimate, then we adjust the amount of the accrued expense or the prepaid expense accordingly.

Stock-based compensation

We measure stock-based awards granted to employees, directors, and non-employee service providers based on their fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. Generally, we issue stock option awards with service-based vesting conditions and record the expense for these awards using the straight-line method such that the aggregate amount of expense recognized is at least the fair value of what was legally vested. In March and April 2024, we granted awards with performance-based conditions to our Chief Executive Officer and Chief Financial Officer. Upon achievement of the performance condition, in April 2024, the stock-based compensation for our performance-based stock options was solely subject to continued service until the fourth anniversary of the issuance of Series B Preferred Stock to settle the Series B tranche right.

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

Recently issued and adopted accounting pronouncements

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

Emerging growth company and smaller reporting company status

The Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different effective dates for public and private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until the earlier of the date that we (i) are no longer an emerging growth company or (ii) irrevocably elect to "opt out" of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for non-public companies.

We are also a "smaller reporting company," as defined in the Securities Exchange Act of 1934, as amended. We may continue to be a smaller reporting company if either (i) the market value of our common stock and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our common stock and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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

As a smaller reporting company, we are not required to provide this information.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are included in this Annual Report on Form 10-K (this "Annual Report") beginning on page F-1. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report.

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

None.

Item 9A. Controls and Procedures.

Management's evaluation of disclosure controls and procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act 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.

In designing and evaluating the disclosure controls and procedures, our 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. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer (our Chief Executive Officer) and principal financial officer (our Chief Financial and Operating Officer), of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K (this "Annual Report"). Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report at the reasonable assurance level.

Management's annual report on internal controls over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with United States generally accepted accounting principles ("GAAP"). Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately, and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in its 2013 Internal Control - Integrated Framework. Based on this assessment, our management has concluded that, as of December 31, 2025, our internal control over financial reporting is effective based on those criteria.

Our independent registered public accounting firm will not be required to opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an "emerging growth company" as defined in the Jumpstart Our Business Startups Act.

Changes in internal control over financial reporting

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

Item 9B. Other Information.

(a) None.

(b) During the quarter ended December 31, 2025, none of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement, as each term is 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.

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

Item 11. Executive Compensation.

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

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

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

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

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

Item 14. Principal Accounting Fees and Services.

Our independent public accounting firm is PricewaterhouseCoopers LLP, Boston, Massachusetts, PCAOB Auditor ID 238.

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

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(1) Financial Statements.

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2) Financial Statement Schedules.

Certain schedules are omitted because they are not applicable, or are not required by smaller reporting companies.

(3) Exhibits.

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of Upstream Bio, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 15, 2024).
3.2	Second Amended and Restated Bylaws of Upstream Bio, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on October 15, 2024).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed on September 18, 2024).
4.2+	Amended and Restated Investors' Rights Agreement, among the Company and certain of its stockholders, dated June 6, 2023 (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 filed on September 18, 2024).
4.3	Description of Securities (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form 10-K filed on March 12, 2025).
10.1#	2021 Stock Option and Grant Plan, as amended, and form of award agreements thereunder (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed on September 18, 2024).
10.2#	Upstream Bio, Inc. 2024 Stock Option and Incentive Plan and form of award agreements thereunder (incorporated by reference to Exhibit 10.2 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on October 7, 2024).
10.3#	Upstream Bio, Inc. 2024 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on October 7, 2024).
10.4#	Form of Indemnification Agreement, by and between the Company and each of its directors and executive officers (incorporated by reference to Exhibit 10.4 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on October 7, 2024).
10.5#	Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.5 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on October 7, 2024).
10.6#	Executive Severance Plan (incorporated by reference to Exhibit 10.6 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on October 7, 2024).
10.7#*	Amended and Restated Non-Employee Director Compensation Policy.
10.8#	Form of Employment Agreement for Executive Officers (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed on September 18, 2024).
10.9†+	Asset Purchase Agreement, by and between the Company and Astellas Pharma Inc., dated October 14, 2021 (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1 filed on September 18, 2024).
10.10†	Letter Agreement, by and among the Company, Astellas Pharma Inc. and Regeneron Pharmaceuticals Inc., dated October 19, 2021 (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 filed on September 18, 2024).
10.11†+	Exclusive License Agreement, by and between the Company and Maruho Co., Ltd., dated October 14, 2021, as amended (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 filed on September 18, 2024).
10.12†+	License Agreement, by and between the Company and Lonza Sales AG, dated October 21, 2021, as amended (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 filed on September 18, 2024).

10.13+	Lease Agreement, by and between the Company and BXP Waltham Woods LLC, dated as of July 3, 2024 (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1 filed on September 18, 2024).
19.1*	Upstream Bio, Inc. Insider Trading Policy
21.1	Subsidiary of the registrant (incorporated by reference to Exhibit 21.1 to the Company's Registration Statement on Form S-1 filed on September 18, 2024).
23.1*	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
24.1*	Power of attorney (included on signature page).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Upstream Bio, Inc. Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K filed on March 12, 2025).
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed herewith.

** The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Annual Report on Form 10-K and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.

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

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

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10) of Regulation S-K.

Item 16. Form 10-K Summary.

None.

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.

UPSTREAM BIO, INC.

Date: March 26, 2026

By: /s/ E. Rand Sutherland
Name: E. Rand Sutherland, M.D.
Title: Chief Executive Officer

POWER OF ATTORNEY

Each individual whose signature appears below hereby constitutes and appoints each of E. Rand Sutherland, M.D. and Michael Paul Gray, M.B.A. as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ E. Rand Sutherland E. Rand Sutherland, M.D.	Chief Executive Officer and Director (*Principal Executive Officer*)	March 26, 2026
/s/ Michael Paul Gray Michael Paul Gray, M.B.A.	Chief Financial and Operating Officer (*Principal Financial Officer and Principal Accounting Officer*)	March 26, 2026
/s/ Ronald C. Renaud, Jr. Ronald C. Renaud, Jr., M.B.A.	Director and Chairman	March 26, 2026
/s/ Daniella Beckman Daniella Beckman	Director	March 26, 2026
/s/ Erez Chimovits Erez Chimovits, M.B.A., M.Sc.	Director	March 26, 2026
/s/ H. Edward Fleming, Jr. H. Edward Fleming, Jr., M.D.	Director	March 26, 2026
/s/ Liam Ratcliffe Liam Ratcliffe, M.B.Ch.B., Ph.D., M.B.A.	Director	March 26, 2026
/s/ Marcella Kuhlman Ruddy Marcella Kuhlman Ruddy, M.D., M.S.	Director	March 26, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Upstream Bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Upstream Bio, Inc. and its subsidiary (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholder's equity (deficit) and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. 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 consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 26, 2026

We have served as the Company's auditor since 2022.

Upstream Bio, Inc.
Consolidated balance sheets
(Amounts in thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 101,578	$ 325,892
Short-term investments	239,931	144,559
Accounts receivable	668	613
Prepaid expenses and other current assets	9,620	8,096
Total current assets	351,797	479,160
Property and equipment, net	559	582
Operating lease right-of-use assets	1,222	1,783
Restricted cash	194	194
Total assets	$ 353,772	$ 481,719
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,726	$ 4,041
Accrued expenses and other current liabilities	10,006	5,992
Operating lease liabilities, current portion	720	704
Total current liabilities	13,452	10,737
Operating lease liabilities, net of current portion	549	1,130
Total liabilities	14,001	11,867
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2025 and December 31, 2024; no shares issued and outstanding at December 31, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value; 500,000,000 shares authorized at December 31, 2025 and December 31, 2024; 54,237,750 and 53,603,398 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	54	53
Additional paid-in capital	673,410	660,604
Accumulated other comprehensive income (loss)	530	(25)
Accumulated deficit	(334,223)	(190,780)
Total stockholders' equity	339,771	469,852
Total liabilities and stockholders' equity	$ 353,772	$ 481,719

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

Upstream Bio, Inc.
Consolidated statements of operations and comprehensive loss
(Amounts in thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	2024
Collaboration revenue	$ 2,854	$ 2,370
Operating expenses:		
Research and development	136,806	62,966
General and administrative	26,409	17,168
Total operating expenses	163,215	80,134
Loss from operations	(160,361)	(77,764)
Other income (expense):		
Change in fair value of preferred stock tranche right liability	—	2,859
Interest income	16,933	12,123
Other expense, net	(15)	(24)
Total other income, net	16,918	14,958
Net loss	$ (143,443)	$ (62,806)
Redeemable convertible preferred stock cumulative dividends	—	(13,589)
Net loss attributable to common stockholders	$ (143,443)	$ (76,395)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.66)	$ (5.58)
Weighted-average common shares outstanding, basic and diluted	53,852,752	13,682,326
Comprehensive loss:		
Net loss	$ (143,443)	$ (62,806)
Unrealized gain (loss) on investments, net of tax	555	(46)
Total other comprehensive income (loss)	555	(46)
Comprehensive loss	$ (142,888)	$ (62,852)

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

Upstream Bio, Inc.
Consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit)
(Amounts in thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	(Deficit)
Balances at December 31, 2023	22,941,170	$ 230,935	2,992,479	$ 3	$ 4,824	$ (127,974)	$ 21	$ (123,126)
Issuance of Series B redeemable convertible preferred stock in connection with the settlement of the tranche right liability, net of issuance costs of $75	8,823,523	149,939	—	—	—	—	—	—
Conversion of convertible preferred stock to common stock upon closing of initial public offering	(31,764,693)	(380,874)	33,321,149	33	380,841	—	—	380,874
Issuance of common stock from initial public offering, net of issuance costs of $3.9 million and underwriting fee of $20.5 million	—	—	17,250,000	17	268,776	—	—	268,793
Exercise of stock options, net of tax withholding	—	—	39,770	—	159	—	—	159
Stock-based compensation expense	—	—	—	—	6,004	—	—	6,004
Unrealized loss on available-for-sale securities, net of tax	—	—	—	—	—	—	(46)	(46)
Net loss	—	—	—	—	—	(62,806)	—	(62,806)
Balances at December 31, 2024	—	—	53,603,398	53	660,604	(190,780)	(25)	469,852
Exercise of stock options, net of tax withholding	—	—	608,155	1	2,278	—	—	2,279
Stock-based compensation expense	—	—	—	—	10,332	—	—	10,332
Issuance of common stock under employee stock purchase plan	—	—	26,197	—	196	—	—	196
Unrealized gain on available-for-sale securities, net of tax	—	—	—	—	—	—	555	555
Net loss	—	—	—	—	—	(143,443)	—	(143,443)
Balances at December 31, 2025	—	$ —	54,237,750	$ 54	$ 673,410	$ (334,223)	$ 530	$ 339,771

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

Upstream Bio, Inc.
Consolidated statements of cash flows
(Amounts in thousands)

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (143,443)	$ (62,806)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	188	89
Stock-based compensation expense	10,332	6,004
Change in fair value of preferred stock tranche right liability	—	(2,859)
Net amortization of premiums and accretion of discounts on short-term investments	(1,502)	(1,655)
Non-cash lease expense	561	182
Changes in operating assets and liabilities:		
Accounts receivable	(55)	(515)
Prepaid expenses and other assets	(1,524)	(1,008)
Accounts payable	(1,281)	2,017
Accrued expenses and other current liabilities	4,014	1,512
Operating lease liabilities	(565)	(133)
Net cash used in operating activities	(133,275)	(59,172)
Cash flows from investing activities:		
Purchases of short-term investments	(385,878)	(290,609)
Maturities of short-term investments	292,563	231,635
Purchases of equipment	(165)	(511)
Net cash used in investing activities	(93,480)	(59,485)
Cash flows from financing activities:		
Proceeds from the issuance of Series B redeemable convertible preferred stock, net of issuance costs paid	—	149,924
Proceeds from initial public offering, net of underwriters discounts and commissions	—	272,723
Payments of initial public offering costs	(34)	(3,896)
Proceeds from exercises of stock options	2,279	159
Proceeds from issuance of common stock under employee stock purchase plan	196	—
Net cash provided by financing activities	2,441	418,910
Net increase (decrease) in cash, cash equivalents and restricted cash	(224,314)	300,253
Cash, cash equivalents and restricted cash at beginning of period	326,086	25,833
Cash, cash equivalents and restricted cash at end of period	$ 101,772	$ 326,086
Cash, cash equivalents and restricted cash at end of period:		
Cash and cash equivalents	$ 101,578	$ 325,892
Restricted cash	194	194
Total cash, cash equivalents and restricted cash at end of period	$ 101,772	$ 326,086
Supplemental cash flow information:		
Right-of-use asset obtained in exchange for operating lease liability	$ —	$ 1,922
Supplemental disclosure of non-cash investing and financing activities:		
Settlement of Series B preferred stock tranche right liability	$ —	$ 15
Initial public offering costs included in accounts payable	$ —	$ 34

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

1. Nature of the business and basis of presentation

Upstream Bio, Inc. was incorporated in April 2021, under the laws of the State of Delaware, and along with its consolidated subsidiary (collectively, the "Company" or "Upstream"), is focused on developing treatments for inflammatory diseases, with an initial focus on severe respiratory disorders. Since its inception, the Company has devoted substantially all of its efforts to raising capital and incurring research and development expenses related to advancing verekitug, a clinical-stage monoclonal antibody that targets and inhibits the Thymic Stromal Lymphopoietin receptor.

Risks and uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, the successful development of verekitug, the development of new technological innovations by competitors, dependence on key personnel, the ability to attract and retain qualified employees, protection of proprietary technology, compliance with governmental regulations and the ability to secure additional capital to fund operations and commercial success of verekitug. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be maintained, that any therapeutic products developed will obtain required regulatory approval or that any approved or consumer products will be commercially viable. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will generate significant product sales.

Stock split

On October 4, 2024, the Company effected a 1.049-for-one stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock (Note 8). Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split and adjustment of the preferred stock conversion ratios.

Liquidity

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year from the issuance of these consolidated financial statements.

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has historically financed its operations principally through the issuance and sale of redeemable convertible preferred stock and the proceeds from its initial public offering ("IPO"), which was completed in October 2024. In connection with its IPO, the Company issued and sold 17,250,000 shares of common stock, including 2,250,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $17.00 per share. As a result of the IPO, the Company received $268.8 million in net proceeds, after deducting $20.5 million in underwriting discounts and commissions, and $3.9 million in other offering costs. The Company has incurred recurring losses and negative cash flows from operations since its inception and expects to continue to incur losses and negative cash flows for the foreseeable future as it continues the research and development of verekitug. The Company incurred net losses of $143.4 million and $62.8 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company had an accumulated deficit of $334.2 million.

The Company expects its cash, cash equivalents and short-term investments will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next twelve months from the date of issuance of these consolidated financial statements. The Company will need additional financing to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant product revenue, if ever, the Company expects to fund its operations through equity offerings or debt financings, credit or loan facilities, potentially other capital resources, or a combination of one or more of these funding sources. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate funds are not available to the Company, the Company may be required to delay, reduce or eliminate clinical programs, obtain funds through arrangements with collaborators on terms unfavorable to the Company or pursue merger or acquisition strategies. There can be no assurances the Company will be able to obtain additional funding. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Basis of presentation

The accompanying consolidated financial statements reflect the operations of the Company. Intercompany balances and transactions have been eliminated in consolidation. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

2. Summary of Significant Accounting Policies

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and the disclosure of contingent assets and liabilities as of and during the reporting period. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company assesses estimates on an ongoing basis; however, actual results could materially differ from those estimates. Significant estimates and assumptions reflected within these consolidated financial statements include, but are not limited to, prepaid and accrued research and development expenses, including those related to contract research organizations ("CROs"), contract manufacturing organizations ("CMOs") and other third-party vendors, the valuation of the Company's common stock prior to the Company's IPO in October 2024 and stock-based awards and the valuation of the preferred stock tranche right liabilities. Changes in estimates are recorded in the period in which they become known.

Concentration of credit risk and of significant suppliers

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents and short-term investments. The Company deposits its cash and cash equivalents in financial institutions in amounts that may exceed federally insured limits, and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company's short-term investments consist of U.S. treasury securities, government agency bonds and corporate debt securities which the Company believes represent minimal credit risk.

The Company is dependent on third-party manufacturers to supply products for research and development activities related to verekitug, including preclinical and clinical studies and testing. In particular, the Company relies and expects to continue to rely on a small number of manufacturers for the supply of verekitug. The Company's preclinical and clinical studies and testing could be adversely affected by a significant interruption in the supply.

Foreign currency gains and losses

The functional currency and the reporting currency of the Company is the U.S. dollar. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the functional currency are included as foreign exchange gains and

losses in other expense, net in the consolidated statements of operations and comprehensive loss. The Company has not recognized material foreign currency transaction gains or losses during the years ended December 31, 2025 and 2024.

Cash and cash equivalents

The Company considers all short-term, highly liquid investments, with an original maturity of three months or less, to be cash equivalents, and as of December 31, 2025 and 2024, includes amounts held in money market funds in the amount of $86.0 million and $321.0 million, respectively and in U.S. treasury securities of $15.0 million and $4.2 million, respectively.

Restricted cash

Restricted cash consisted of a letter of credit totaling $0.2 million as of December 31, 2025 and 2024, that is required to be maintained in connection with the Company's lease arrangements. The letter of credit is in the name of the Company's landlord and is required to fulfill lease requirements in the event the Company should default on its lease obligations. As of December 31, 2025 and 2024, the Company classified its restricted cash as non-current assets on the consolidated balance sheets based on the release date of the restriction.

Short-term investments

Available-for-sale securities consist of investments with original maturities greater than 90 days at acquisition date. The Company classifies any investments with maturities beyond one year as short term, based on their highly liquid nature and because such available-for-sale securities represent the investment of cash that is available for current operations.

The Company’s debt security investments are classified as available-for-sale and are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders’ equity. Realized gains and losses and declines in fair value due to credit-related factors are based on the specific identification method and are included as other expense, net in the consolidated statements of operations and comprehensive loss. The Company recorded interest income on available-for-sale investments of $16.9 million and $12.1 million during the years ended December 31, 2025 and 2024, respectively, which is classified as interest income in the consolidated statements of operations and comprehensive loss.

At each balance sheet date, the Company assesses available-for-sale debt securities in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in other expense, net. The Company evaluates whether it intends to sell, or it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. The Company also evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other expense, net. The portion that is not credit-related is treated in accordance with other unrealized losses as a component of accumulated other comprehensive income (loss) in stockholders’ equity. There have been no impairment or credit losses recognized during any of the periods presented.

Fair value measurements

Certain assets and liabilities of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1	Quoted prices in active markets for identical assets or liabilities.
Level 2	Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3	Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of the Company's accounts receivables, prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities. The Company's cash equivalents, short-term investments and the preferred stock tranche right liability are carried at fair value (Note 3).

Property and equipment

The Company records property and equipment at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset, as follows:

	Estimated Useful Life
Lab equipment	5 years
Computer equipment	3 years
Office equipment	5 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Estimated useful lives are periodically assessed to determine if changes are appropriate. Leasehold improvements are amortized using the straight-line method over the lesser of the lease term or its estimated economic useful life. Lease terms are based upon the initial lease agreement and do not consider potential renewals or extensions until such time that the renewals or extensions are contracted. Expenditures for maintenance and repairs that do not improve or extend the life of the respective assets are expensed as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation or amortization are eliminated from the consolidated balance sheets and any resulting gains or losses are included in the consolidated statements of operations and comprehensive loss in the period of disposal. Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service.

Impairment of long-lived assets

The Company evaluates its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value. For the years ended December 31, 2025 and 2024, the Company did not record any impairment losses on long-lived assets.

Operating leases

The Company determines if an arrangement is or contains a lease, as defined by ASU 2016-02, *Leases* (Topic 842) ("ASC 842"), at the lease inception date by evaluating whether the arrangement conveys the right to use an identified asset and whether the Company obtains substantially all of the economic benefits from and has the ability to direct the use of the asset. If an arrangement is determined to be or contain a lease, the lease is assessed for classification as either an operating or finance lease at the lease commencement date, defined as the date on which the leased asset is made available for use by the Company, based on the economic characteristics of the lease.

ASC 842 includes certain practical expedients that can be elected for new leases that are executed after the adoption of the new requirements. The Company elected the practical expedient to not separate lease and non-lease components. The Company also elected to apply the short-term lease recognition exemption which eliminates the requirement to present on the consolidated balance sheets leases with a term of 12 months or less. These two practical expedients were elected for all classes of underlying assets.

At the lease commencement date, the Company recognizes a lease liability and a right-of-use ("ROU") asset representing its right to use the underlying asset over the lease term. The initial measurement of the lease liability is calculated as the present value of the future lease payments in the contract and the ROU asset is measured as the lease liability plus initial direct costs and prepaid lease payments, less lease incentives granted by the lessor. The subsequent measurement of a lease is dependent on whether the lease is classified as an operating lease or a finance lease. Operating lease cost is recognized on a straight-line basis over the lease term in the consolidated statements of operations and comprehensive loss.

The Company's leases require other payments such as costs related to taxes, insurance, maintenance, and other expenses. These costs are generally variable in nature and based on the actual costs incurred and required by the lease. As the Company has elected to not separate lease and non-lease components for all classes of underlying asset, all variable costs associated with the lease are expensed in the period incurred and presented and disclosed as variable lease costs. The Company's lease agreements do not contain any material residual value guarantees or material restrictive financial covenants.

ASC 842 requires that a lessee use the rate implicit in the lease when measuring the lease liability and ROU asset. If the rate implicit in the lease is not readily determinable, the Company is permitted to use its incremental borrowing rate, which is defined as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Since the rate implicit in the lease is not readily determinable, the Company uses its incremental borrowing rate when measuring its leases. The incremental borrowing rate is calculated by considering the Company's credit standing, the lease term and the impact of collateral.

Most leases include options to renew and, or, terminate the lease, which can impact the lease term. The exercise of these options is at the Company's discretion. Periods covered by an option to extend a lease are not included in the lease term as the Company is not reasonably certain it will exercise this option. Additionally, periods covered by an option to terminate the lease are included in the lease term as it is reasonably certain that the Company will not exercise this option.

Classification and accretion of redeemable convertible preferred stock

The holders of Preferred Stock (as defined in Note 8) have certain redemption rights in the event of a deemed liquidation event that, in certain situations, are not solely within the control of the Company and would call for the redemption of the then outstanding Preferred Stock (Note 8). Therefore, the Preferred Stock is classified as mezzanine equity outside of stockholders' equity on the consolidated balance sheets. The Company recorded the Preferred Stock at fair value upon issuance, net of tranche right liabilities (Note 8) and associated issuance costs. The net carrying value of redeemable convertible preferred stock were accreted to their redemption values through a charge to additional paid-in capital or accumulated deficit over the period from date of issuance to the earliest date on which the holders could, at their option, elect to redeem their shares. In connection with the IPO, all outstanding shares of convertible preferred stock converted into an aggregate of 33,321,149 shares of the Company's common stock.

Preferred stock tranche right liabilities

The purchase agreements for the Company's Preferred Stock provide the Company an obligation to issue additional Preferred Stock in subsequent closings upon the satisfaction of certain conditions (the "preferred stock tranche rights") (Note 8).

The Company classified such preferred stock tranche rights as liabilities on its consolidated balance sheets (the "preferred stock tranche right liabilities") as each preferred stock tranche right was determined to be a freestanding financial instrument that may require the Company to transfer assets to settle its obligation upon events outside of its control. The preferred stock tranche right liabilities were initially recorded at fair value upon the issuance date and are subsequently remeasured to fair value at each reporting date and immediately prior to being settled. Changes in fair value of the preferred stock tranche right liabilities are recognized as a component of other income, net in the consolidated statements of operations and comprehensive loss. Upon settlement of the tranche rights, the Company derecognized the related liability, and stopped recognizing changes in the fair value of the preferred stock tranche right liability. Any issuance costs allocated to the preferred stock tranche right liabilities were immediately expensed.

Revenue recognition

The Company enters into license arrangements, pursuant to which it may provide research and development services for third parties.

To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, Revenue from Contracts with Customers, ("ASC 606"), the Company performs the following five steps: (i) identify the promised goods or services in the contract; (ii) determine whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measure the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations; and (v) recognize revenue when, or as, the Company satisfies each performance obligation. At contract inception, the Company assesses whether the goods or services promised within each contract are a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services until a distinct bundle is identified. The Company then allocates the transaction price, the amount of consideration the Company expects to be entitled to from a customer in exchange for the promised goods or services, to each performance obligation and recognizes the associated revenue when each performance obligation is satisfied.

In determining the appropriate amount of revenue to be recognized, the Company uses judgment to determine: (a) the number of performance obligations; (b) the transaction price; (c) the stand-alone selling price for each performance obligation identified in the contract; and (d) the contract term and pattern of satisfaction of the performance obligations. The Company uses judgment to determine whether milestones or other variable consideration should be included in the transaction price. The transaction price is allocated to the identified performance obligations on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At contract inception, the Company estimates the total costs required to satisfy the performance obligation and subsequently updates the estimate at each reporting period. Accordingly, the Company's estimates may change in the future and those changes could result in a change in amounts of revenue recognized and could be material.

During the years ended December 31, 2025 and 2024, the Company generated revenue from a research and development arrangement with Maruho Co., Ltd ("Maruho"), which is accounted for under ASC 606. Pursuant to the agreement, the Company provides to Maruho research and development services related to verekitug in Japan, and Maruho reimburses the Company for these costs incurred in performing the research and development services (Note 15).

The Company records accounts receivable when its right to receive consideration is solely based on the passage of time. Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company's consolidated balance sheets. Amounts expected to be recognized as revenue within one year following the balance sheet date are classified as current deferred revenue. Amounts not expected to be recognized as revenue within one year following the balance sheet date are classified as deferred revenue, net of current portion. Payment terms and conditions generally require payment within 60 days of invoicing.

Segment information

Operating segments are defined as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision maker ("CODM") in deciding how to allocate resources and assess performance. The Company's CODM, its Chief Executive Officer, views the Company's operations and manages its business on a consolidated basis as a single operating segment, which is the business of developing treatments for inflammatory diseases, with an initial focus on severe respiratory disorders. Revenue is generated exclusively from certain transactions with Maruho located in Japan and all assets are held in the United States (Note 18).

Research and development expenses

Research and development expenses are expensed as incurred. Research and development expenses include salaries and benefits, stock-based compensation expense, licensed technology, external costs of third-party vendors that conduct research and development activity on behalf of the Company, and other operational costs related to the Company's research and development activities including costs related to a research and development arrangement with Maruho.

Prepaid and accrued research and development expenses

The Company recognizes research and development expense and records accruals for estimated costs of research and development activities conducted by third-party service providers, which include CROs that conduct research, preclinical studies and clinical trials on the Company's behalf, including in connection with the Company's research and development arrangement, and CMOs that manufacture the Company's product candidate for use in preclinical and clinical trials. The majority of the Company's service providers invoice in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. The Company makes estimates of the accrued expenses and includes these costs in accrued liabilities in the consolidated balance sheets and within research and development expense in the

consolidated statements of operations and comprehensive loss based on facts and circumstances known to the Company at that time. These costs are a significant component of the Company's research and development expenses.

The Company accrues for these costs based on factors such as estimates of the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and in accordance with agreements established with its third-party service providers for such services. The Company makes significant judgments and estimates in determining the accrued research and development liabilities balance at each reporting period. As actual costs become known, the Company adjusts its accrued estimates. To date, there have been no material adjustments to the Company's estimates of accrued research and development expenses. The Company records advance payments to service providers as prepaid expenses and other current assets, which are expensed as the contracted services are performed. If the actual timing of the performance of services varies from the estimate, then the Company adjusts the amount of the accrued expense or the prepaid expense accordingly.

General and administrative expenses

General and administrative expenses consist primarily of salaries and benefits, including stock-based compensation expense; professional fees for legal, accounting, auditing, tax and consulting services; travel expenses; and facility-related expenses, which include expenses for rent and maintenance of facilities and other operating costs. The Company expenses all general and administrative expenses as incurred.

Patent and trademarks

Costs to secure, defend and maintain patents, including those in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Stock-based compensation expense

The Company measures all stock-based awards granted to employees, directors, and non-employee service providers based on fair value on the date of the grant, and recognizes the resulting fair value over the requisite service period. The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options granted. The Company has elected to recognize stock-based compensation expense for service-based stock options with graded vesting on a straight-line basis over the requisite service period, which is generally the vesting period. The Company recognizes expense related to stock options that contain performance conditions only when it is considered probable that the performance condition will be achieved. Stock-based compensation expense for stock options with performance conditions is recognized using graded vesting. The Company accounts for forfeitures as they occur.

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

Comprehensive loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from nonowner sources, including unrealized gains and losses on marketable securities held as available for sale. For the years ended December 31, 2025 and 2024, comprehensive loss includes net loss and unrealized gains (losses) on short-term investments.

Net loss per share

The Company calculated basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for companies with participating securities. The Company's Preferred Stock is considered to be a participating security as the holders are entitled to receive dividends at a dividend rate payable in preference and priority to the holders of common stock. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period has been distributed. There is no

allocation required under the two-class method during periods of loss since the participating securities do not have a contractual obligation to share in the losses of the Company.

Under the two-class method, basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share attributable to common stockholders is computed by (i) adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities and (ii) dividing the diluted net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, including potential dilutive common shares. For purposes of this calculation, Preferred Stock and stock options to purchase common stock are considered potential dilutive common shares.

The Company has generated a net loss for each of the periods presented. Accordingly, basic and diluted net loss per share attributable to common stockholders are the same because the inclusion of the potentially dilutive securities would be anti-dilutive.

Income taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company utilizes a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained upon tax authority examination, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement.

Recently adopted accounting pronouncements

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures*, which focuses on the rate reconciliation and income taxes paid. ASU No. 2023-09 requires a public business entity (“PBE”) to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. For PBEs, the new standard is effective for annual periods beginning after December 15, 2024, with early adoption permitted. An entity has the option to adopt this ASU prospectively or retrospectively. As of December 31, 2025, the Company adopted this new ASU retrospectively and it only impacts the Company's income tax disclosures with no impact to its operations, cash flows, or financial condition.

Recently issued accounting pronouncements not yet adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company qualifies as an ‘‘emerging growth company,’’ as defined in the Jumpstart Our Business Startups Act of 2012, and has elected not to ‘‘opt out’’ of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and non-public companies, the Company can adopt the new or revised standard at the time non-public companies adopt the new or revised standard and can do so until such time that the Company either (i) irrevocably elects to ‘‘opt out’’ of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for non-public companies.

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses*, which requires more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation, amortization, and depletion) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements and related disclosures.

3. Fair value measurements

The following tables present information about the Company’s financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values (in thousands):

	Fair Value Measurements at December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 85,866	$ —	$ —	$ 85,866
U.S. treasury securities	—	14,991	—	14,991
Short-term investments:				
U.S. treasury securities	—	159,455	—	159,455
Corporate debt securities	—	75,216	—	75,216
Government agency bonds	—	5,260	—	5,260
	$ 85,866	$ 254,922	$ —	$ 340,788

	Fair Value Measurements at December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 321,047	$ —	$ —	$ 321,047
U.S. treasury bills	4,173	—	—	4,173
Short-term investments:				
U.S. treasury bills	—	77,165	—	77,165
U.S. government agency bonds	—	67,394	—	67,394
	$ 325,220	$ 144,559	$ —	$ 469,779

There were no transfers between Level 1, Level 2 and Level 3 during the years ended December 31, 2025 and 2024.

The Company classifies its U.S. treasury securities, corporate debt securities and government agency bonds as short-term based on each instrument's availability for use in current operations. The fair value of the Company's U.S. treasury securities, corporate debt securities and government agency bonds are classified as Level 2 because they are valued using observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency.

Short-term investments consisted of the following (in thousands):

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
U.S. treasury securities	$ 159,033	$ 422	$ —	$ 159,455
Corporate debt securities	75,117	102	(3)	75,216
Government agency bonds	5,253	7	—	5,260
Total short-term investments:	$ 239,403	$ 531	$ (3)	$ 239,931

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
U.S. treasury bills	$ 77,142	$ 37	$ (14)	$ 77,165
U.S. government agency bonds	67,442	34	(82)	67,394
Total short-term investments:	$ 144,584	$ 71	$ (96)	$ 144,559

The contractual maturities of the Company's short-term investments in available-for-sale securities held were as follows (in thousands):

	December 31, 2025	December 31, 2024
Due within one year	$ 221,506	$ 109,943
Due after one year through two years	18,425	34,616
Total available-for-sale securities	$ 239,931	$ 144,559

Valuation of preferred stock tranche right liabilities

The fair value of the preferred stock tranche right liability in the table below is composed of the fair value of the obligation to issue Series B redeemable convertible preferred stock ("Series B Preferred Stock") (Note 8). The fair value of the preferred stock tranche right liability was based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy.

The fair value of the Series B Preferred Stock tranche right liability was determined using an option pricing model as it represents an option for the Series B Option Shares (as defined in Note 8). The valuation considered as inputs the estimated fair value of the Series B Preferred Stock as of each valuation date, the risk-free interest rate, volatility, expected dividends, and estimated time to the tranche closing.

The most significant assumption in the valuation model impacting the fair value of the preferred stock tranche right liability is the fair value of the Company's Series B Preferred Stock as of each measurement date. The Company determined the fair value per share of the underlying Series B Preferred Stock by taking into consideration the most recent sales of its Series B Preferred Stock, results obtained from third-party valuations and additional factors the Company deemed relevant. In April 2024, upon satisfaction of certain conditions, the Company issued and sold 8,823,523 shares of Series B Preferred Stock at a price of $17.00 per share, which resulted in the settlement of the associated Series B preferred stock tranche right liability. The fair value of Series B Preferred Stock was $17.002 per share upon the closing.

The following table presents a roll-forward of the fair value of the Series B preferred stock tranche right liability during the year ended December 31, 2024, for which fair value was determined using Level 3 inputs (in thousands):

	Series B Preferred Stock Tranche Right Liability
Fair value at December 31, 2023	$ 2,874
Change in fair value of Series B preferred stock tranche right liability	(2,859)
Final settlement of Series B preferred stock tranche right liability	(15)
Fair value at December 31, 2024	$ —

4. Prepaid expenses and other current assets

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

	December 31, 2025	December 31, 2024
Prepaid research and development expense	$ 6,204	$ 6,125
Interest receivable	1,653	567
Prepaid insurance	881	852
Prepaid employee-related costs	155	58
Other	727	494
	$ 9,620	$ 8,096

5. Property and equipment, net

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

	December 31, 2025	December 31, 2024
Office equipment	$ 559	$ 465
Computer equipment	202	202
Leasehold improvements	87	71
Lab Equipment	55	—
	903	738
Less: Accumulated depreciation and amortization	(344)	(156)
Property and equipment, net	$ 559	$ 582

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

6. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued external research and development expenses	$ 5,057	$ 2,807
Accrued employee compensation and benefits	4,192	2,697
Accrued consultant and professional fees	757	488
	$ 10,006	$ 5,992

7. Leases

As of December 31, 2025, the Company was a party to a lease related to commercial real estate under a non-cancelable lease term and a short-term lease related to commercial real estate.

In July 2024, the Company entered into an operating lease agreement for office space located at 890 Winter Street in Waltham, Massachusetts. The lease commenced in September 2024 and the Company began paying monthly rent starting one month after the lease commenced. The Company occupies approximately 16,801 square feet of space under a three-year agreement expiring in October 2027. Initial base rent was approximately $0.7 million for the first year and approximately $0.8 million for the second and third year.

During the year ended December 31, 2024, the Company had an operating lease for office space at 460 Totten Pond Road, Waltham, Massachusetts. In July 2024, the Company provided notice of termination. This notice became effective on October 9, 2024, after which the Company's rights and obligations under this lease ceased. The lease expired on June 30, 2024, after which the Company continued to pay rent on a month-to-month basis until October 9, 2024. Under its lease, the Company pays a proportional share of operating expenses. Such operating expenses are subject to annual adjustment and are accounted for as variable payments in the period in which they are incurred.

The components of lease cost, which are included in the consolidated statements of operations and comprehensive loss, were as follows (in thousands):

	December 31,	
	2025	2024
Lease Cost:		
Operating lease cost	$ 739	$ 256
Short-term lease cost	—	202
Variable lease cost	—	19
Total lease cost	$ 739	$ 477

Supplemental disclosure of cash flow information related to leases were as follows (in thousands):

	December 31,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities	$ 742	$ 207

The weighted-average discount rate and remaining lease term were as follows:

	December 31,	
	2025	2024
Weighted-average discount rate — operating leases	11.7%	11.7%
Weighted-average remaining lease term — operating leases	1.8	2.8

The maturities of operating lease liabilities were as follows (in thousands):

Year Ended December 31,	Amount
2026	759
2027	644
Total lease payments	1,403
Less: imputed interest	(134)
Present value of lease liabilities	1,269
Less: operating lease liabilities, current portion	(720)
Operating lease liabilities, net of current portion	$ 549

8. Redeemable convertible preferred stock

The Company has issued Series A Preferred Stock ("Series A Preferred Stock") and Series B Preferred Stock, which are collectively referred to as the Preferred Stock.

Immediately prior to the closing of the Company's IPO on October 15, 2024, pursuant to the stock split and a proportional adjustment to the existing conversion ratios of each series of the Company's Preferred Stock as discussed further below, all of the Company's outstanding shares of convertible preferred stock were converted into an aggregate of 33,321,149 shares of common stock.

Issuance and sale of Series B redeemable convertible preferred stock

In June 2023, the Company executed the Series B Stock Preferred Purchase Agreement (the "Series B Agreement") to issue and sell up to 11,764,693 shares of Series B Preferred Stock at a price of $17.00 per share. In the initial closing in June 2023, the Company issued 2,941,170 shares of Series B Preferred Stock resulting in gross cash proceeds of $50.0 million and incurred $0.6 million of issuance costs, of which $0.1 million was allocated to the preferred stock tranche right liability and recognized in the consolidated statement of operations and comprehensive loss as general and administrative expense. Pursuant to the Series B Agreement, the Company has the right ("Series B Option") to issue and sell an additional 8,823,523 shares of Series B Preferred Stock ("Series B Option Shares") at the same price of $17.00 per share after the initial closing but prior to March 31, 2024 upon approval of at least six (6) board of directors of which at least one (1) has to be appointed by the holders of Series B Preferred Stock. If the Company does not exercise the Series B Option prior or at a date which would occur at the earlier of (i) March 31, 2024 or (ii) the closing of an acquisition agreement signed prior to March 31, 2024, the holders of Series B Preferred Stock will have the right but not obligation to require the Company to issue and sell the Series B Option Shares at the same purchase price of $17.00 per share (the "Series B preferred stock tranche right"). Upon the initial closing of the Series B Preferred Stock, the Company recorded a preferred stock tranche right liability of $11.8 million and a corresponding reduction to the carrying value of the Series B Preferred Stock. The fair value of the Series B preferred stock tranche right was allocated from the gross cash proceeds of $50.0 million of the Series B Preferred Stock issuance, and the residual value was then allocated to the Series B Preferred Stock.

In April 2024, pursuant to the satisfaction of the Series B Option contemplated in the Series B Agreement, the Company issued and sold 8,823,523 shares of Series B Preferred Stock at a price of $17.00 per share, which resulted in gross cash proceeds of $150.0 million. As a result of this issuance, the Series B preferred stock tranche right liability of less than $0.1 million was settled and the Series B Preferred Stock was recorded at its fair value of $150.0 million. The Company incurred less than $0.1 million of issuance costs in connection with the Series B Option closing.

Upon issuance of the Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities and determined that such features did not require the Company to separately account for these features.

As of December 31, 2025 and 2024, there were no shares of redeemable convertible preferred stock issued or outstanding.

The Company's third amended and restated certificate of incorporation authorized the issuance of preferred stock with a par value of $0.001 per share. The number of shares of preferred stock authorized to be issued is 10,000,000 shares as of December 31, 2025. The shares of preferred stock are currently undesignated and no shares are issued or outstanding

9. Common stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the Preferred Stock.

As of December 31, 2025 and 2024, the Company's third amended and restated certificate of incorporation authorized the issuance of 500,000,000 shares of common stock, par value $0.001 per share. As of December 31, 2025 and 2024, there were 54,237,750 shares and 53,603,398 shares of common stock issued and outstanding, respectively.

10. Stock-based compensation

2021 Stock incentive plan

The Company's 2021 Stock Option and Grant Plan (the "2021 Plan") provided for the Company to grant incentive stock options, non-qualified stock options, restricted stock awards, unrestricted stock awards and restricted stock units (collectively, the "Awards") to among others, members of the board of directors, employees, consultants and other key persons to the Company and its affiliates. The 2021 Plan is administered by the board of directors, or at the discretion of the board of directors, by a committee of the board.

In October 2024, the Company completed its IPO, and in connection with the closing, the board of directors determined that no further awards would be granted under the 2021 Plan and any remaining options available for grant would cease to be available. Awards outstanding under the 2021 Plan will continue to be governed by their existing terms. Shares of unused common stock underlying any awards that are forfeited, canceled or reacquired by the Company prior to vesting will again be available for the grant of awards under the 2024 Plan.

2024 Stock option and incentive plan

On August 19, 2024, the Company's board of directors adopted, and on October 4, 2024 its stockholders approved, the 2024 Stock Option and Incentive Plan (the "2024 Plan"), which became effective upon the date immediately preceding the date on which the IPO registration statement was declared effective by the SEC. The 2024 Plan allows the Company to make equity-based and cash-based incentive awards to its officers, employees, directors, and consultants. The 2024 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, restricted shares of common stock and other stock-based awards. The number of shares reserved under the 2024 Plan is subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization. In addition, the number of shares reserved and available for issuance under the 2024 Plan will automatically increase on January 1, 2025 and each January 1 thereafter, by five percent of the outstanding number of shares of its common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Company's compensation committee. On January 1, 2026, the number of shares of common stock that may be issued under the 2024 Plan increased by 2,711,887 shares of common stock.

The shares of common stock underlying any awards under the 2024 Plan and the 2021 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2024 Plan.

As of December 31, 2025, the Company had a total of 11,483,191 shares of common stock reserved under the 2024 Plan and the 2021 Plan, and 3,522,463 shares available for future issuance under the 2024 Plan.

2024 Employee stock purchase plan

On August 19, 2024, the Company's board of directors adopted, and on October 4, 2024 its stockholders approved, the 2024 Employee Stock Purchase Plan (the "2024 ESPP"), which became effective on the date immediately preceding the date on which the IPO registration statement was declared effective by the SEC. A total of 488,467 shares of common stock were initially reserved for issuance under this plan. The 2024 ESPP provides that the number of shares reserved and available for issuance will automatically increase on the first day of each fiscal year, beginning with the fiscal year commencing on January 1, 2025 and continuing each January 1 thereafter through January 1, 2034, by the least of (i) 976,934 shares of common stock, (ii) one percent of the outstanding number of shares of common stock on the immediately preceding December 31, or (iii) such lesser number of shares of common stock as determined by the administrator of the 2024 ESPP. The number of shares reserved under the 2024 ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization. On January 1, 2026, there was no increase to the number of shares of common stock that may be issued under the 2024 ESPP Plan.

As of December 31, 2025, 26,197 shares have been issued under the 2024 ESPP.

Fair value inputs

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected option term is calculated based on the simplified method for awards with service-based conditions, which uses the midpoint between the vesting date and the contractual term, as the Company does not have sufficient historical data to develop an estimate based on participant behavior. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted-average basis, the assumptions used in the Black-Scholes option-pricing model to determine the fair value of stock options granted:

	Year Ended December 31,	
	2025	2024
Expected volatility	92.4%	79.1%
Expected dividends	0%	0%
Expected term (in years)	6.0	6.2
Risk-free rate	4.24%	3.41%

Stock options

The Company generally grants stock-based awards with service-based vesting. During the year ended December 31, 2024, the Company granted performance-based stock options to certain employees and directors for the purchase of an aggregate 1,206,249 shares of common stock with a vesting commencement date contingent upon the achievement of the Series B Option closing, which was achieved in April 2024. The Company determined that it met all the conditions to establish a grant date for these performance-based stock options at the original issuance date and that the performance condition was deemed probable of achievement, as the board of directors had approved the Series B Option closing prior to the grant date. The vesting of the performance-based stock options is also subject to the grantees' continued service until the fourth anniversary of the Series B Option closing.

The following table summarizes the activity of stock options with service-based and performance-based vesting conditions during the year ended December 31, 2025:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Intrinsic Value (in thousands)
Outstanding as of December 31, 2024	6,490,571	$ 5.54	7.9	$ 71,266
Granted	2,222,826	9.45		
Exercised	(608,155)	3.95		
Forfeited	(52,151)	7.37		
Cancelled	(92,363)	3.57		
Outstanding as of December 31, 2025	7,960,728	$ 6.77	8.0	$ 162,277
Options exercisable December 31, 2025	3,619,126	$ 5.50	7.2	$ 78,346
Vested and expected to vest December 31, 2025	7,960,728	$ 6.77	8.0	$ 162,277

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2025 and 2024 was $7.8 million and $0.3 million, respectively.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2025 and 2024 was $7.32 and $5.10, respectively.

As of December 31, 2025, there was $21.4 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.4 years.

Modification of certain stock-based compensation awards

In February 2024, the Company entered into a separation agreement with the Company's former Chief Operating Officer ("COO"), effective March 2024. Under the terms of the separation agreement, stock options for the purchase of 142,935 shares of common stock, representing all of the vested options held by the former COO as of the date of her termination, became exercisable for one year following her termination.

In March 2024, the Company entered into a separation agreement with the Company's former Chief Executive Officer ("CEO"), effective March 2024. Under the terms of the separation agreement, vesting of options for the purchase of 38,245 shares of common stock held by the former CEO were accelerated with no change to the exercise price of such options. In addition, stock options for the purchase of 532,553 shares of common stock, representing all of the vested options held by the former CEO as of the date of her termination, became exercisable for two years following her termination.

As a result of these modifications, the Company recognized $0.7 million of incremental stock-based compensation during the year ended December 31, 2024.

The following table illustrates the classification of stock-based compensation in the consolidated statements of operations and comprehensive loss (in thousands):

	Year Ended December 31,	
	2025	2024
General and administrative	$ 7,478	$ 4,842
Research and development	2,854	1,162
	$ 10,332	$ 6,004

11. Income Taxes

The Company's entire pretax loss for the year ended December 31, 2025 and 2024 was from its U.S. domestic operations. During the years ended December 31, 2025 and 2024, the Company did not record a provision for income taxes because it has incurred net operating losses since inception and maintains a full valuation allowance against its deferred tax assets.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows (amount in thousands):

	Year Ended December 31, 2025	
	Amount	Rate
U.S. federal statutory income tax rate	$ (30,123)	21.0%
State and local income taxes, net of federal income tax effect	—	0.0
Effect of changes in tax laws or rates enacted in the current period	—	0.0
Tax Credits		
Research and development tax credits	(2,136)	1.5
Change in valuation allowance	32,342	(22.5)
Nontaxable or nondeductible items		
Other	(83)	0.0
Effective income tax rate	$ —	(0.0)%

	Year Ended December 31, 2024	
	Amount	Rate
U.S. federal statutory income tax rate	$ (13,189)	21.0%
State and local income taxes, net of federal income tax effect	—	0.0
Effect of changes in tax laws or rates enacted in the current period	—	0.0
Tax Credits		
Research and development tax credits	(2,897)	4.6
Change in valuation allowance	16,270	(25.9)
Nontaxable or nondeductible items		
Other	(184)	0.3
Effective income tax rate	$ —	(0.0)%

The Company's effective tax rate does not include any impact from state and local income taxes as the Company has been in losses since inception.

The significant components of the Company's deferred tax assets and liabilities are summarized as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 19,917	$ 10,994
Research and development tax credit carryforward	6,616	3,754
Operating lease liability	347	501
Accrued expenses	1,118	705
Stock-based compensation	3,828	2,261
Capitalized research and development expense	56,357	25,525
Amortization of acquired IPR&D	15,928	17,412
Total deferred tax assets before valuation allowance	104,111	61,152
Valuation allowance	(103,632)	(60,664)
Total deferred tax assets - net of valuation allowance	$ 479	$ 488
Deferred tax liabilities:		
ROU asset	(334)	(488)
Other	(145)	—
Total deferred tax liabilities	$ (479)	$ (488)
Net deferred tax asset (liability)	$ —	$ —

As of December 31, 2025, the Company had federal and state net operating loss ("NOLs") carryforwards of $66.9 million and $92.9 million, respectively. As of December 31, 2024, the Company had federal and state NOLs carryforwards of $37.6 million and $49.1 million, respectively. The federal NOLs are not subject to expiration and are limited in utilization to 80% of taxable income and the state NOLs begin to expire in 2041. The Company also has federal and state research and development credits of $5.7 million and $1.2 million, respectively, which will, if not utilized, begin to expire in 2043 and 2037, respectively.

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Under the applicable accounting standards, management has considered the Company's history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of its federal and state deferred tax assets. Accordingly, a full valuation allowance of $103.6 million and $60.7 million has been established as of December 31, 2025 and 2024, respectively.

Changes in valuation allowance for deferred tax assets during the years ended December 31, 2025 and 2024 related primarily to the increase in NOL carryforwards and research and development tax credit carryforwards, offset by amortization of acquired IPR&D in 2025 and were as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Valuation allowance at beginning of year	$ (60,664)	$ (39,695)
Increases recorded to income tax provision	(42,968)	(20,969)
Valuation allowance at end of year	$ (103,632)	$ (60,664)

Utilization of the NOL and research and development credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not completed a study to assess whether a change of ownership has occurred, or whether there have been multiple ownership changes since its formation, due to the significant cost and complexity associated with a study. There could also be additional ownership changes in the future which may result in additional limitations on the utilization of NOL carryforwards and credits.

As of December 31, 2025, the Company has not recorded any amounts for uncertain tax positions. The Company's policy is to recognize interest and penalties accrued on any uncertain tax positions as a component of income tax expense, if any, in its consolidated statements of operations and comprehensive loss. For the years ended December 31, 2025 and 2024, no estimated interest or penalties were recognized on uncertain tax positions.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company's tax years are still open under statute from December 31, 2021, to the present. Earlier years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods. The resolution of tax matters is not expected to have a material effect on the Company's consolidated financial statements.

The Company does not pay income taxes at the federal or state level as it has been in losses since inception.

12. Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (dollar amounts in thousands):

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (143,443)	$ (62,806)
Preferred Stock cumulative dividends	—	(13,589)
Net loss attributable to common stockholders	$ (143,443)	$ (76,395)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	53,852,752	13,682,326
Net loss per share attributable to common stockholders, basic and diluted	$ (2.66)	$ (5.58)

Prior to June 2023, the Company's Series A Preferred Stockholders were not entitled to cumulative dividends. In connection with the Series B Agreement in June 2023, the Company modified the dividend rights for its Series A Preferred Stockholders such that they became entitled to cumulative dividends based on the original issuance dates of the respective Series A Preferred Stock. As such, for the year ended December 31, 2024, the Company calculated its net loss attributable to common stockholders by adjusting its net loss for the aggregate cumulative dividends that had accrued since the original issuances dates in the period in which the Preferred Stockholders became legally entitled to such dividends.

The Company's potentially dilutive securities, which include stock options to purchase common stock and Preferred Stock, have

been excluded from the computation of diluted net loss per share as the effect would be anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The following potentially dilutive securities have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	As of December 31,	
	2025	2024
Stock options to purchase common stock	7,960,728	6,490,571

13. Commitments and contingencies

Legal matters

The Company is subject to contingent liabilities, such as legal proceedings and claims, that arise in the ordinary course of business activities. The Company accrues for loss contingencies when losses become probable and are reasonably estimable. If the reasonable estimate of the loss is a range and no amount within the range is a better estimate, the minimum amount of the range is recorded as a liability on the consolidated balance sheets. The Company does not accrue for contingent losses that, in its judgment, are considered to be reasonably possible, but not probable; however, it discloses the range of reasonably possible losses. As of December 31, 2025 and 2024, the Company was not a party to any material legal proceedings or claims and no liabilities were recorded for loss contingencies.

Contracts

The Company enters into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, testing, manufacturing, and other services. These contracts generally provide for termination upon notice and are cancellable without significant penalty or payment, and do not contain any minimum purchase commitments.

Guarantees and indemnifications

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with all board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2025 and 2024.

14. License agreements

License agreement with Lonza

In October 2021, in connection with an asset purchase agreement entered into with Astellas Pharma, Inc. (“Astellas”), the Company and Lonza Sales AG (“Lonza”) entered into a license agreement (as amended, the “Lonza License Agreement”). Pursuant to the Lonza License Agreement, the Company obtained a worldwide, non-exclusive, sublicensable (subject to Lonza’s right of pre-approval with respect to any sublicense of manufacturing activities) license to certain intellectual property rights owned by Lonza. Lonza was the originator of the master cell bank for verekitug (formerly referred to as ASP7266 and UPB-101, collectively referred to as “the Compound”) developed by Astellas.

As consideration for the rights and licenses granted to the Company under the Lonza License Agreement, the Company agreed to pay Lonza certain royalties and annual payments, both payable in Swiss francs, in respect of the manufacturing and sale of the Compound, such amounts to be determined by the party manufacturing the Compound, and range from no annual payment to up to a mid-six-figure annual payment, and a less-than-one percent to a low-single-digit percentage royalty on net sales of the Compound. In accordance with the Lonza License Agreement, the Company entered into a sublicense with Wuxi Biologics (Hong Kong) Limited to manufacture the Compound, requiring the Company to pay a mid-six-figure annual fee to Lonza pursuant to this provision.

Any royalties due under the Lonza License Agreement are payable on a country-by-country basis until ten years from the first commercial sale of the Compound in that particular country.

During the years ended December 31, 2025 and 2024, the Company did not make any royalty payments to Lonza under the Lonza License Agreement. The Lonza agreement continues for an indefinite period of time unless otherwise terminated. The Company has the right to terminate the Lonza License Agreement at any time by providing prior written notice to Lonza.

During each of the years ended December 31, 2025 and 2024, the Company made an annual payment in the amount of $0.5 million to Lonza pursuant to the Lonza License Agreement and recognized it as research and development expense in the consolidated statements of operations and comprehensive loss.

15. Revenue

Maruho agreement

In October 2021, in connection with an asset purchase agreement entered into with Astellas, the Company entered into an agreement (as amended, the "Maruho Agreement"), under which it granted Maruho an exclusive, irrevocable, perpetual, royalty-free, sublicensable (subject to its right of first negotiation) license. Pursuant to the Maruho Agreement, the Company maintains its responsibility for and controls the global research and development of the Maruho license product, including in Japan. The Company will conduct specified clinical trial activities for Japan as part of its global research and development plan. Maruho will reimburse the Company for the costs of these research and development activities, including the cost of drug supply. Maruho has the right to terminate the Maruho Agreement at any time by providing 60 days prior written notice to the Company with no substantial penalty.

The Company concluded that Maruho is a customer under the Maruho Agreement, and as such, the Maruho Agreement falls within the scope of ASC 606. The Company identified one performance obligation under the Maruho Agreement related to the performance of research and development services, which are an output of the Company's ordinary activities, in Japan. The Company determined that the transaction price of the Maruho Agreement as of December 31, 2025 consisted solely of variable consideration. The variable consideration was estimated using the expected value method based on the Company's experience and best judgment of the total reimbursable costs expected to be incurred through the period of performance.

The transaction price is being recognized as revenue over time using the cost-to-cost input method, which the Company believes best depicts the transfer of control to the customer. Under the cost-to-cost input method, the extent of progress towards completion is measured based on the ratio of actual costs incurred in Japan to the total estimated costs expected to satisfy the performance obligation. The calculation of the total estimated costs to fulfill the performance obligation includes costs associated with employees, clinical and development, manufacturing, and out-of-pocket costs expected to be paid to third parties. The estimate of the Company's measure of progress and estimate of variable consideration to be included in the transaction price will be updated at each reporting period as a change in estimate. The Company excludes disclosures related to the aggregate amount of the transaction price allocated to the performance obligation that are unsatisfied as of the end of the reporting period because the contract has an initial expected term of one year or less. The Company currently expects to continue providing research and development services to Maruho under the Maruho Agreement through the completion of its Phase 2 clinical trials, and if successful, through any Phase 3 clinical trials.

16. Related parties

In October 2021, the Company entered into the Maruho Agreement (Note 15). Through the date of the IPO, Maruho was considered to be a related party because it was one of the co-founders of the Company and had representation on the Company's board of directors. Since the closing of the IPO in October 2024, Maruho is no longer considered a related party as they no longer have representation on the Company's board of directors. During the years ended December 31, 2025 and 2024, the Company

received payments of $2.8 million and $1.9 million, respectively, in cost reimbursements from Maruho. The Company recorded collaboration revenue of $2.9 million and $2.4 million during the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025 and 2024, there was $0.7 million and $0.6 million in accounts receivable, respectively, representing amounts due for qualifying reimbursable expenses related to the Maruho Agreement.

17. Employee benefit plan

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Matching contributions to the plan may be made at the discretion of the Company's board of directors. The Company made $0.4 million and $0.2 million in contributions to the plan during the years ended December 31, 2025 and 2024, respectively.

18. Segment reporting

The Company currently has a single reportable operating segment and revenue generated exclusively from the Maruho Agreement. The Company's chief executive officer, who is the CODM, manages the Company on a consolidated basis and utilizes consolidated net loss as a basis for resource allocation and decision making. The CODM considers budget-to-actual variances for each of the disaggregated components of operating expenses when making decisions about allocating resources and evaluating performance. The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets. In addition, the CODM is regularly provided information on total cash, which is inclusive of cash, cash equivalents and short-term investments, as a measure of segment assets. As of December 31, 2025, the Company's cash, cash equivalents and short-term investments were $341.5 million.

The Company's consolidated and segment net loss, including disaggregated components of operating expenses is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Collaboration revenue	$ 2,854	$ 2,370
Operating expenses:		
Research and development:		
Verekitug program:		
Asthma indication	47,694	28,069
COPD indication	34,562	3,115
CRSwNP indication	7,564	10,524
Manufacturing costs	23,013	6,580
Personnel expenses	18,343	9,911
Professional fees and other	5,630	4,767
Total research and development expenses	136,806	62,966
General and administrative:		
Personnel expenses	15,188	10,842
Professional fees	6,718	4,349
Other	4,503	1,977
Total general and administrative expenses	26,409	17,168
Total operating expenses	163,215	80,134
Loss from operations	(160,361)	(77,764)
Other income (expense):		
Change in fair value of preferred stock tranche right liability	—	2,859
Interest income	16,933	12,123
Other expense, net	(15)	(24)
Total other income, net	16,918	14,958
Segment and consolidated net loss	$ (143,443)	$ (62,806)

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UPSTREAM BIO, INC.

CORPORATE AND OTHER INFORMATION

Board of Directors

E. Rand Sutherland, M.D.
Chief Executive Officer,
Upstream Bio, Inc.

Ronald C. Renaud, Jr., M.B.A.
Board Chair, Upstream Bio, Inc.
President and Chief Executive Officer,
Kailera Therapeutics, Inc.

Daniella Beckman
Former Chief Financial Officer,
Tango Therapeutics, Inc.

Erez Chimovits, M.B.A., M.Sc.
Partner, OrbiMed

H. Edward Fleming, Jr., M.D.
Executive Vice President,
Enavate Sciences

Liam Ratcliffe, M.B.Ch.B., Ph.D., M.B.A.
Head of Biotechnology,
Access Industries

Marcella Kuhlman Ruddy, M.D., M.S.
Chief Medical Officer,
Tectonic Therapeutic, Inc.

Executive Officers

E. Rand Sutherland, M.D.
Chief Executive Officer

Michael Paul Gray, M.B.A.
Chief Financial Officer and
Chief Operating Officer

Aaron Deykin, M.D.
Chief Medical Officer and
Head of Research and Development

Adam Houghton, Ph.D., M.B.A.
Chief Business Officer

Allison Ambrose, J.D.
Sr. Vice President, General Counsel

Principal Executive Office

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Boston, Massachusetts

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Visit Our Website

www.upstreambio.com

Form 10-K

The Company's Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 26, 2026, except for exhibits, is printed as part of this 2025 Annual Report.

Additional copies are available without charge upon written request. Please address all requests to:

Upstream Bio, Inc.
Attention: Corporate Secretary
890 Winter Street, Suite 200
Waltham, MA 02451