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 001-42938

Evommune, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**85-0742575**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1841 Page Mill Road, Suite 100	
Palo Alto, CA	**94304**
(Address of principal executive offices)	(Zip Code)

(925) 247-4481

(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.0001 per share	EVMN	New York Stock Exchange

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

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

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

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

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

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

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

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

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

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

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

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

The registrant was not a public company as of June 30, 2025, the last business day of its most recently completed second fiscal quarter, and therefore, cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliated as of such date. The registrant's common stock began trading on the New York Stock Exchange on November 6, 2025.

The number of shares of Registrant's Common Stock outstanding as of March 3, 2026 was 36,018,372.

Documents Incorporated by Reference

Portions of the Registrant's definitive proxy statement relating to its 2026 annual meeting of stockholders to be filed pursuant to Regulation 14A with the Securities and Exchange Commission are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days following the end of the Registrant's fiscal year ended December 31, 2025.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains express or implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, 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"). Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials of our most-advanced product candidates, EVO756 and EVO301, and any future product candidates;
- the characteristics and potential advantages of our product candidates;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- our ability to obtain regulatory approval for our current or future product candidates that we may identify or develop;
- our ability to ensure adequate supply of our current or future product candidates;
- our ability to maintain third-party relationships necessary to conduct our business;
- our heavy dependence upon the success of our research to generate and advance additional product candidates;
- our ability to establish an adequate safety or efficacy profile for our current or future product candidates;
- the implementation of our strategic plans for our business, our current or future product candidates we may develop and our technology;
- our intellectual property position, including the scope of protection and contractual rights that we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- estimates of the number of patients with certain diseases, market sizes for certain diseases, conditions we intend to treat and the number of subjects that we intend to enroll in our clinical trials;
- our plans relating to the further development and manufacturing of our product candidates, including additional indications for which we may pursue;
- the rate and degree of clinical utility for our current or future product candidates and their acceptance by physicians, patients, third-party payors and others in the medical community;
- our estimates about the size of market opportunities relating to our product candidates;
- our expectations related to our capital requirements and our needs for additional financing;
- our ability to maintain and establish collaborations, licensing or other arrangements, including our ability to comply with our obligations pursuant to the terms of such agreements;
- our financial performance and liquidity;
- our ability to effectively manage our potential growth;
- developments relating to our competitors and our industry, including the impact of government regulation and policy;
- our ability to retain the continued service of our key professionals and consultants and to identify, hire and retain additional qualified professionals;
- our ability to maintain adequate internal controls over financial reporting and to manage our business in accordance with applicable laws and the highly regulated industry in which we participate; and
- other risks and uncertainties, including those listed under the section titled "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. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements.

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 on Form 10-K, 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.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

Our business faces significant risks and uncertainties. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. You should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. Some of the more significant risks include the following:

- We will need substantial additional funding in order to maintain our operations and advance the development and commercialization of our product candidates, if approved. Failure to obtain this necessary capital when needed, or on acceptable terms, may force us to delay, reduce or eliminate certain of our research operations or development.
- Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential product candidates. These decisions may prove to have been wrong and may adversely affect our ability to develop our own programs, our attractiveness as a commercial partner and may ultimately have an adverse impact on our commercial success.
- Preclinical and clinical drug development is a lengthy and expensive process, with uncertain timelines and outcomes. If preclinical studies or clinical trials of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our therapeutic candidates or any of our future therapeutic candidates on a timely basis or at all.
- Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.
- Our product candidates may be associated with serious adverse, undesirable or unacceptable side effects or other properties or safety risks, which may delay or halt their clinical development, prevent their marketing approval, or lead to limited market demand, if approved. If such side effects are identified during the development of our product candidates or following approval, we may suspend or abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval.
- Our product candidates are subject to extensive regulatory and compliance obligations, which is costly and time-consuming and which may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.
- We currently have no marketing, sales or distribution capabilities, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing, sales or distribution capabilities or enter into agreements with third parties to perform such activities, we may not be able to generate product revenue.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- We rely on third-party manufacturers, contract research organizations ("CROs"), contract development and manufacturing organizations ("CDMOs") and suppliers to supply, develop and test components of our product candidates. The loss of our third-party manufacturers, CROs, CDMOs or suppliers, their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, or changes in methods of product candidate manufacturing, development or formulation would materially and adversely affect our business.
- We are highly dependent on the services of our senior management team and if we are not able to retain members of our management team and recruit and retain additional management, clinical and scientific personnel, our business will be harmed.
- Our existing collaborations are, and our future collaborations may be, important to our business. If we are unable to enter into new collaborations, or, if our collaborations are not successful, our business could be adversely affected.
- We have licensed intellectual property rights from third parties and may do so in the future. Such licenses may be subject to early termination if we fail to comply with our obligations in our licenses with third parties, which could result in the loss of rights or technology that are material to our business.
- We may rely on one or more in-licenses from third parties. If we lose these rights, our business may be materially adversely affected, and if disputes arise with one or more licensors, we may be subject to future litigation as well as the potential loss of or limitations on our ability to develop and commercialize products and technologies covered by these license agreements.

PART I

Item 1. Business.

Overview

Evommune is a clinical-stage biotechnology company developing innovative therapies that target key drivers of chronic inflammatory diseases, with initial clinical development programs focusing on chronic spontaneous urticaria ("CSU"), atopic dermatitis ("AD") and ulcerative colitis ("UC"). Chronic inflammation is a significant healthcare problem in the world, substantially impacting patients' quality of life and leading to life-threatening conditions. These conditions, if not prevented, ultimately lead to fatal diseases, such as cardiovascular diseases, diabetes and cancer, which contribute to three out of every five deaths worldwide and result in an estimated $90 billion of annual cost to the healthcare system in the United States.

Our mission is to improve patients' daily lives and prevent the long-term effects of uncontrolled inflammation that are a consequence of the limitations of existing therapies. To achieve this, we are advancing a portfolio of differentiated product candidates that target key drivers of chronic inflammation.

Our management team's proven drug development expertise and experience in the field of immunology and inflammation, combined with advanced scientific tools, enable us to identify and advance potent, highly selective molecules with distinctive mechanisms of action. By identifying treatment gaps of chronic inflammatory diseases, we strive to transform the treatment landscape, developing therapies that have the potential to offer rapid symptom relief and provide safe, durable resolution of the underlying disease. Among our portfolio of programs, we currently have two product candidates, EVO756 and EVO301, in Phase 2 development. We are initially developing EVO756 for the treatment of CSU and AD, and EVO301 for the treatment of AD and UC. We see broad expansion potential for both programs across additional chronic inflammatory diseases. We also intend to advance additional preclinical programs into clinical development.

Our most advanced clinical-stage product candidate, EVO756, is a potent and highly selective oral small molecule antagonist of MRGPRX2, a receptor predominantly found on mast cells and peripheral sensory neurons. Dysregulated MRGPRX2 activity can play a key role as both a catalyst and perpetuator of disease pathogenesis across a multitude of systemic chronic inflammatory diseases. By targeting MRGPRX2, we believe EVO756 is the only dual mechanism clinical approach that modulates both mast cells and peripheral sensory neurons, representing a new potential therapeutic option to reduce inflammation and provide rapid relief of itch (pruritus). Mast cells are critical regulators of immune response and can be found in most vascularized tissues including skin, lung and the digestive tract. These cells tend to be distributed in close proximity to peripheral sensory neurons, where the activation of the neurons can trigger the inflammatory cascade and mast cells are implicated in further perpetuating neuroinflammation and its related symptoms. We believe MRGPRX2 is the only clinical approach aimed at inhibiting this neuroimmune interaction.

We previously announced the topline results from a Phase 1 proof-of-concept trial in 132 healthy volunteers designed to assess the safety, tolerability, pharmacokinetic ("PK") properties and pharmacodynamic ("PD") properties of orally administered EVO756. Comprehensive trial results were presented at the UCARE Global Urticaria Forum meeting in December 2024. EVO756 was observed to be well-tolerated at all doses tested, with no serious adverse events ("SAEs"), and PK results supporting daily dosing. A skin challenge test was also conducted in the multiple ascending dose ("MAD") portion of the trial in which icatibant, a known MRGPRX2 ligand, representative of a broad class of disease relevant ligands, was administered via intradermal injection to healthy volunteers creating measurable wheals on their skin. EVO756 was observed to robustly decrease the healthy volunteers' wheals induced by icatibant, evidencing meaningful target engagement at all doses tested. We are currently conducting a Phase 2b trial of EVO756 in CSU and have completed a Phase 2 trial of EVO756 in chronic inducible urticaria ("CIndU" and together with CSU, chronic urticarias or "CU").

In May 2025, we reported topline results from our U.S. multicenter Phase 2 trial of EVO756 in CIndU that demonstrated clinical activity (including improvement in FricTest score and pruritus numerical rating score ("pruritus-NRS"), as described below) in a patient population with symptomatic dermographism. The trial was designed to generate additional patient data in a population with symptomatic dermographism, which we believe is highly translatable to the CSU patient population due to overlapping disease biology and shared pathophysiology. Third party trials have demonstrated that symptomatic dermographism affects approximately 25% of the CSU patient population; similarly, we believe EVO756's clinical activity in symptomatic dermographism patients strongly supports the role of MRGPRX2 in neurogenic inflammation, which plays a crucial role in AD.

A total of 30 patients were enrolled in the trial, with 11 patients enrolled in the 300 mg once daily ("QD") cohort and 19 patients enrolled in the 50 mg twice daily ("BID") cohort. Rapid clinical activity was observed in both dosing regimens, with some patients demonstrating responses by week one in both FricTest score (a clinician-rated measure of symptomatic dermographism severity ranging from 0 to 4, with higher scores indicating greater severity) and pruritus-NRS. 70% (n=19) of the 27 observed patients demonstrated improvement at just four weeks, with 30% (n=8) of the observed patients achieving a complete response (achieving a FricTest score of zero), of which 50% were immunoglobulin E ("IgE") high (as defined by a serum IgE level of ≥100 IU/mL). An additional 11% (n=3) achieved a partial response as defined by a ≥2-point decrease in FricTest score and a further 30% (n=8) demonstrated a one-point decrease in FricTest score. The population of subjects observed at four weeks does not include three patients who were unevaluable or lost to follow-up. Observed patients in the 300 mg QD cohort saw an average reduction of 1.4 points in FricTest score after four weeks and observed patients in the 50 mg BID cohort saw an average reduction of 1.5 points. By comparison, in separate, independent trials conducted by third parties, patients treated with 300 mg omalizumab saw a reduction of 1.4 points and patients treated with 300 mg barzolvolimab saw a reduction of 1.6 points in FricTest score after four weeks. EVO756 was observed to be well-tolerated at both dose levels, including the higher 300 mg QD dose. No SAEs were observed and there were no discontinuations due to adverse events ("AEs").

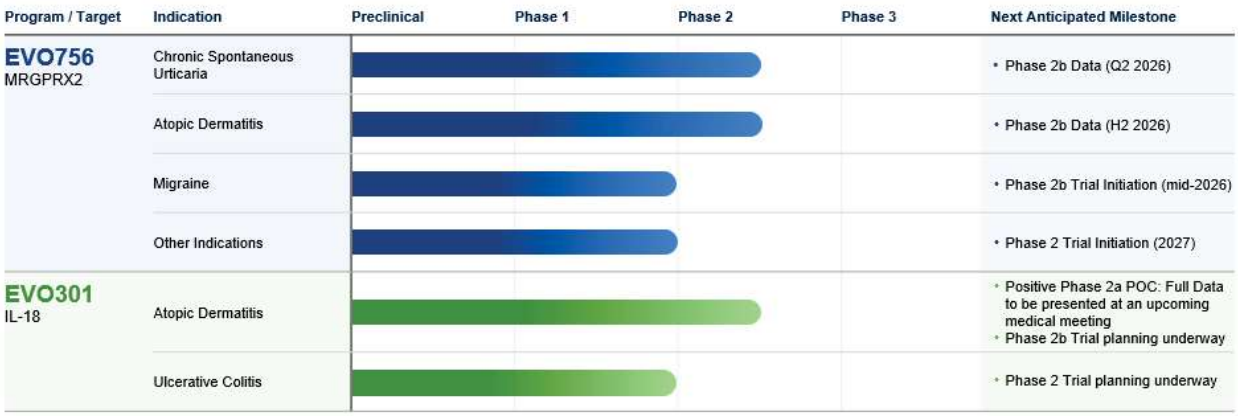
We initiated a Phase 2b dose-ranging trial in CSU in April 2025 and expect to report initial results in the second quarter of 2026. We also initiated a Phase 2b dose-ranging trial in moderate-to-severe AD patients in August 2025 and expect to report initial results in the second half of 2026. We plan to evaluate EVO756 in additional indications in which mast cell degranulation and neuroinflammation are key drivers of disease, with migraine being our next indication of interest where we plan to initiate a Phase 2b trial in mid-2026.

Our second clinical-stage product candidate, EVO301, is a long-acting fusion protein consisting of an IL-18 binding protein ("BP") and an anti-serum albumin Fab-associated ("SAFA") domain. IL-18 is a pro-inflammatory cytokine of the IL-1 family that regulates various immune processes that drive inflammation and is a potent modulator of ongoing inflammation. The IL-18 pathway is believed to play a key role in the severity and progression of several large, highly prevalent chronic inflammatory disease populations with a significant number of uncontrolled patients, including AD and UC. The SAFA domain incorporated into EVO301 utilizes neonatal fragment crystallizable receptor ("FcRn")-mediated recycling of serum albumin to extend half-life. We believe EVO301's optimized approach to IL-18 binding and neutralization could enable significant advantages and differentiated clinical outcomes for patients, including with respect to efficacy, tissue distribution, dosing profile and reduced immunogenicity risk. In addition, EVO301's distinct mechanism and modality complement those of EVO756, providing us with multiple potential avenues to bring innovative therapeutics to the large, underserved and rapidly expanding population of patients suffering from chronic inflammatory diseases.

In February 2026, we announced positive top-line results from a randomized, double-blind, placebo-controlled Phase 2a trial evaluating EVO301 in adult patients with moderate-to-severe AD. The trial met its primary efficacy endpoint at week 12 and achieved highly statistically significant outcomes in adult patients with moderate-to-severe AD. The 70-patient trial was designed to evaluate the safety and efficacy of intravenous dosing of 5 mg/kg on day 1 and day 28 (n=48 active, n=22 placebo) over 12 weeks. The trial met its primary endpoint, demonstrating clinically meaningful activity in AD with statistical significance over placebo achieved at weeks 4, 8 and 12 at $p<0.01$. We believe demonstrating this activity with an IL-18 targeting therapy supports the relevance of this pathway in disease pathophysiology and reinforces that pathways beyond classic Th2 biology can contribute meaningfully to disease activity. Expanding therapeutics to target novel mechanisms like IL 18 could offer benefit for patients who remain uncontrolled on existing therapies and reinforces the urgent need to develop more options across the growing AD population. We plan to rapidly move a subcutaneous formulation of EVO301 into a Phase 2b trial in AD where we believe optimized and more frequent dosing of EVO301 could achieve potential best-in-class Eczema Area and Severity Index ("EASI") activity.

Beyond AD, we are evaluating a potential Phase 2 trial in moderate-to-severe UC patients. We may also evaluate EVO301 in Crohn's disease, certain cardiovascular-related inflammatory conditions, and other additional indications, in which dysregulation of the IL-18 pathway contributes to chronic inflammation and tissue damage driving disease pathology. The figure below provides an overview of our current clinical pipeline:

Figure 1: Our Clinical Pipeline



Notes: (1) Other potential indications for EVO756 include asthma, interstitial cystitis, irritable bowel syndrome and pruritus. To date, based on our data from the successful completion of our Phase 1 proof-of-concept trial of EVO756 in healthy volunteers, we believe there is a path to proceed to Phase 2 clinical development for these other indications, similar to our initiation of our Phase 2b trial in AD, subject to standard regulatory requirements. (2) We are currently prioritizing development in other indications ahead of CIndU and may conduct additional CIndU trials in the future.

In addition to our clinical programs, we are advancing a pipeline of preclinical candidates for immunology and inflammation indications and aim to deliver a steady cadence of data for our new programs.

Our Approach to Drug Development and Chronic Inflammation

Collectively, our team members have held leadership roles at over 25 companies and have played key roles in the discovery and development of nearly 30 approved small molecules and biologics, primarily in immunology and inflammation, including Ebglyss (lebrikizumab), Cimzia (certolizumab pegol) and Rezurock (belumosudil). These therapies have significantly impacted patient outcomes, generated billions of dollars in sales and have led to multiple company acquisitions. This experience has informed our approach to drug development and commercialization to become one focused on identifying the areas of highest unmet need in chronic inflammatory diseases, identifying the molecules with the highest probability of improving patient outcomes in those diseases and then advancing our molecules through rigorous and thoughtful development programs.

Our deep knowledge of immunology and inflammation enables us to focus our efforts on key drivers of disease in which a single therapeutic could treat a broad range of indications and address areas of significant unmet need. We prioritize targets with high potential for meaningful patient outcomes and commercial value.

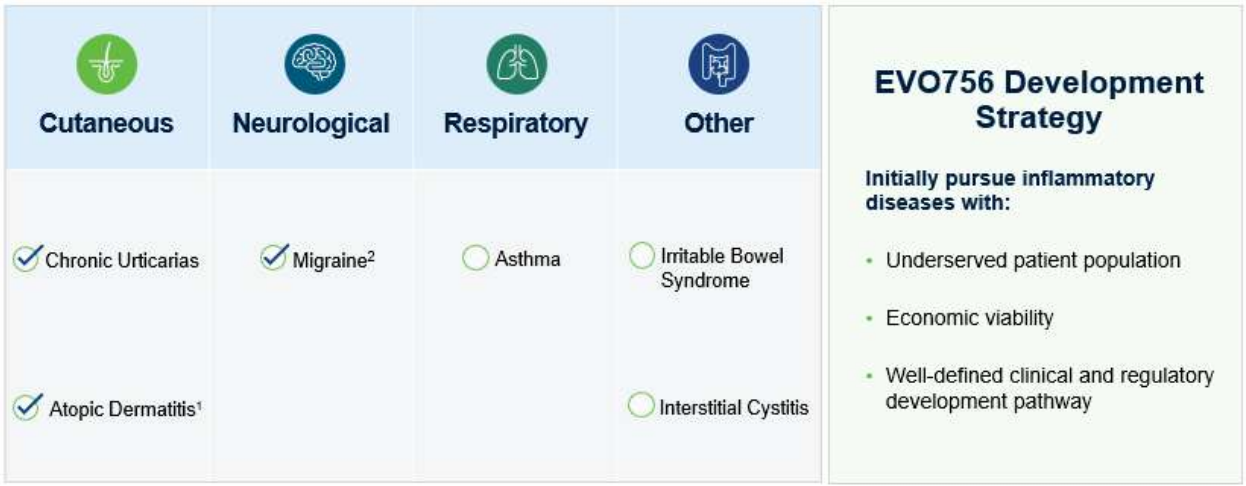
As we discover or in-license product candidates and advance them into the clinic, we design development strategies to rapidly establish proof-of-concept and apply stringent criteria to decide which product candidates should move forward. At every stage, we focus on advancing differentiated candidates that we believe have the highest potential for clinical advancement, guided by regulatory, clinical and commercial considerations.

EVO756, Targeting MRGPRX2 for Chronic Inflammatory Diseases

Our most advanced clinical-stage product candidate, EVO756, is a potent and highly selective oral small molecule antagonist of MRGPRX2, a receptor predominantly found on mast cells and peripheral sensory neurons. Dysregulated MRGPRX2 activity can play a key role as both a catalyst and perpetuator of disease pathogenesis across a multitude of systemic chronic inflammatory diseases. By targeting MRGPRX2, we believe EVO756 is the only dual mechanism clinical approach that modulates both mast cells and peripheral sensory neurons, representing a new potential therapeutic option to reduce inflammation and provide rapid relief of itch (pruritus).

Mast cells are critical regulators of immune response and can be found in most vascularized tissues including skin, lung and the digestive tract. These cells tend to be distributed in close proximity to peripheral sensory neurons, where the activation of the neurons can trigger the inflammatory cascade and mast cells are implicated in further perpetuating neuroinflammation and its related symptoms. We believe MRGPRX2 is the only clinical approach aimed at inhibiting this neuroimmune interaction. In addition, the cytoplasm of mast cells contains numerous membrane-bound granules that are filled with inflammatory mediators such as histamine and tryptase. When activated under normal conditions, mast cells degranulate, releasing their inflammatory mediators to protect against infections and toxins. They also may play a role in wound healing, angiogenesis (formation of new blood vessels) and initiating adaptive immune responses. However, aberrant activation of MRGPRX2 triggers excessive inflammation, resulting in symptoms such as hives (urticarial wheals), itch, pain, swelling and redness in a multitude of systemic chronic inflammatory diseases across organ systems. We are initially developing EVO756 for the treatment of CSU and AD, but we see broad expansion potential across additional chronic inflammatory diseases as illustrated in the figure below.

Figure 2: EVO756 Proof-of-Concept Roadmap



Notes: (1) Proof-of-concept based on skin challenge test in healthy volunteers.
(2) Proof-of-concept supported by positive clinical data for PACAP (MRGPRX2 ligand) inhibition in migraine prophylaxis (Lundbeck)

EVO756 for the Treatment of Chronic Spontaneous Urticaria

We are progressing the development of EVO756 for CSU, our current lead indication, and have completed an exploratory trial in CIndU. Many patients with CSU are known to also suffer from CIndU. Given the overlapping patient populations and shared underlying biology, we believe aspects of clinical development in CIndU can meaningfully inform that of CSU. In the United States, there are currently an estimated 3,000,000 patients with CSU and 850,000 patients with CIndU. CSU is a chronic inflammatory disease characterized by spontaneous and recurrent hives and angioedema without a known environmental trigger. In contrast, CIndU is triggered by specific physical stimuli such as cold, pressure, friction or heat.

The current landscape of approved and investigational therapeutics for CSU and CIndU lacks a safe, convenient and efficacious treatment option that could be utilized by a broad range of prescribers as a first-line treatment post-antihistamines. While initial treatment for these patients consists of over-the-counter oral antihistamines, it is estimated that greater than half of these patients do not achieve adequate symptom or disease control. There are currently only three available treatments for antihistamine-refractory patients, Xolair (omalizumab), a once monthly subcutaneous IgE mAb, Dupixent (dupilumab), a twice monthly subcutaneous mAb modulating the IL-4 and IL-13 signaling cascade, and Rhapsido (remibrutinib), a twice daily oral Bruton's tyrosine kinase (BTK) inhibitor approved September 2025, all of which have significant limitations. Xolair has been on-market since 2004 and was approved for use in CSU in 2014; however, its use in CSU has been constrained by safety concerns and limited efficacy, as well as barriers related to monitoring requirements after in-office administration. Dupixent was first approved in 2017 for AD and was subsequently approved for CSU in 2025. Nonetheless, Dupixent has failed in multiple CIndU trials and has failed to show statistically significant improvements in efficacy over the standard of care in omalizumab-refractory or intolerant CSU patients. Early efficacy and itch improvement remains a concern for CSU patients, with approximately 55% to 66% of patients

treated with Xolair experiencing itch and hives at 12 weeks and approximately 70% of Xolair-naïve patients treated with Dupixent experiencing itch and hives at 24 weeks. Rhapsido has side effects on its label including nasopharyngitis, bleeding, headache, nausea and abdominal pain, along with drug interactions recommending against its use with multiple classes of drugs. We believe these limitations play a role in these treatments only being utilized by an estimated 10% of antihistamine-refractory patients. Given there are currently over 3,000,000 patients living with CSU and more than 850,000 patients living with CIndU, we estimate that over 500,000 CU patients who are antihistamine-refractory are untreated and have uncontrolled disease.

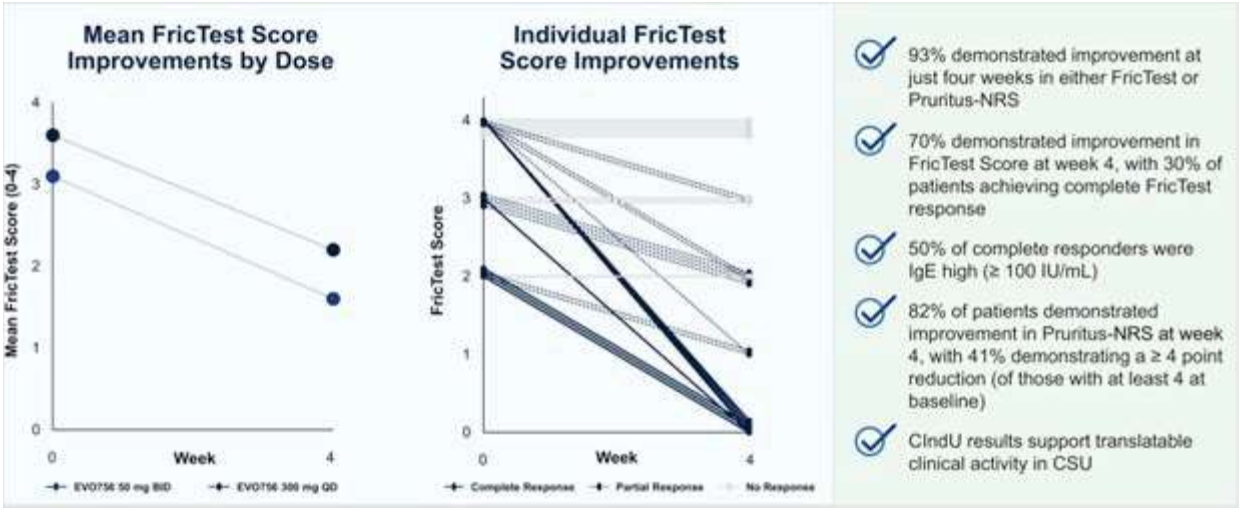
We conducted a Phase 1 proof-of-concept randomized, placebo-controlled trial in 132 healthy volunteers designed to assess the safety, tolerability, PK properties and PD properties of orally administered EVO756. Comprehensive trial results were presented at the UCARE Global Urticaria Forum meeting in December 2024. The Phase 1 trial enrolled 55 healthy adults in a single ascending dose ("SAD") portion and 77 healthy adults in a MAD portion in which participants were treated for 14 days. EVO756 was observed to have an encouraging tolerability profile at all doses tested, including the highest QD dose of 500 mg, with no SAEs observed. A skin challenge test was also conducted in the MAD portion of the trial in which icatibant, representative of a broad class of disease relevant ligands, was administered via intradermal injection to healthy volunteers creating measurable wheals on their skin. EVO756 was observed to robustly decrease the healthy volunteers' wheals induced by icatibant, evidencing meaningful target engagement at all doses tested. We believe this proof-of-concept portion of the trial supports the potential benefits of EVO756 in CSU.

In May 2025, we reported topline results from our U.S. multicenter Phase 2 trial of EVO756 in CIndU that demonstrated clinical activity (including improvement in FricTest score and pruritus-NRS, as described below) in a patient population with symptomatic dermographism. CIndU is a form of urticaria that has known environmental triggers, including pressure or exposure to cold and has underlying disease pathogenesis similar to CSU. The trial was designed to generate additional patient data in a population with symptomatic dermographism, which we believe will be highly translatable to the CSU patient population given the shared pathologies. Third party trials have demonstrated that symptomatic dermographism affects approximately 25% of the CSU patient population; similarly, we believe EVO756's clinical activity in symptomatic dermographism patients strongly supports the role of MRGPRX2 in neurogenic inflammation, which plays a crucial role in AD.

A total of 30 patients were enrolled in the trial, with 11 patients enrolled in the 300 mg QD cohort and 19 patients enrolled in the 50 mg BID cohort. Rapid clinical activity was observed in both dosing regimens, with some patients demonstrating responses by week one in both FricTest score (complete response score of zero) and pruritus-NRS (≥2-point decrease). 70% (n=19) of the 27 observed patients demonstrated improvement at just four weeks, with 30% (n=8) of the observed patients achieving a complete response (achieving a FricTest score of zero (a clinician rated measure of symptomatic dermographism severity ranging from 0 to 4, with higher scores indicating greater severity)), of which 50% were IgE high (as defined by a serum IgE level of ≥100 IU/mL). An additional 11% (n=3) achieved a partial response as defined by a ≥2-point decrease in FricTest score and a further 30% (n=8) demonstrated a one-point decrease in FricTest score. The population of subjects observed at four weeks does not include three patients who were unevaluable or lost to follow-up. Observed patients in the 300 mg QD cohort saw an average reduction of 1.4 points in FricTest score after four weeks and observed patients in the 50 mg BID cohort saw an average reduction of 1.5 points. By comparison, in separate, independent trials conducted by third parties, patients treated with 300 mg omalizumab saw a reduction of 1.4 points and patients treated with 300 mg barzolvolimab saw a reduction of 1.6 points in FricTest score after four weeks as shown in Figures 4 and 5 below.

Both the QD and BID regimens were observed to result in rapid and meaningful itch relief. Observed patients in the 300 mg QD cohort experienced an average reduction of 2.4 in pruritus-NRS, while those in the 50 mg BID cohort saw an average reduction of 2.1 points. Importantly, 93% (n=25) of observed patients demonstrated improvement at just four weeks in either FricTest or pruritus-NRS. Further, 75% (n=6) of those who did not achieve a decrease in FricTest score demonstrated a decrease in pruritus-NRS, evidencing the impact of EVO756 on itch at this early time-point, even in the absence of FricTest response. EVO756 was observed to be well-tolerated at both dose levels, including the higher 300 mg QD dose. No SAEs were observed and there were no discontinuations due to AEs. The figure below illustrates the clinical data, including FricTest improvement at four weeks, generated in our Phase 2 CIndU trial of EVO756:

Figure 3: EVO756 FricTest Score Improvements and Other Observed Data



The figures below illustrate the clinical improvements over time for omalizumab and barzolvolimab:

Figure 4: Omalizumab Clinical Activity Improved Over Time

Notes: Direct comparisons cannot be made in the absence of head-to-head trials because of differences in trial design, patient population and other factors.

Figure 5: Barzolvolimab Clinical Activity Improved Over Time

Notes: Direct comparisons cannot be made in the absence of head-to-head trials because of differences in trial design, patient population and other factors.

Examining historical trial data from mast cell targeting therapeutic agents that have been evaluated in CSU and CIndU suggests that CIndU response rate may correlate with clinical response in treating CSU. Our Phase 2 trial of EVO756 in CIndU was designed to generate additional patient data in a population with symptomatic dermographism, which we believe will be highly translatable to the CSU patient population given the shared pathologies. Figure 6 below details selected competitor therapeutic agents that have entered clinical development in CU, highlighting that targeting mast cells potentially indicates translatability from CIndU to CSU:

Figure 6: CIndU Response as a Potential Indicator of Future CSU Profile

Correlation Between CIndU Success and CSU Benefit

MOA	Cell Target	Drug	CIndU	CSU
IgE	Mast Cells Basophils Eosinophils	omalizumab	✓	✓
KIT	Mast Cells Hematopoietic Stem Cells Germ Cells Melanocytes	barzolvolimab	✓	✓
BTK	Mast Cells B Cells Basophils Myeloid Cells	remibrutinib	✓	✓
IL-4 / IL-13	Th2 Cells Epithelial Cells Macrophages	dupilumab	✗	✓

Notes: Direct comparisons cannot be made in the absence of head-to-head trials because of differences in trial design, patient population and other factors. Data is presented for information only and does not account for differences in enrollment populations or other cross-trial variabilities.

In CSU, we initiated a Phase 2b dose-ranging trial in approximately 160 moderate-to-severe antihistamine-refractory CSU patients and expect initial data from that trial in the second quarter of 2026. This is a randomized, double-blind, placebo-controlled trial in which participants will receive one of three active dose regimens or placebo. The primary endpoint of the trial is change in a patient's Urticaria Activity Score over seven days ("UAS7") at 12 weeks. Beyond the primary endpoint, we are also evaluating other measures of disease, including itch, hive severity and angioedema.

EVO756 for the Treatment of Atopic Dermatitis

Atopic dermatitis, commonly referred to as eczema, is one of the most prevalent chronic inflammatory diseases and is characterized by acute flares of itchy, red, exudative papules and persistently dry, scaly skin. The hallmark feature of AD is intense inflammatory itch, known as pruritus, with episodic flares of rash and underlying chronic inflammation. For most moderate-to-severe AD patients, the disease significantly impacts patients' quality of life, driven primarily by relentless itch, sleep disruption and visible skin symptoms. The intense itch associated with AD often triggers an itch-scratch cycle, further compromising the epidermal barrier and exacerbating disease. While AD commonly begins in childhood, it is also highly and increasingly prevalent in adults, with about 15% to 20% of children and 1% to 3% of adults impacted, significantly disrupting their quality of life.

Research indicates that mast cells and peripheral sensory neurons play a key role in the pathogenesis of AD. One known driver of AD is the chronic and cyclical release of pro-inflammatory mediators associated with mast cell degranulation. Heightened mast cell activity promotes inflammation and drives itch, while activation of peripheral sensory neurons amplifies the sensation of itch. Third party studies have shown increased mast cell density, elevated MRGPRX2 expression and neuroinflammation correlate with disease severity in lesional AD skin. For example, a third-party study examined the number of mast cells from lesional and non-lesional skin of AD patients and skin of healthy volunteers. The biopsies showed that in AD lesional skin, more mast cells were found as compared to non-lesional skin. In addition, in a third-party preclinical mouse study, AD severity was shown to be specifically associated with MRGPRX2 expression. Internal research conducted by us identified key MRGPRX2 ligands and MRGPRX2 as more abundant in lesional skin. Additionally, our internal research has verified MRGPRX2 expression in sensory neurons and that EVO756 robustly decreased sensory neuron activation when stimulated. Collectively, we believe these findings highlight the MRGPRX2 activation pathway in AD and support the rationale for targeting MRGPRX2 to resolve both skin lesions and itch by modulating mast cells and peripheral sensory neurons.

The current standard of care for first-line treatment of AD are primarily topical corticosteroids and targeted treatments (for example, topical Janus kinase ("JAK") inhibitor). However, approximately 40% to 50% of AD patients have a moderate-to-severe form of the disease and thus are uncontrolled by topical therapies. For these patients, new systemic agents have emerged as the preferred advanced treatments that target several different inflammatory mediators that contribute to underlying inflammation and flare-ups, including Dupixent (dupilumab), Rinvoq (upadacitinib) and Cibinqo (abrocitinib). Despite the effectiveness of these therapies, some of them are associated with serious risk of life-threatening side effects and carry boxed warnings.

We are developing EVO756 for the treatment of moderate-to-severe AD in adult and pediatric patients whose disease remains uncontrolled with prescription topical therapies. We initiated a Phase 2b dose-ranging trial in moderate-to-severe AD patients in August 2025 and expect to report initial results in the second half of 2026. The primary endpoint is change in EASI score at 12 weeks, and we also plan on assessing Investigator Global Assessment ("IGA") and pruritus-NRS. In addition, should EVO756 demonstrate a positive treatment effect on itch in the Phase 2b dose-ranging trial, we may subsequently evaluate its potential in other forms of inflammatory itch (pruritus).

Additional Development Opportunities for EVO756

Beyond CSU and AD, there are a number of other systemic chronic inflammatory diseases in which mast cell degranulation and neuroinflammation are implicated, including areas where we believe EVO756 could fulfill significant unmet patient needs. Additional diseases in which we are exploring the potential of MRGPRX2 inhibition include migraine, asthma, interstitial cystitis, irritable bowel syndrome and pruritus. Our next indication of interest is migraine and we plan to initiate a Phase 2b trial in mid-2026. Initiation of a Phase 2 trial in any of these additional indications will be determined based on ongoing trials and corporate resources. To date, based on our data from the successful completion of our Phase 1 proof-of-concept trial of EVO756 in healthy volunteers, we believe there is a path to proceed to Phase 2 clinical development for these other indications, similar to our initiation of our Phase 2b trial in AD, subject to standard regulatory requirements.

EVO301, Our SAFA Binding Protein Targeting IL-18 for Chronic Inflammatory Diseases

Our second clinical-stage product candidate, EVO301, is currently in Phase 2 development for the treatment of moderate-to-severe AD. In June 2024, we secured exclusive global rights to develop and commercialize EVO301 from AprilBio Co. Ltd. ("AprilBio") (Kosdaq: 397030), a biopharmaceutical company based in South Korea dedicated to developing specialized biologics and antibody drugs, after they progressed EVO301 through a Phase 1 trial.

IL-18 is a pro-inflammatory cytokine of the IL-1 family that not only regulates various immune processes that drive inflammation, but also acts as a potent modulator of ongoing inflammation. The IL-18 pathway is believed to play a role in the severity and progression of several large, highly prevalent chronic inflammatory disease populations with a significant number of uncontrolled patients, including AD and UC.

EVO301 is a long-acting injectable SAFA-IL-18BP fusion protein consisting of a native human IL-18BP domain linked to a human Fab antibody fragment-targeting albumin, designed to neutralize the IL-18 inflammatory pathway. We believe this design, differentiated from mAbs targeting IL-18, potentially confers several advantages including improved activity, decreased immunogenicity and better distribution to sites of inflammation. Based on learnings from biologics targeting other inflammatory targets, we believe these benefits may provide faster onset of action and deliver comparable or better efficacy results to commercially available biologics while potentially offering better tolerability, durability, safety and more convenient dosing.

In a Phase 1 randomized, placebo-controlled SAD trial conducted in 31 healthy volunteers, EVO301 was observed to be well-tolerated at all doses tested, with no SAEs or discontinuations due to AEs. PK observations were favorable and support monthly dosing.

In February 2026, we announced positive top-line results from a randomized, double-blind, placebo-controlled Phase 2a trial evaluating EVO301 in adult patients with moderate-to-severe AD. The trial met its primary efficacy endpoint at week 12 and achieved highly statistically significant outcomes in adult patients with moderate-to-severe AD. The 70-patient trial was designed to evaluate the safety and efficacy of intravenous dosing of 5 mg/kg on day 1 and day 28 (n=48 active, n=22 placebo) over 12 weeks. The trial met its primary endpoint, demonstrating clinically meaningful activity in AD with statistical significance over placebo achieved at weeks 4, 8 and 12 at $p<0.01$. We believe demonstrating this activity with an IL-18 targeting therapy supports the relevance of this pathway in disease pathophysiology and reinforces that pathways beyond classic Th2 biology can contribute meaningfully to disease activity. Expanding therapeutics to target novel mechanisms like IL 18 could offer benefit for patients who remain uncontrolled on existing therapies and reinforces the urgent need to develop more options across the growing AD population. We plan to rapidly move a subcutaneous formulation of EVO301 into a Phase 2b trial in AD where we believe optimized and more frequent dosing of EVO301 could achieve potential best-in-class EASI activity.

Beyond AD, we are evaluating a potential Phase 2 trial in moderate-to-severe UC patients. We may also evaluate EVO301 in Crohn's disease, certain cardiovascular-related inflammatory conditions, and additional indications in which dysregulation of the IL-18 pathway may contribute to chronic inflammation and tissue damage driving disease pathology. To date, based on the data from the successful completion of the Phase 1 and Phase 2 trials of EVO301, we believe there is a path to proceed to Phase 2 clinical development for these other indications, subject to standard regulatory requirements.

We believe EVO301's distinct mechanism and modality complement those of EVO756, providing us with multiple potential avenues to bring innovative therapeutics to the large, underserved and rapidly expanding patient population suffering from chronic inflammatory diseases.

Other Drug Discovery and Development

Beyond our clinical-stage product candidates, we are advancing a suite of discovery-stage programs to broaden and diversify our portfolio. We aim to deliver a steady cadence of clinical data, in line with our vision of addressing chronic inflammatory diseases across multiple pathways and indications.

EVO756: Our MRGPRX2 Antagonist

Overview

Our most advanced clinical-stage product candidate, EVO756, is a potent and highly selective oral small molecule antagonist of MRGPRX2. Dysregulated MRGPRX2 activity is implicated in a range of systemic chronic inflammatory diseases, acting both as a catalyst and perpetuator of disease pathology. The blockade of MRGPRX2 represents an innovative, targeted, dual mechanism approach for the treatment of multiple systemic chronic inflammatory diseases across different organs by inhibiting both mast cell degranulation and neuroinflammation mediated via peripheral sensory neurons.

EVO756 represents a differentiated strategy with the potential to deliver a safe, effective and convenient daily oral treatment. We believe this approach could address significant unmet need in chronic inflammation, align with the preferences of both patients and prescribers, enable broader prescribing beyond specialists and expand the reach of treatment to millions of underserved patients.

Clinical and preclinical data from our team and third parties suggest that blocking MRGPRX2 activation can selectively prevent mast cell degranulation and the release of pro-inflammatory mediators. By selectively inhibiting MRGPRX2, we aim to avoid the safety risks of therapies that deplete mast cells or cause broad immunosuppression.

We are initially developing EVO756 in CSU and AD, two diseases with well-established MRGPRX2 biology and high unmet need, while also planning to expand into additional chronic inflammatory indications.

We conducted a Phase 1 proof-of-concept trial in 132 healthy volunteers designed to assess the safety, tolerability, PK and PD properties of orally administered EVO756. Comprehensive trial results were presented at the UCARE Global Urticaria Forum meeting in December 2024. A skin challenge test was conducted in the MAD portion of the trial in which icatibant, representative of a broad class of disease relevant ligands, was administered via intradermal injection to healthy volunteers creating measurable wheals on their skin. EVO756 was observed to robustly decrease the healthy volunteers' wheals induced by icatibant, evidencing meaningful target engagement at all doses tested.

We are currently conducting a Phase 2b trial of EVO756 in CSU and have completed a Phase 2 trial of EVO756 in CIndU. In May 2025, we reported topline results from our U.S. multicenter Phase 2 trial of EVO756 in CIndU that demonstrated clinical activity (including improvement in FricTest score and pruritus-NRS, as described below) in a patient population with symptomatic dermographism. Rapid clinical activity was observed in both dosing regimens, with some patients demonstrating responses by week one in both FricTest score (complete response score of zero) and pruritus-NRS (≥2-point decrease). 70% (n=19) of the 27 observed patients demonstrated improvement at just four weeks, with 30% (n=8) of the observed patients (n=8) achieving a complete response (achieving a FricTest score of zero), of which 50% were IgE high. An additional 11% (n=3) achieved a partial response as defined by a ≥2-point decrease in FricTest score and a further 30% (n=8) demonstrated a one-point decrease in FricTest score. The population of subjects observed at four weeks does not include three patients who were unevaluable or lost to follow-up. Both observed dosing levels were observed to result in rapid and meaningful itch relief to patients, with observed patients in the 300 mg QD cohort experiencing an average reduction of 2.4 in pruritus-NRS while observed patients in the 50 mg BID cohort saw an average reduction of 2.1 points. Importantly, 93% (n=25) of observed patients demonstrated improvement at just four weeks in either FricTest or pruritus-NRS. Further, 75% (n=6) of those who did not achieve a decrease in FricTest score demonstrated a decrease in pruritus-NRS, evidencing the impact of EVO756 on itch at this early time-point, even in the absence of FricTest response. EVO756 was observed to be well-tolerated at both dose levels, including the higher 300 mg QD dose. No SAEs were observed and there were no discontinuations due to AEs. We expect to report initial data from the Phase 2b trial of EVO756 in CSU in the second quarter of 2026. We also initiated a Phase 2b dose-ranging trial in AD in August 2025 and expect to report initial results in the second half of 2026.

MRGPRX2 as an Ideal Target for Chronic Inflammatory Disease

MRGPRX2 is highly expressed on mast cells and peripheral sensory neurons and is activated by multiple ligands that are elevated in inflamed tissues, including neuropeptides, host defense peptides, proteases and cytokines. Such ligands have been found to be upregulated in a range of chronic inflammatory diseases including CSU, AD, migraine, asthma, interstitial cystitis and irritable bowel syndrome. Our management team has deep expertise with MRGPRX2, having worked with the target for over a decade, which we believe provides us with powerful insight into the biology, patient needs and treatment landscape in this space.

Mast cells are critical regulators of the immune response and can be found in most vascularized tissues, including skin, lung and the digestive tract. When ligands activate MRGPRX2 on mast cells, they trigger a signaling cascade that induces degranulation, which initiates the release of inflammatory mediators including histamine, chemokines, leukotrienes, prostaglandins, tryptase and chymase. Activation of MRGPRX2 also drives neuroinflammation on peripheral sensory neurons, located in various tissues including skin and lung. Aberrant activation of mast cells and peripheral sensory neurons via the MRGPRX2 receptor can lead to a variety of disease pathologies depending on the affected tissue, resulting in uncontrolled symptoms that are characteristic of many chronic inflammatory diseases such as hives, itch, pain, swelling and redness. Disease pathology is further amplified by the observation that mast cells and peripheral sensory neurons are concurrently activated in certain diseases, such as CSU and AD, which creates upregulated MRGPRX2-dependent feedback loops and intensified symptoms. The following figures illustrate MRGPRX2's role in mast cell activation and neuroinflammation and as a nexus for mast cell and neuron activation by multiple ligands:

Figure 7: MRGPRX2 in Mast Cell Activation and Neuroinflammation

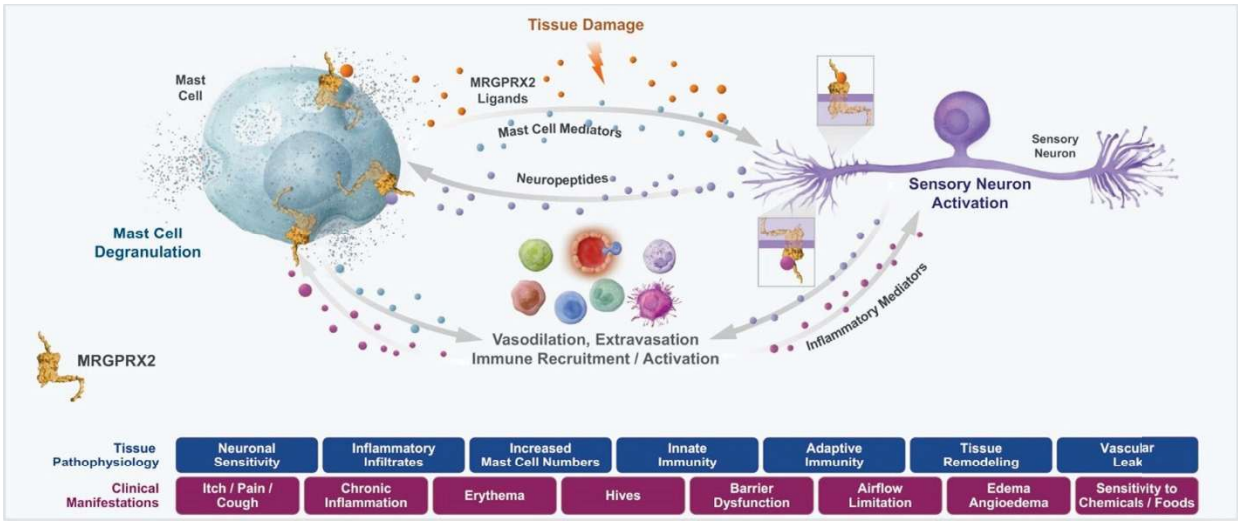
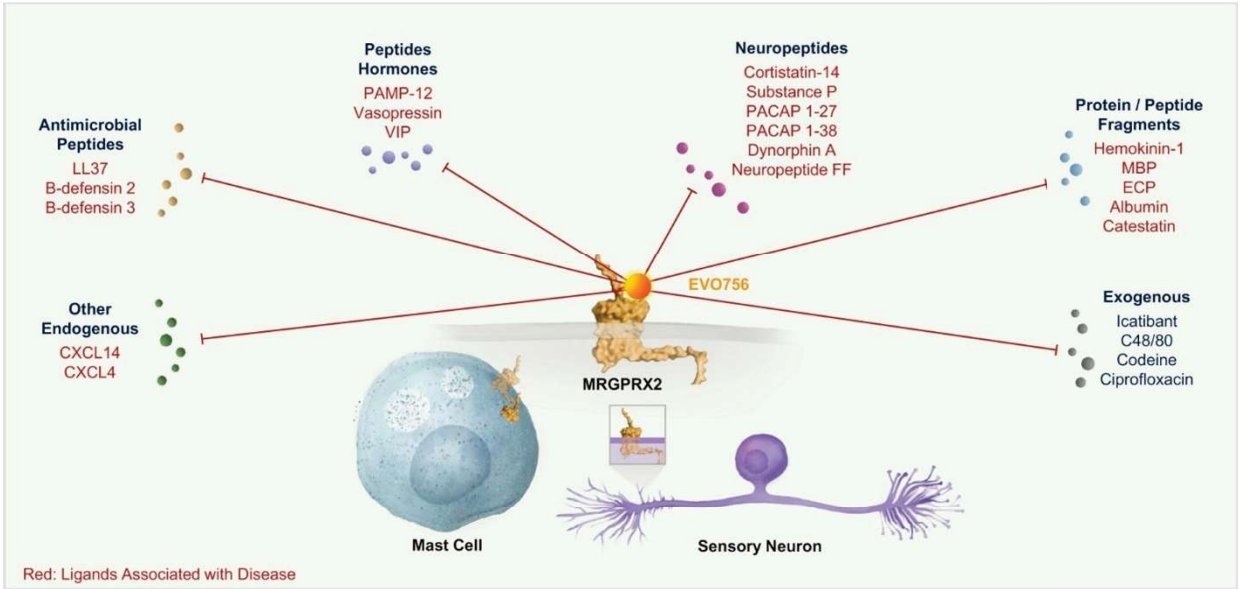


Figure 8: MRGPRX2, A Nexus for Mast Cell/Neuron Activation by Multiple Ligands



Based on MRGPRX2's concentrated expression on these two cell types, we believe there is potential for synergistic mast cell and peripheral sensory neuron activation by disease-relevant ligands. We believe MRGPRX2 is the only clinical approach aimed at inhibiting this neuroimmune interaction. We also believe MRGPRX2 antagonism presents a differentiated and compelling safety profile. Existing methods of modulating mast cells include anti-IgE therapies and targeting the receptor tyrosine kinase KIT.

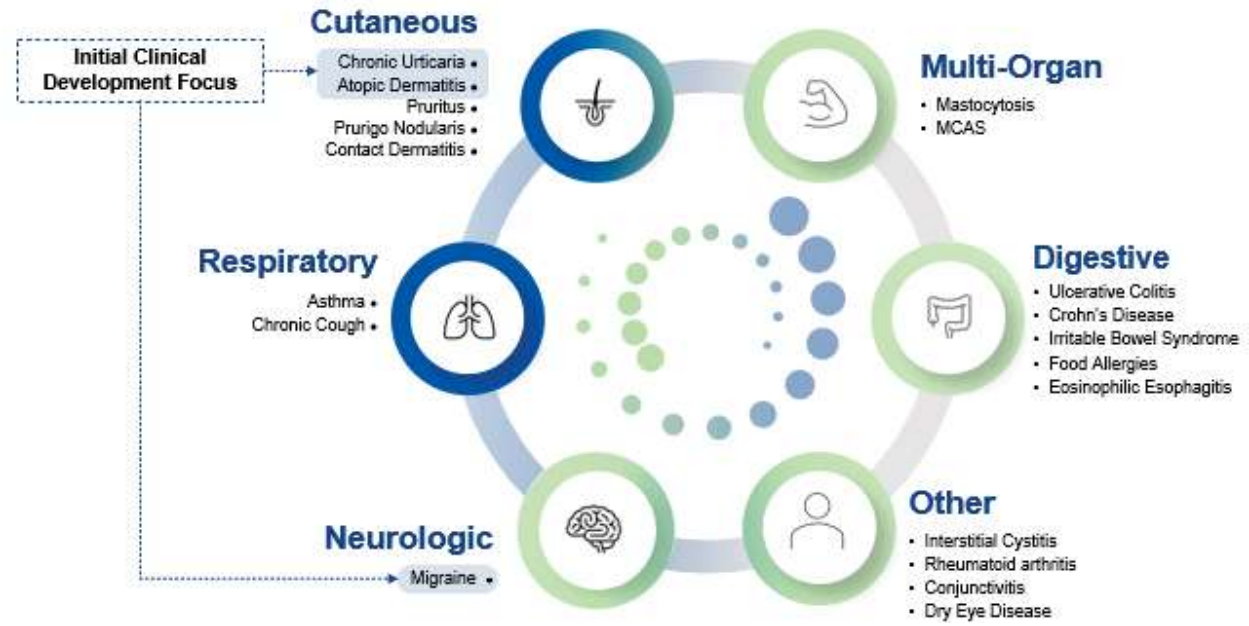
Anti-IgE therapies block mast cell activation but are associated with the risk of anaphylaxis and KIT inhibition, which depletes mast cells, affects many biological processes and has demonstrated a heightened potential for on-target toxicity in clinical trials. Similarly, downstream inhibitors like JAK or Bruton's tyrosine kinase ("BTK") reduce inflammation by broadly suppressing immune pathways, leading to potential systemic side effects and safety concerns. In contrast, MRGPRX2 is selectively expressed in mast cells and sensory neurons, which we believe leads to a narrower range of inflammatory outcomes and ultimately lowers the potential for on-target toxicity.

Market Opportunity

We believe EVO756 has the potential to be used for the treatment of a broad spectrum of highly prevalent and debilitating chronic inflammatory diseases in which mast cell and peripheral sensory neuron regulation is central to disease pathogenesis, including cutaneous diseases (such as CU and AD), neurologic conditions (such as migraine), respiratory conditions (such as asthma) and other diseases (such as interstitial cystitis). Standards of care for these diseases, particularly for patients with refractory or moderate-to-severe forms of their disease, are often limited by suboptimal safety or efficacy, as well as barriers related to administration or monitoring, which result in low utilization.

Our initial focus for EVO756 development is CSU and AD, where we see clear paths to create benefits based on high unmet patient need, well-defined clinical endpoints and the potential for both rapid symptom relief and disease-modifying effects through targeted mast cell and peripheral sensory neuron modulation. We also plan to explore additional indications in which mast cell degranulation and neuroinflammation are key drivers of disease, expanding the potential reach of EVO756 across a broad range of chronic inflammatory diseases. The following illustration depicts the broad universe of conditions where we believe targeting MRGPRX2 could potentially provide meaningful clinical benefit:

Figure 9: Targeting MRGPRX2 Creates Broad Opportunity



The prevalence in the United States of certain diseases of interest in which mast cell degranulation and neuroinflammation are believed to play a role is significant, as shown in the table below:

Figure 10: Prevalence of Select Chronic Inflammatory Diseases

Diseases	Estimated U.S. Prevalence
Chronic Spontaneous Urticaria	3,000,000
Chronic Inducible Urticaria	850,000
Atopic Dermatitis	16,000,000[1]
Asthma	20,000,000
Chronic Inflammatory Pruritus	100,000,000
Migraine	39,000,000
Interstitial Cystitis	12,000,000

Notes: (1) Estimated adult AD prevalence.

Our Solution: EVO756, Our MRGPRX2 Antagonist

We are developing EVO756 as an oral therapy targeting MRGPRX2 to address a broad spectrum of inflammatory indications. We believe EVO756 can be a first-line therapy for CSU and AD and is currently the most advanced program in clinical development targeting MRGPRX2. EVO756's molecular properties, measured in our *in vivo* studies, are consistent with Lipinski's Rule of Five, a set of guidelines used in drug discovery to predict oral bioavailability and avoid off-target effects. Its low molecular weight, low lipophilicity reflected by a favorable cLogP, as well as a high rate of free fraction, make us confident that EVO756 is designed and optimized for oral delivery. We believe EVO756's carefully designed molecular and PK profile, with high bioavailability and limited off-target potential, differentiates it from other known attempts to mechanistically target MRGPRX2 in chronic inflammatory diseases. The following table depicts select characteristics of EVO756:

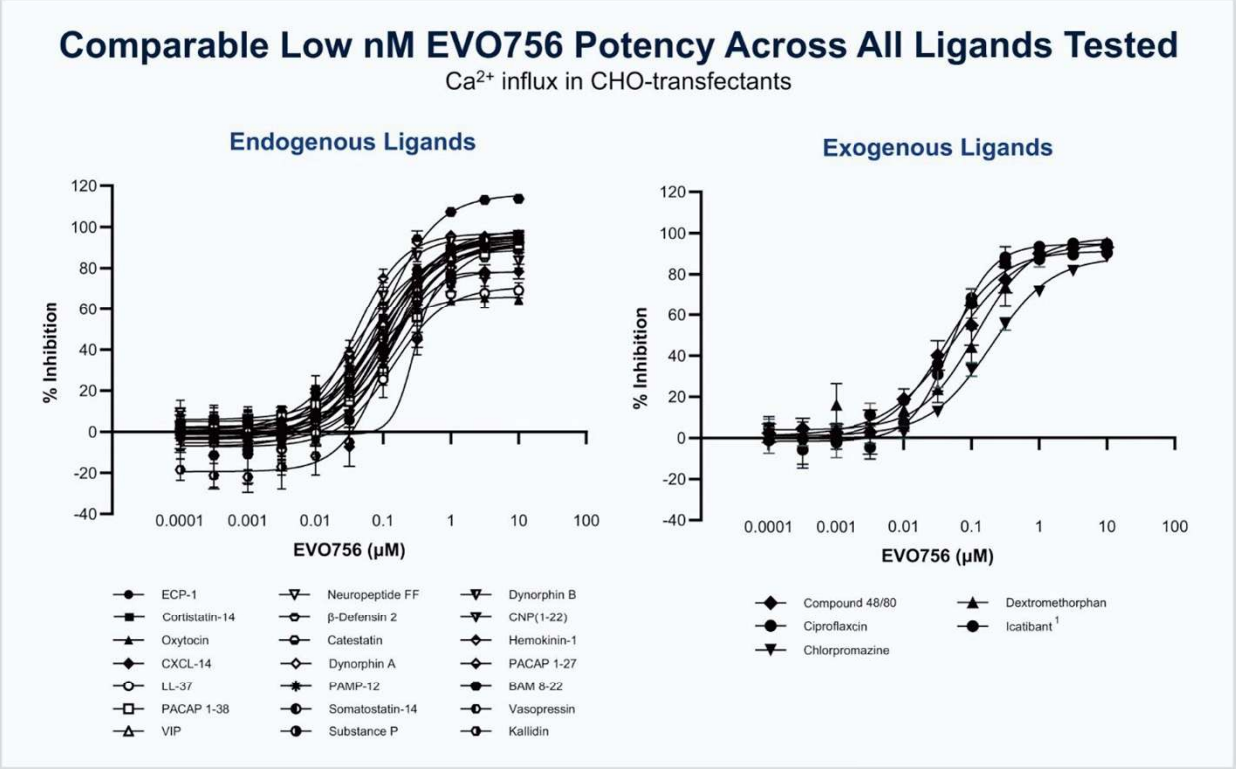
Figure 11: Select Characteristics of EVO756

EVO756	
Potency	Primary Mast Cells: IC_{50} Low nM
Molecule	MW < 350, LogD < 3 PPB > 10% unbound
ADME	Favorable ADME / PK profile Limited DDI potential
Anticipated Human Dose	< 200 mg daily
High-throughput screening discovered inhibitor with favorable properties	

Notes: ADME = Absorption, Distribution, Metabolism, and Excretion; MW = Molecular Weight; PPB = Plasma Protein Binding; DDI = Drug-Drug Interaction.

We have observed that EVO756 exhibits potent activity across a broad and representative panel of inflammatory ligands known to act through MRGPRX2. Because chronic inflammation in individual patients may be driven by varying combinations of disease-associated ligands, we evaluated multiple known ligand classes (as shown in Figure 12 below). Based on preclinical studies and the MAD portion of our Phase 1 proof-of-concept trial, EVO756 was observed to consistently and robustly inhibit degranulation across all tested ligands—both endogenous and exogenous—as shown in Figure 12 below:

Figure 12: EVO756 Is a Highly Potent Oral Small Molecule



Notes: (1) Icatibant used as agonist for PD challenge.

In our completed Phase 1 trial, EVO756 was observed to cause decreases in skin response as measured by changes in icatibant-induced wheals, which we believe confirms target engagement and suggests the potential of EVO756 to block disease relevant ligands in CSU. EVO756 was observed to be well-tolerated at all doses tested, with no SAEs observed, and PK results supporting daily oral dosing.

Chronic Urticaria Background

Urticaria, also known as hives, is a disease characterized by the presence of wheals, itching and angioedema, which is swelling in subcutaneous tissue, often in the lips, face and extremities. This disease is characterized as CU when lasting for a period of more than six weeks. The two forms of CU are CSU and CIndU. CSU is a chronic inflammatory skin disease characterized by spontaneous and recurrent hives and angioedema without a known environmental trigger. In contrast, CIndU is triggered by specific physical stimuli such as pressure, cold, friction or heat. Both are driven by aberrant mast cell activation, leading to the repeated release of histamine and other pro-inflammatory mediators. This activation causes vasodilation, immune cell recruitment, swelling and stimulation of peripheral sensory neurons, resulting in intense, persistent itch. Uncontrolled CU can last months or even years and significantly impact patients through the disruption of daily living and reduction in quality of life.

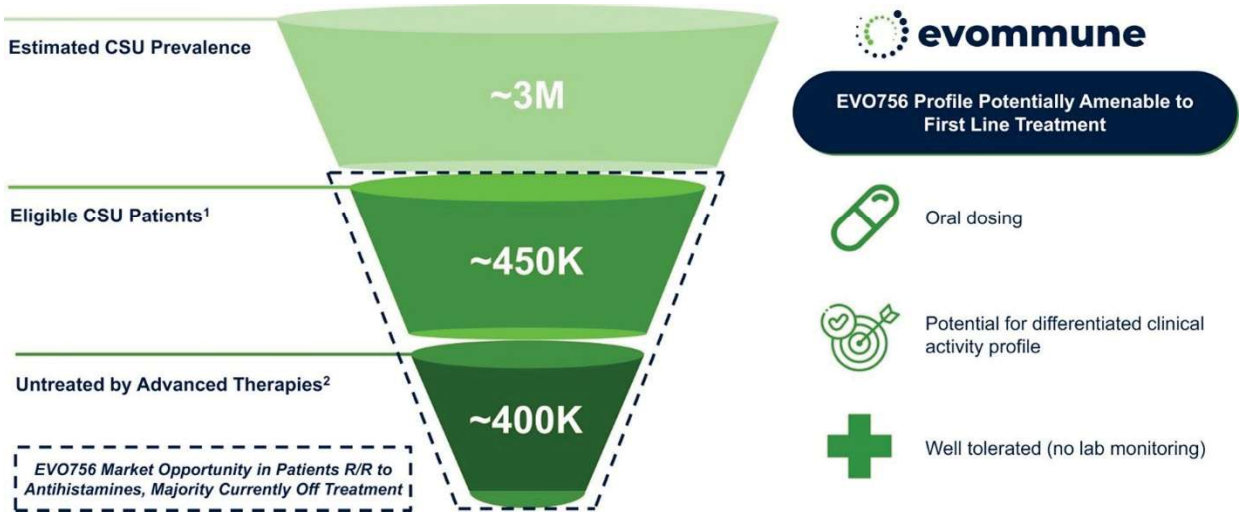
Currently, in the United States, we estimate that there are more than 3,000,000 patients living with CSU and over 850,000 patients living with CIndU. The current range of existing and potential therapeutics for CU collectively lacks a safe, convenient, efficacious treatment option that could be prescribed by a broad range of prescribers.

Current Treatment Paradigm

Antihistamines are generally the initial treatment for CU due to their availability over-the-counter, low price and benign safety profile. However, approximately 50% of patients treated with antihistamines experience inadequate symptom control. There are only three approved therapeutics available as a therapy for antihistamine-refractory CSU patients: (i) Xolair (omalizumab), a once monthly injectable anti-IgE mAb which contains a black box warning for anaphylaxis, (ii) Dupixent (dupilumab), a twice monthly subcutaneous mAb modulating the IL-4 and IL-13 signaling cascade and (iii) Rhapsido (remibrutinib), a twice daily oral BTK inhibitor.

Approximately two-thirds of the CSU patients treated with Xolair do not experience complete symptom control. In addition, Xolair has safety concerns regarding its black box warning for anaphylaxis and has burdensome monitoring requirements including in-office administration for three consecutive months. We believe these concerns have limited adoption predominantly to allergists and have led to Xolair being significantly underutilized by dermatologists, primary care physicians and pediatricians, with approximately 10% penetration in the antihistamine-refractory CSU market. Overall, we estimate that approximately 450,000 CSU patients in the United States are either untreated or have uncontrolled disease and are not well served by the existing treatment paradigm, as illustrated in the figure below:

Figure 13: CSU Is an Underserved Market with Limited Treatment Options

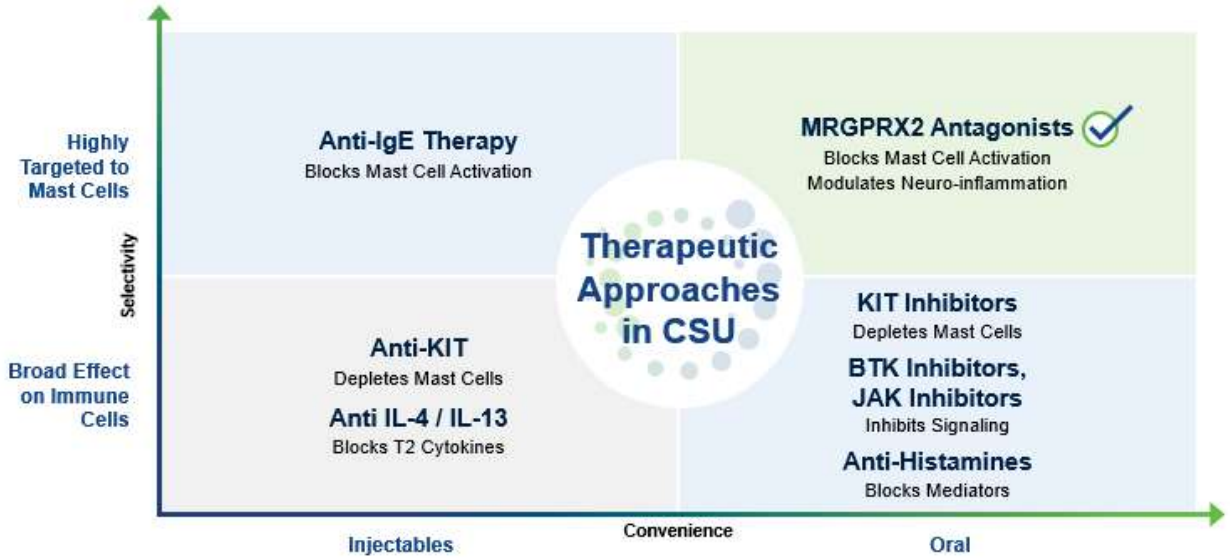


Notes: (1) In the United States, "Eligible" defined as CSU patients with incomplete response to over-the-counter H1-antihistamines and eligible for targeted therapy; (2) Approximately 50,000 patients currently treated with a biologic.

Dupixent was approved for CSU in April 2025. Despite having shown success in other immunology indications, Dupixent has more limited efficacy in CSU compared with Xolair, with less than a third of Xolair-naïve patients dosed reaching a complete response (as defined by UAS7=0) at week 24 (and notably only a 16% complete response rate at week 12, the common endpoint for competitor CSU trials). Furthermore, Dupixent failed to meet the primary endpoint of ISS7 reduction in a Phase 3 trial in omalizumab-refractory or intolerant patients. Additionally, Dupixent has been associated with conjunctivitis and injection site reactions. Due to these limitations, we estimate there is a significant number of patients who either remain untreated or untreatable with current treatment options. We believe EVO756 may ultimately be a first line treatment option across prescriber types, if approved.

Beyond Xolair and Dupixent, the next most advanced product candidate is Rhapsido, an orally administered BTK inhibitor approved for the treatment of CSU in September 2025. While Rhapsido has been observed in clinical trials to have greater clinical activity than Dupixent, Rhapsido has adverse reactions on its label including nasopharyngitis, bleeding, headache, nausea and abdominal pain, along with drug interactions recommending against its use with multiple classes of drugs. Furthermore, we believe BTK inhibitors as a class have a more concerning safety profile with multiple labeled warnings and precautions. We are also aware of KIT inhibitor programs in development for the treatment of CSU. KIT inhibitors have a proven ability to limit mast cell development and therefore significantly reduce hives for urticaria patients. However, KIT inhibitors also impact the development of a range of other cells, resulting in a variety of side effects, including neutropenia, changes in taste and hair color and spermatogenesis. We believe these challenges could limit KIT inhibitors to a later-line treatment option. The following graphic compares MRGPRX2 to other mechanisms of action being evaluated in CSU:

Figure 14: Potential for EVO756 to Address an Urticaria Market with Significant Therapeutic Opportunity



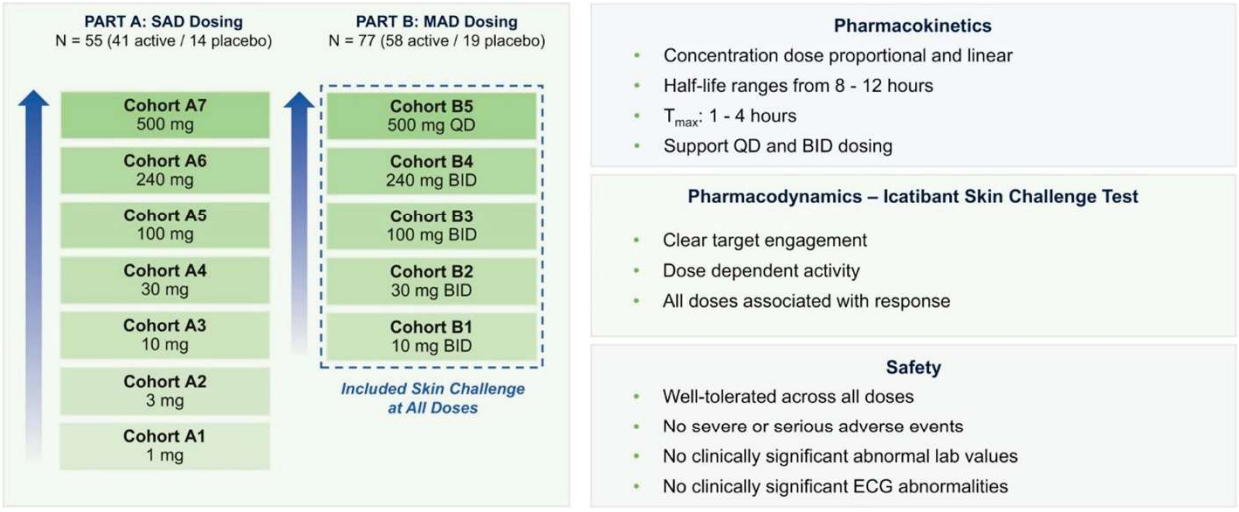
We believe that MRGPRX2-targeted therapies have the potential to show a superior safety and comparable efficacy profile to Xolair, Dupixent, Rhapsido, and other therapeutic candidates in development, thus having the potential to become the first-line treatment for antihistamine-refractory patients. Nonclinical and clinical data generated internally and by third parties support the potential for MRGPRX2-targeted therapies to emerge with an attractive class profile with efficacy in the range of approved treatments while delivering improved safety, faster symptom relief through direct modulation of peripheral sensory neurons and the convenience of a daily oral. Furthermore, we believe the safety results observed to-date and convenient oral dosing of EVO756 may not only position it to become the backbone therapy for CSU, if approved, but it also has the potential to be used in combination treatment with existing approved biologics, such as Xolair and Dupixent.

Clinical Data

Our Completed Phase 1 Trial

In July 2024, we announced the topline results from a Phase 1 proof-of-concept trial in 132 healthy volunteers designed to assess the safety, tolerability, PK properties and PD properties of orally administered EVO756. Comprehensive trial results were presented at the UCARE Global Urticaria Forum meeting in December 2024. The Phase 1 trial was a SAD and MAD trial in healthy volunteers and was conducted in the United States. The figure below depicts the design of this trial:

Figure 15: Phase 1 Proof-of-Concept Trial Design and Summary



Notes: ECG = electrocardiogram

In the trial, 55 individuals (including placebo) were administered a single dose in the SAD portion and 77 individuals (including placebo) were dosed once or twice daily for 14 days in the MAD portion. In the SAD portion, doses from 1 mg to 500 mg were administered in ascending order across seven cohorts of approximately eight participants each (six active and two placebo). In the MAD cohorts, ascending doses of 10 mg, 30 mg, 100 mg and 240 mg twice daily were administered across four cohorts of 16 subjects each (12 active and four placebo) and a fifth cohort of approximately 16 subjects (12 active and four placebo) were administered 500 mg once daily. A skin challenge test was also conducted in the MAD portion of the trial in which icatibant, representative of a broad class of disease relevant ligands, was administered via intradermal injection to create measurable wheals on their skin.

Safety Results

EVO756 was observed to be well-tolerated at all doses administered in both the SAD and MAD portions of the trial, including up to the 500 mg QD dose. No SAEs were observed and all AEs reported were considered mild or moderate and included headache, dizziness, catheter site pain, diarrhea and lymphadenopathy. There was one discontinuation, which was not considered treatment-related, as the patient withdrew consent prior to completion of treatment. In addition, there were no clinically significant electrocardiogram ("ECG") or lab abnormalities. The following table summarizes the safety results of this trial:

Figure 16: Safety Results of Phase 1 Trial

Subject Disposition		
Total Enrolled	132	
	SAD	**MAD**
Placebo	14	19
EVO756	41	58
AE Summary	**Placebo**	**Active**
Total AEs (events/subjects)	21 (.64)	65 (.66)
Subjects with AEs	14 (42%)	32 (32%)

PK Results and Trial Dosing

In the MAD portion of the trial, increased dosing from 10 mg twice daily to 240 mg twice daily, and 500 mg once daily, resulted in approximately dose-proportional increases in serum concentrations of EVO756, with about a two-fold accumulation observed from day 1 through day 14. In this trial, serum concentrations of EVO756 were above the IC_{90} for MRGPRX2 inhibition at trough at all dosing levels 30 mg twice daily and higher.

Phase 1 Proof-of-Concept Skin Challenge Test

The Phase 1 trial included a skin challenge test based on work published out of Johns Hopkins University. In a clinical setting, MRGPRX2 ligands, administered intradermally in a skin challenge test, have been shown to produce functional and measurable skin responses (wheals) in healthy individuals and a heightened response in individuals with CU.

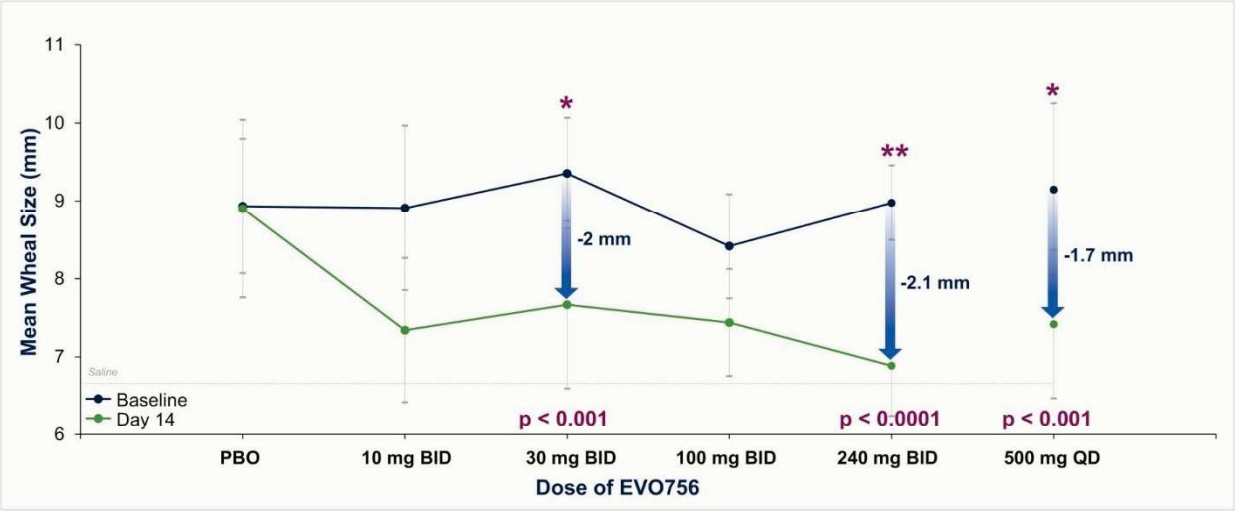
We assessed the PD potential of EVO756 in the MAD portion of the trial in which icatibant, whose pharmacology effectively represents typical characteristics of MRGPRX2 ligands, was administered intradermally. Figure 17 below outlines the mechanism and design of this skin challenge test:

Figure 17: Skin Challenge Test: Proof-of-Concept and Target Engagement for Chronic Urticaria

In the skin challenge test, intradermal administration of 10 and 100 µg/mL icatibant-induced wheals consistent with those observed previously in the work performed by Johns Hopkins (Shtessel *et al.*) resulted in measurable skin responses in a highly controlled setting.

We believe this PD assessment provides proof-of-concept for EVO756 in the treatment of CU as EVO756 was observed to engage MRGPRX2, block the impact of a known MRGPRX2 ligand and robustly reduce the mean size of icatibant-induced wheals (10 µg/mL (7.6 µM) icatibant), as shown in the following chart:

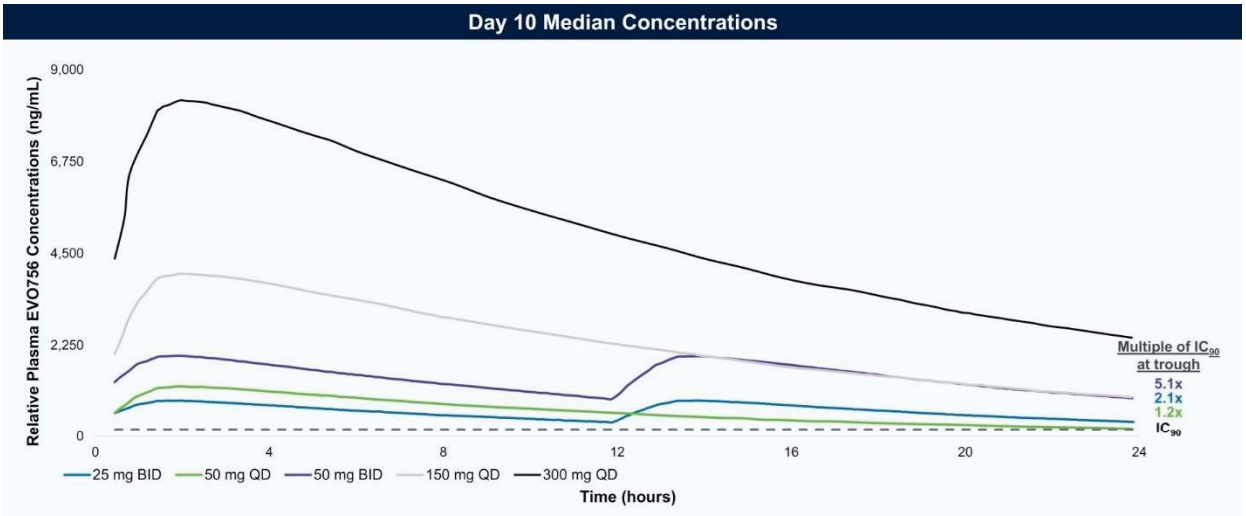
Figure 18: EVO756 Robustly Decreased Icatibant-Induced Wheals



*Notes: Error bars represent standard deviation; *p < 0.001; **p < 0.0001; p-value from LS-means change from baseline in wheal size in a Mixed Model Repeated Measures analysis. Bonferroni adjustment made for multiple comparisons – only comparisons which reached statistical significance of p < 0.001 are noted.*

At 10 µg/mL of icatibant, which we believe to be the most appropriate comparison for real-world ligand concentrations in humans based on quantitative evaluation of ligand concentrations from biopsies, we observed statistically significant decreases in mean wheal size by EVO756 after two weeks of dosing, as compared to wheal size at baseline after intradermal icatibant injection. Thus, the above results suggest EVO756 may have activity at low dosage levels in what we believe is the most pharmacologically relevant model for a diseased patient. In addition, in our PK research, we have observed high human PK interstitial fluid concentrations ("ISF"), with average ISF compared to plasma PK concentrations ranging from approximately 55–70% over a 24-hour period following a 200 mg dose of EVO756, supporting robust exposure at target site. Further, EVO756 showed dose-dependent response at 100 µg/mL of icatibant, which we believe is a supraphysiological concentration.

Figure 19: PK Modeling of EVO756 Based on Clinical Data Generated to Date

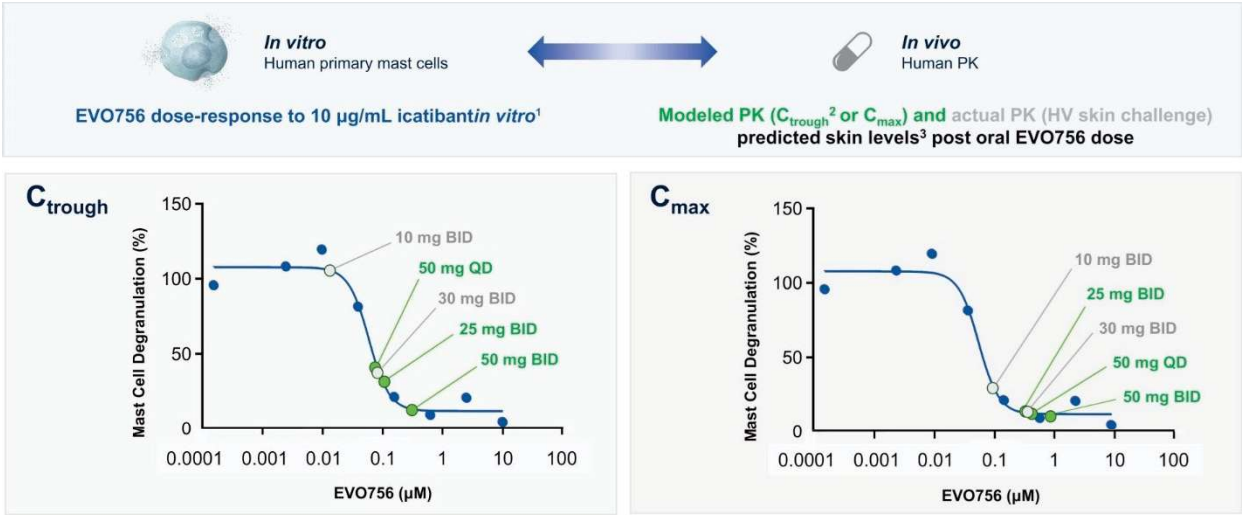


Notes: IC_{90}Primary Mast Cells = 180 ng/mL.

Based on the PK profile generated in this study, we were able to create a model that predicts various once- and twice-daily doses that maintain serum concentrations above the IC_{90}, as illustrated in Figure 19 above. Additionally, mass spectrometry identified MRGPRX2 ligands upregulated in disease tissue, confirming the relevance of ligands used in *in vitro* mast cell assays and the icatibant skin challenge test.

To further explore the translatability of our PK modeling, we overlayed our modeled human EVO756 drug exposures (skin level-adjusted C_{trough} and C_{max}, respectively) at the expected Phase 2 dose levels on the concentration plots from our *in vitro* mast cell degranulation assays. The figure below depicts EVO756's dose response to 10 µg/mL icatibant *in vitro* (blue plotted dots) as well as the modeled *in vivo* tissue concentrations (at both C_{trough} (left) and C_{max} (right)) at planned Phase 2 dose levels and previously conducted Phase 1 dose levels (grey) where activity has been observed.

Figure 20: EVO756 Target Coverage and Dosing Response



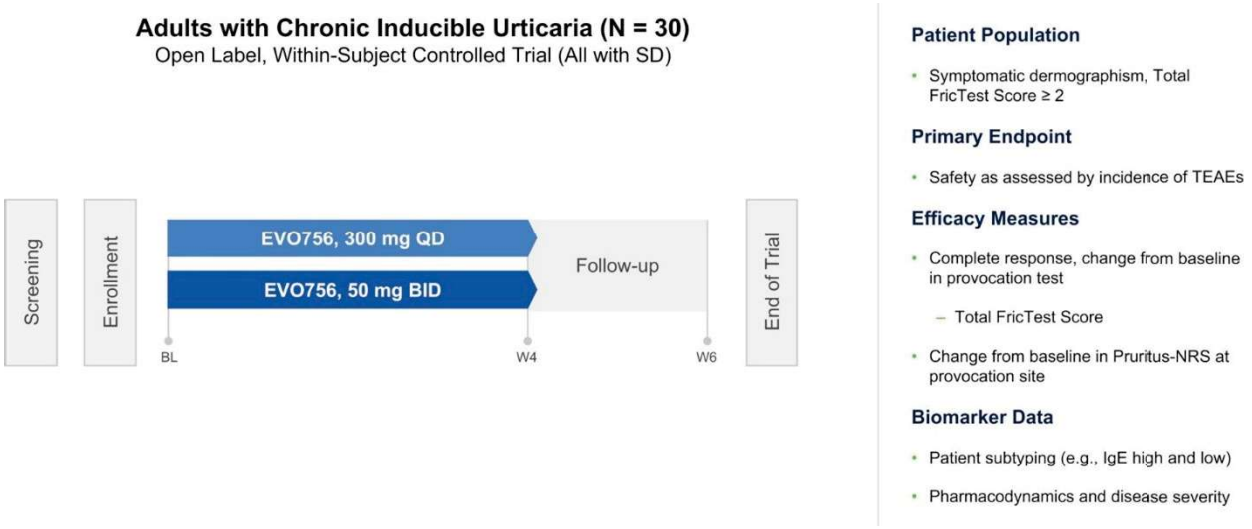
Notes: (1) Mast cell degranulation was determined via CD63 externalization on mast cells by flow cytometry. CD63 externalization was normalized to 100% of max (e.g., icatibant stimulation alone); (2) C_{trough} is the modeled drug level in serum at 12 or 24 hours post last BID or QD dose, respectively; (3) Assumes 70% skin distribution and 16% free drug.

Following analysis of our Phase 1 trial results, we initiated our Phase 2 clinical development program and enrolled the first patient in a multi-center CIndU trial in September 2024 and the first patient in a global CSU trial in April 2025, with both trials designed to evaluate the safety and efficacy of EVO756 in CU.

Our Phase 2 Trial in CIndU

In May 2025, we reported topline results from our U.S. multicenter Phase 2 trial of EVO756 in CIndU that demonstrated FricTest score improvement at four weeks, as described below. CIndU is a form of urticaria that has known environmental triggers, including pressure or exposure to cold and has underlying disease pathogenesis similar to CSU. The trial was designed to generate additional patient data in a population with symptomatic dermographism, which we believe will be highly translatable to the CSU patient population, given the shared pathologies. Third party studies have demonstrated that symptomatic dermographism affects approximately 25% of the CSU patient population; similarly, we believe EVO756's clinical activity in symptomatic dermographism patients strongly supports the role of MRGPRX2 in neurogenic inflammation, which plays a crucial role in AD. Efficacy endpoints included changes from baseline in disease specific provocation thresholds that are used as objective markers to quantify disease severity and response to treatment. EVO756 was administered orally for four weeks with either a once or twice daily dose and was evaluated for safety and efficacy at weekly visits during treatment, with patients serving as their own control. Figure 21 below depicts the trial design of our Phase 2 CIndU trial:

Figure 21: Phase 2 CIndU Trial Design



Notes: SD = symptomatic dermographism; TEAE = Treatment Emergent Adverse Events; BL = Baseline.

A total of 30 patients were enrolled in the Phase 2 trial, with 11 patients assigned to the 300 mg QD cohort and 19 patients to the 50 mg BID cohort. Duration of disease at baseline in the 300 mg QD and 50 mg BID cohorts was 6.3 years and 6.4 years, respectively. A total of 28 patients completed the trial and 27 evaluable patients contributed to the four-week data. Baseline characteristics and patient dispositions for enrolled patients are detailed in Figure 22 below:

Figure 22: Phase 2 CIndU Trial Disposition

Patient Baseline Characteristics

	300 mg QD	50 mg BID	All
N	11	19	30
Age (mean, years)	38.8	34.8	36.3
Gender (female, %)	63.6%	89.5%	80.0%
Weight (mean, kg)	76.6	72.9	74.3
Duration of Disease (years)	6.3	6.4	6.4
IgE High (≥ 100 IU/mL)	27.3%	21.1%	23.3%
Baseline Fric Score (mean, 0 - 4)	3.5	3.2	3.3
Baseline Pruritus-NRS (mean, 0 - 10)	5.1	4.2	4.5

Patient Disposition

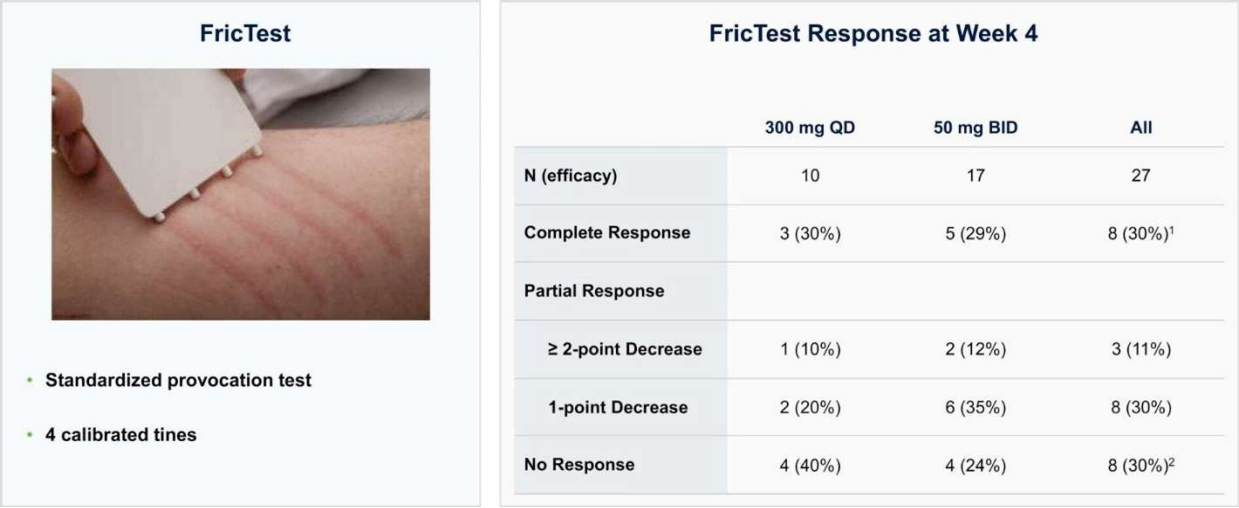
	300 mg QD	50 mg BID	All
N	11	19	30
Week 4 (observed)	10	17	27
Week 6 (observed)	10	18	28
Unevaluable / LTFU	1	1	2

Notes: LTFU = Lost-to-Follow-Up

Efficacy Results

To evaluate the efficacy of EVO756, we used a provocation challenge known as FricTest to assess each patient's threshold for wheal formation. An instrument with four calibrated tines was applied to the patients' skin to determine the minimum pressure required to elicit a wheal response. 70% (n=19) of the 27 observed patients demonstrated improvement at just four weeks, with 30% (n=8) of the observed patients achieving a complete response (achieving a FricTest score of zero), of which 50% were IgE high. An additional 11% (n=3) achieved a partial response as defined by a ≥2-point decrease in FricTest score and a further 30% (n=8) demonstrated a one-point decrease in FricTest score. The population of subjects observed at four weeks does not include three patients who were unevaluable or lost to follow-up. The following figures summarize observed patient FricTest response at four weeks in the Phase 2 trial:

Figure 23: FricTest Response at Week 4

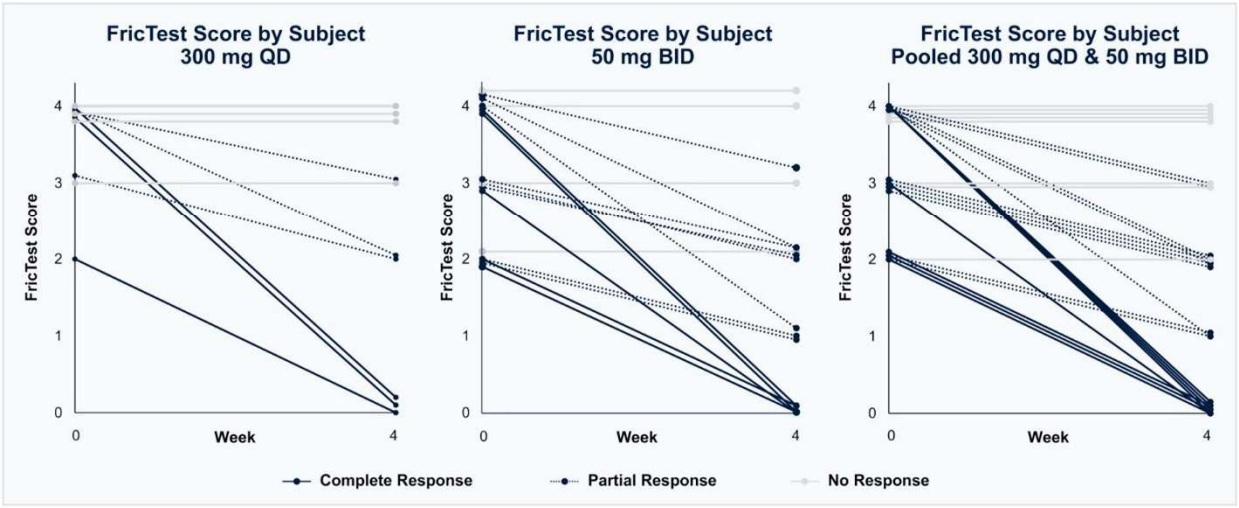


FricTest Response at Week 4

	300 mg QD	50 mg BID	All
N (efficacy)	10	17	27
Complete Response	3 (30%)	5 (29%)	8 (30%)[1]
Partial Response			
≥ 2-point Decrease	1 (10%)	2 (12%)	3 (11%)
1-point Decrease	2 (20%)	6 (35%)	8 (30%)
No Response	4 (40%)	4 (24%)	8 (30%)[2]

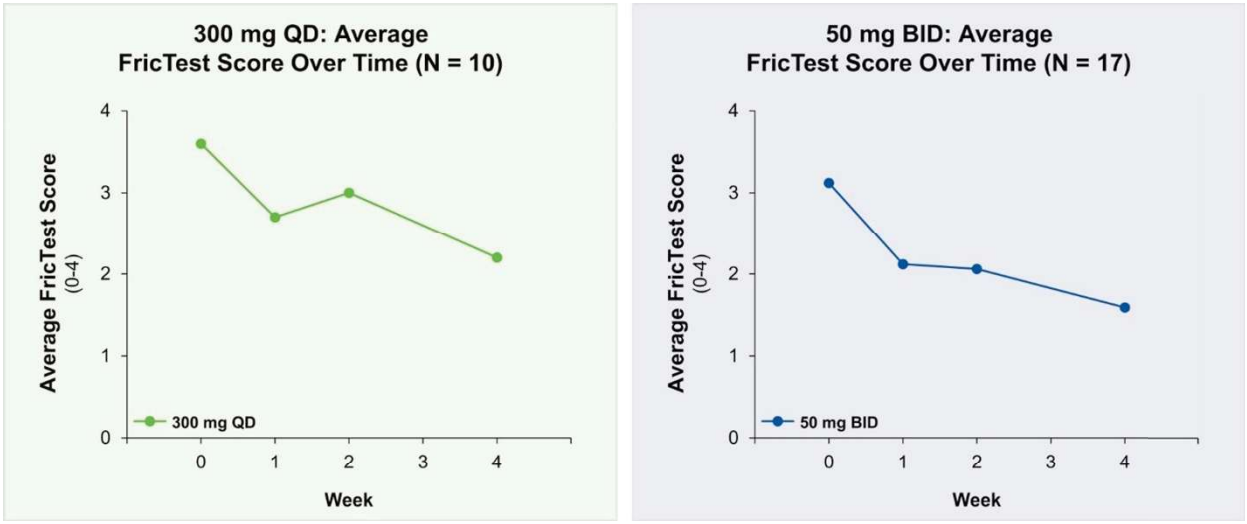
Notes: (1) Four of the complete responders were IgE high. (2) 75% (N = 6) of those who did not achieve a decrease in FricTest score demonstrated a decrease in pruritus-NRS, evidencing the impact of EVO756 on itch at this early time-point, even in the absence of FricTest response.

Figure 24: FricTest Scores by Subject at Week 4



Observed patients within both cohorts of the Phase 2 trial experienced meaningful reductions in total FricTest score during the duration of the trial, with observed patients in the 300 mg QD cohort experiencing an average reduction in total FricTest score of 1.4 points and observed patients in the 50 mg BID cohort experiencing an average reduction in total FricTest score of 1.5 points. The figure below illustrates total reduction in observed patient FricTest scores over time from week zero to week four in both cohorts of the Phase 2 trial:

Figure 25: Average FricTest Score Over Time by Cohort

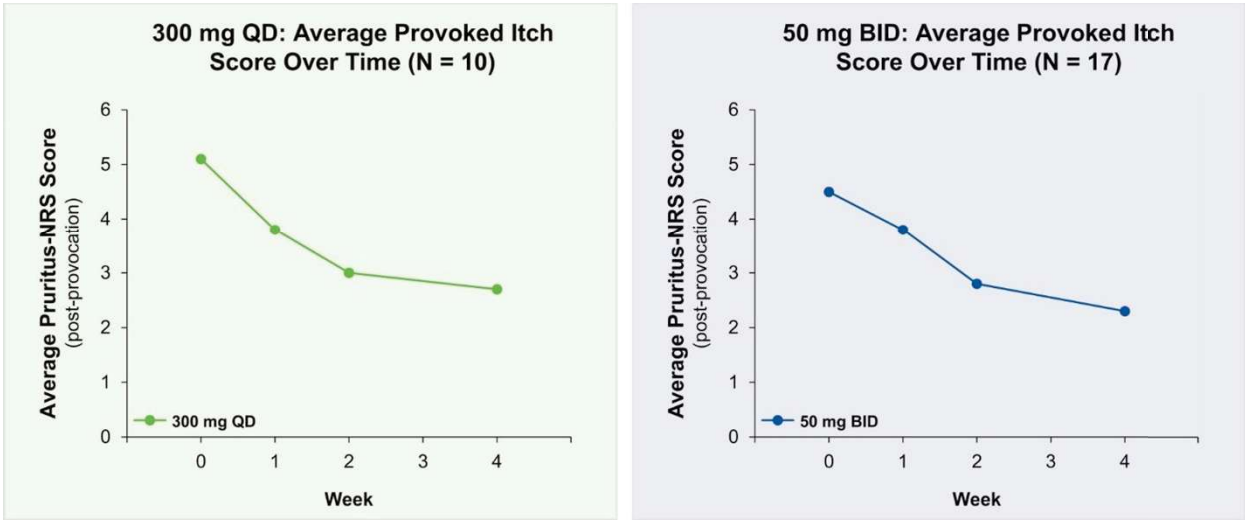


Overall, topline results from the Phase 2 CIndU trial of EVO756 included, in both the 300 mg QD and the 50 mg BID cohorts, meaningful and rapid responses in FricTest scores at one week, with three patients achieving a complete response on FricTest at one week. Initial Phase 2 data of mean FricTest reduction from EVO756 in CIndU were similar to previously reported four week data generated by third-party competing agents used for the treatment of CIndU, including the biologics omalizumab (Phase 2 trial, n=37) and barzolvolimab (Phase 2 trial, n=66). In these clinical trials, which had patient populations with comparable baseline levels of disease severity as the EVO756 Phase 2 trial in CIndU, each of omalizumab and barzolvolimab was observed to result in deepening of clinical response beyond week four.

In addition to degree of change in FricTest scores, we also evaluated patients' change from baseline pruritus-NRS at provocation site, a single-item, patient-reported outcome measure used to assess itch severity. Both the 300 mg QD and the 50 mg BID dose of EVO756 were observed to result in rapid itch relief to patients, with observed patients in the 300 mg QD cohort experiencing an average reduction in pruritus-NRS score of 2.4 points and observed patients in the 50 mg BID cohort experiencing an average reduction of 2.1 points.

Importantly, 93% (n=25) of observed patients demonstrated improvement at just four weeks in either FricTest or pruritus-NRS. Further, 75% (n=6) of those who did not achieve a decrease in the FricTest score demonstrated a decrease in pruritus-NRS, evidencing the impact of EVO756 on itch at this early time-point, even in the absence of FricTest response. The figure below illustrates reduction in provoked itch over time from week zero to week four observed in both cohorts of the Phase 2 trial:

Figure 26: Average Provoked Itch Score Over Time by Cohort



Additionally, both the 300 mg QD and the 50 mg BID dose of EVO756 demonstrated meaningful itch relief to patients with high baseline pruritus-NRS. The table below depicts the pruritus-NRS response at week four in subjects with baseline pruritus-NRS ≥4:

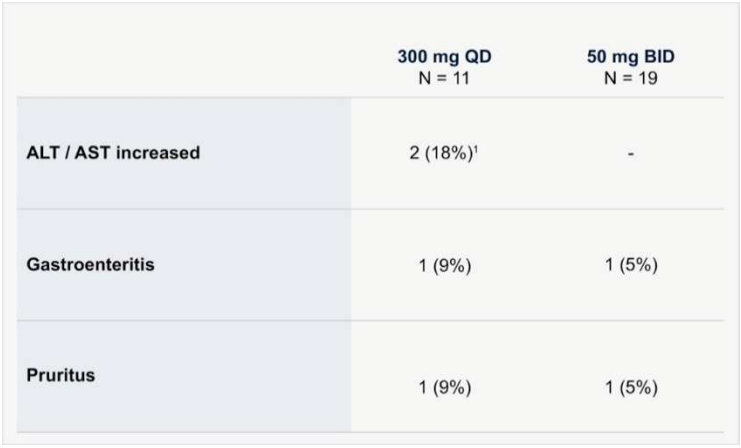
Figure 27: Pruritus-NRS Response at Week 4 in Subjects with Baseline Pruritus-NRS ≥4

	300 mg QD	50 mg BID	All
Subjects with Baseline Pruritus-NRS ≥ 4	6	11	17
Mean Change from Baseline in Pruritus-NRS	-3.3	-3.0	-3.1
Subjects with ≥ 4 point Reduction in Pruritus-NRS from Baseline	3 (50%)	4 (36%)	7 (41%)

Safety Results

EVO756 was observed to be well-tolerated at both doses administered in the Phase 2 trial. No SAEs were observed and there were no discontinuations due to AEs. Figure 28 below shows all AEs that occurred in more than one subject in this trial. The two subjects in the 300 mg QD cohort with AEs of increased ALT and AST had asymptomatic transaminase elevations that were greater than ten times the upper limit of normal at four weeks, which were not present at baseline, week 1 or week 2 and later returned to baseline. Other liver tests, including bilirubin and alkaline phosphatase were within normal limits. Both of these subjects had confounding factors that may have contributed to these elevations. No AEs of ALT or AST elevation were reported in subjects in the 50 mg BID cohort.

Figure 28: Phase 2 CIndU Trial Summary of Treatment Emergent Adverse Events in More than One Subject



	300 mg QD N = 11	50 mg BID N = 19
ALT / AST increased	2 (18%)[1]	-
Gastroenteritis	1 (9%)	1 (5%)
Pruritus	1 (9%)	1 (5%)

Notes: (1) The two subjects in the 300 mg QD cohort with AEs of increased ALT and AST had asymptomatic transaminase elevations that were greater than ten times the upper limit of normal at four weeks, which were not present at baseline, week 1 or week 2 and later returned to baseline. Other liver tests, including bilirubin and alkaline phosphatase were within normal limits. Both of these subjects had confounding factors that may have contributed to these elevations.

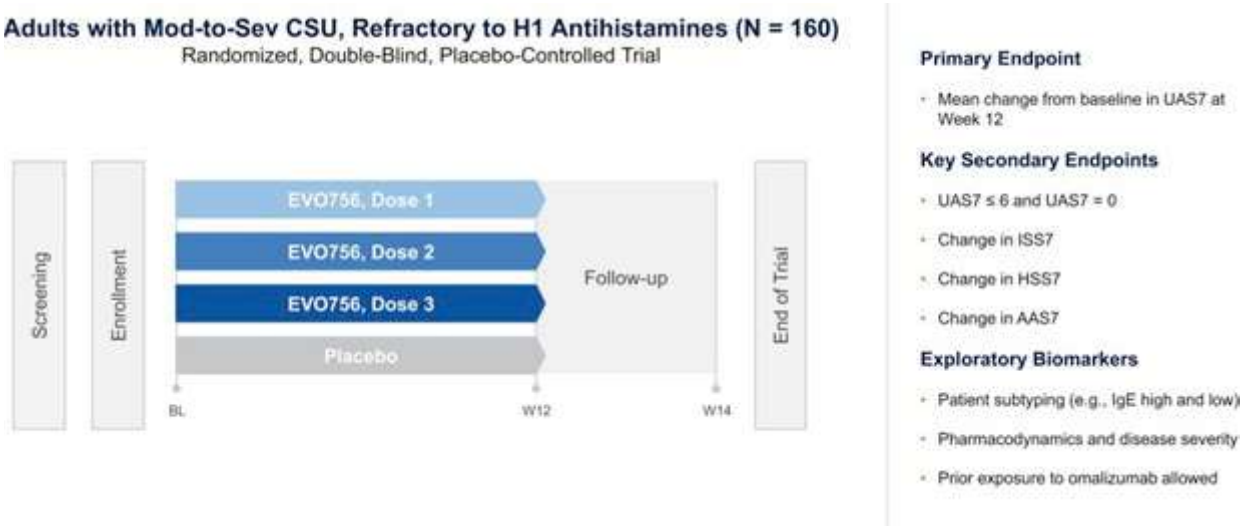
In our ongoing Phase 2b clinical trials of EVO756 in CSU and AD, the current protocols include doses ranging up to 150 mg daily.

Clinical Development Plan and Status

Our Ongoing Phase 2b Dose-Ranging Clinical Trial in Chronic Spontaneous Urticaria

In April 2025, we initiated a Phase 2b dose-ranging trial in approximately 160 moderate-to-severe antihistamine-refractory CSU patients in the United States, Europe, Canada and Japan. The global, multi-center, randomized, double-blind, placebo-controlled trial will evaluate the safety, tolerability and efficacy of EVO756 at three doses compared to placebo. Patients will be treated for 12 weeks and evaluated at several pre-specified time points. The primary endpoint of the trial is change in a patient's UAS7 at 12 weeks. Beyond the primary endpoint, we also intend to evaluate other measures of disease including itch, hive severity and angioedema. The results of the trial are expected to inform dose selection and other trial design considerations for Phase 3 EVO756 development. We anticipate reporting initial data from this trial in the second quarter of 2026. The following figure depicts the trial design of our Phase 2b CSU trial.

Figure 29: Phase 2b CSU Trial Design



Notes: UAS7 = Urticaria Activity Score over 7 days; ISS7 = Itch Severity Score component of UAS7; HSS7 = Hives Severity Score component of UAS7; AAS7 = Angioedema Activity Score; BL = Baseline; Mod-to-Sev = Moderate-to-Severe

Nonclinical Data

We have also been characterizing EVO756 through nonclinical studies on primary pharmacology, safety pharmacology, PK and toxicology. We conducted *in vitro* primary PD studies and observed the ability of EVO756 to inhibit the activation of MRGPRX2 and confirmed that EVO756 is human-specific and does not inhibit functional orthologue receptors to MRGPRX2 in animal species.

We included characterization of KO mice that lack the murine receptor functional orthologues of the human MRGPRX2 in the toxicology program to document the natural history of complete receptor ablation in target tissues as a proxy for traditional nonclinical on-target safety assessment.

Off-target safety assessment conducted in the good laboratory practice ("GLP") repeat-dose toxicity studies in rats and dogs for up to 13 weeks identified no adverse histopathology findings and the corresponding No Observed Adverse Effect Levels identified support the current clinical development plan.

EVO756 was not observed to be genotoxic in the bacterial reverse mutation test, *in vitro* chromosome aberration test or *in vivo* micronucleus test in rats. EVO756 was not observed to be phototoxic in the 3T3 neutral red uptake phototoxicity test *in vitro*. Characterization of KO mice conducted to derive potential on-target effects of EVO756 suggested no noteworthy or adverse changes related to genetic alterations resulted from the absence of Mrgpra1 and Mrgprb2 through 26 weeks. Furthermore, no fetal malformations were observed in pregnant Mrgpra1 and Mrgprb2 KO mice in preliminary studies. Additionally, no impact on the central nervous system, cardiovascular or respiratory function was observed, and no fetal malformations were observed in the preliminary embryo-fetal toxicology studies.

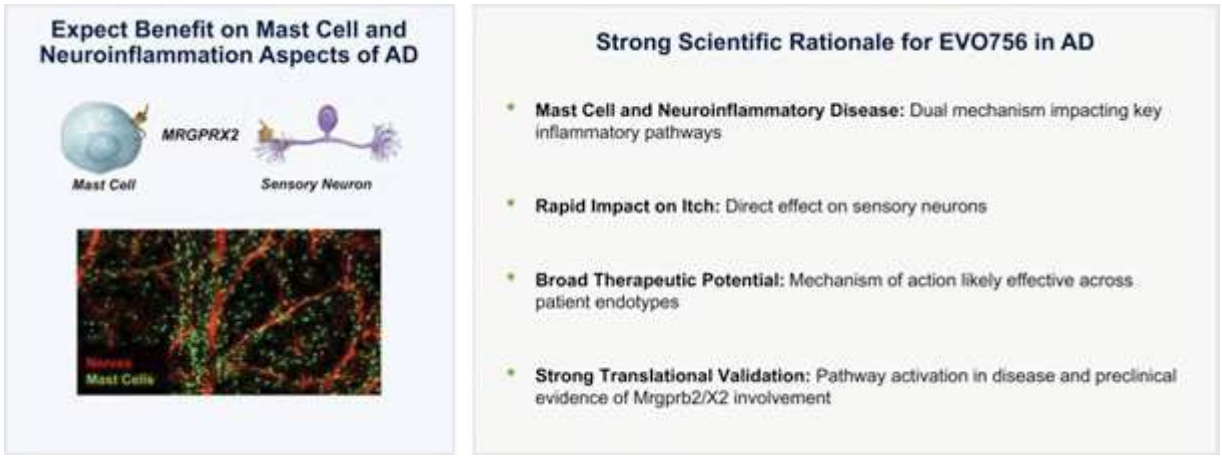
EVO756 for the Treatment of Atopic Dermatitis

Atopic Dermatitis Background

Atopic dermatitis, commonly referred to as eczema, is one of the most prevalent chronic inflammatory diseases and is characterized by acute flares of itchy, red exudative papules (raised skin lesions that ooze fluid) and persistently dry, scaly skin. The hallmark of AD is intense inflammatory itch, known as pruritus, and episodic flares of rash and underlying chronic inflammation. For most moderate-to-severe AD patients, the disease significantly impacts patients' quality of life, driven primarily by relentless itch, sleep disruption and visible skin symptoms. The intense itch associated with AD often triggers an itch-scratch cycle, further compromising the epidermal barrier and exacerbating disease. While AD commonly begins in childhood, it is also highly and increasingly prevalent in adults, with about 15% to 20% of children and 1% to 3% of adults impacted.

Research indicates that mast cells and peripheral sensory neurons play key roles in the pathogenesis of AD. One known driver of AD is the chronic and cyclical release of pro-inflammatory mediators associated with mast cell degranulation. Heightened mast cell activity promotes inflammation and drives itch, while activation of peripheral sensory neurons amplifies the sensation of itch. Third party studies have shown increased mast cell density, elevated MRGPRX2 expression, neuroinflammation and disease severity in lesional AD skin, supporting the rationale for targeting MRGPRX2 to both resolve skin lesions and relieve symptoms. Mast cells are in close proximity and recruited to sensory neurons in inflamed tissue, primarily in response to neuronal release of substance P and other neuropeptides, as well as local production of pro-inflammatory cytokines that enhance mast cell-neuron interactions. We believe that MRGPRX2 is the only target currently being pursued clinically that impacts both mast cells and neuroinflammation, making it uniquely positioned as a potential therapy for AD as illustrated in the figure below:

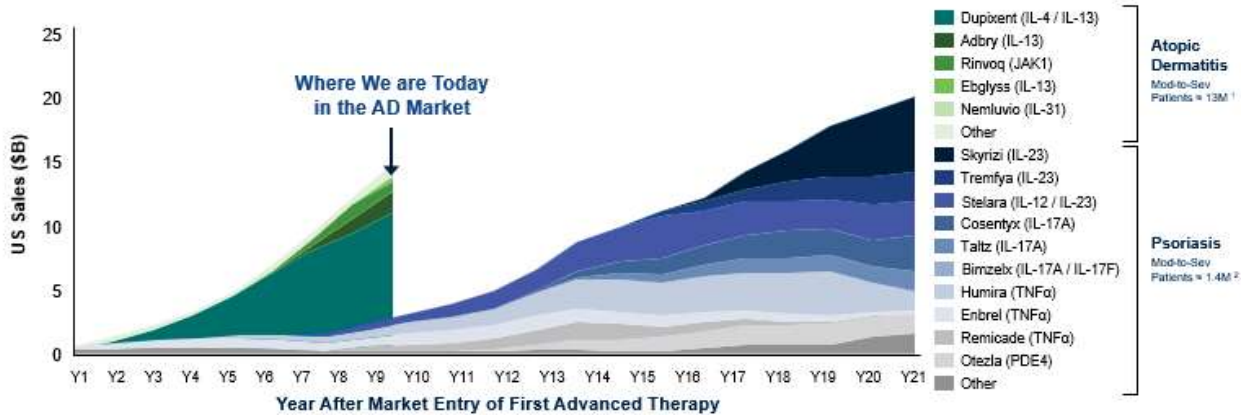
Figure 30: Rationale for EVO756 in AD



Current Treatment Paradigm

The current standard of care for first-line treatment of AD is primarily topical corticosteroids and targeted treatments (for example, topical JAK inhibitors). However, approximately 40% to 50% of AD patients have a moderate-to-severe form of the disease and thus are uncontrolled by topical therapies. For these patients, new systemic agents have emerged as advanced treatments that systemically target several different inflammatory mediators that contribute to underlying inflammation and flare-ups. Dupixent, an anti-IL-4 receptor alpha that modulates the signaling of IL-4 and IL-13 cytokines, is the preferred biologic for moderate-to-severe AD. The initial dose is two injections followed by one injection every two weeks and is considered to have category-high efficacy with 36% of patients reaching EASI-90 in 16 weeks. While treatment with Dupixent has also been shown to reduce itch (as measured by peak pruritus-NRS) by up to approximately 50%, it typically takes 16 weeks to achieve this level of efficacy and plateaus thereafter. Despite Dupixent's efficacy, over 60% of AD patients remain uncontrolled and patients may be burdened with potential side effects, including conjunctivitis and injection site reactions, and the burden of twice-monthly injections. Two oral JAK inhibitors, Rinvoq and Cibinqo, have also been approved for the disease and offer improved efficacy with over 40% of patients exceeding EASI-90 at 16 weeks, but are reserved for later lines of treatment due to safety concerns including black box warnings on cardiac events and malignancies. Another biologic, Ebglyss (lebrikizumab), an IL-13 inhibitor, was recently approved by the FDA for the treatment of AD based on clinical results wherein approximately 33% to 43% of patients were observed to achieve IGA 0/1 with ≥2-point improvement from baseline to week 16. Several biologics are in development with differing mechanisms of action including product candidates that target IL-13, OX-40 and IL-18, including our own EVO301. We believe the market for AD therapeutics is in a nascent stage, particularly when compared to the growth observed in the market for psoriasis, which has grown meaningfully since the launch of Enbrel in 2004 as illustrated in the figure below:

Figure 31: Expansion of AD Market Outpacing That of Psoriasis



Notes: "Year 1" for AD represents 2017 (year of Dupixent launch); "Year 1" for psoriasis represents 2004 (year of Enbrel launch in plaque psoriasis). May represent projections and not actual sales.

The following figure provides an illustration of the potential market opportunity for EVO756 in AD in the United States, if approved:

Figure 32: AD Is an Underserved Market Lacking a First Line Oral Option

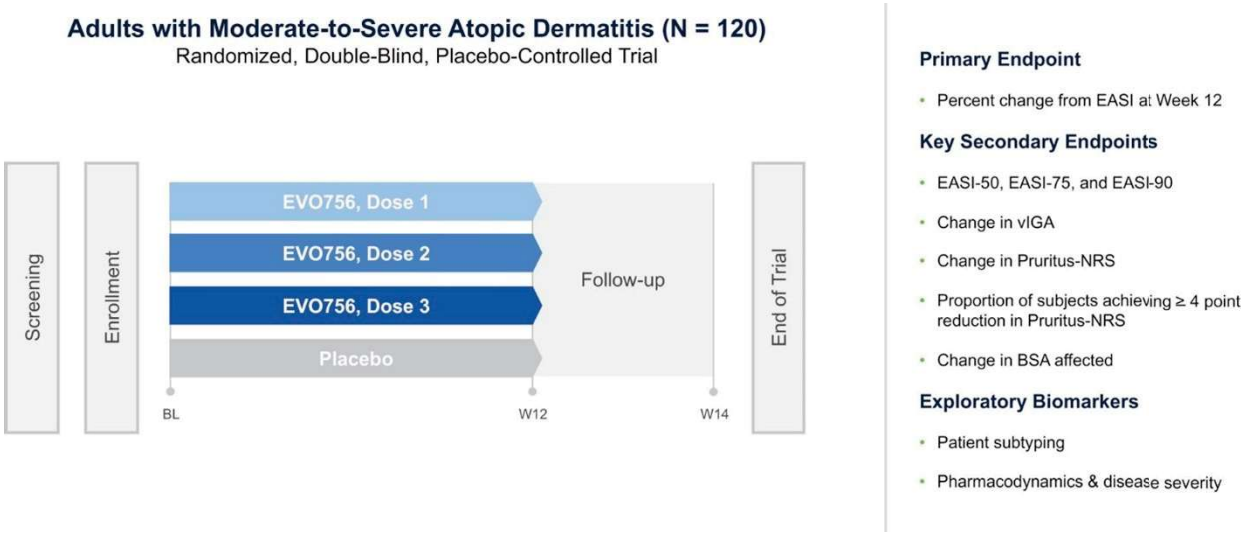
Given that a significant number of patients with AD remain uncontrolled, we see the need for a therapy with a meaningful efficacy profile, improved safety profile, a fast onset of itch relief and the convenience of daily oral therapy. We believe a treatment option with this product profile would have broad applicability, first-line potential in moderate-to-severe disease and could be utilized by a wider range of prescribers, expanding access. We believe MRGPRX2 is the only target impacting both mast cells and neuroinflammation, two key factors underlying AD.

Clinical Development Plan and Status

Our Ongoing Phase 2b Dose-Ranging Trial in Atopic Dermatitis

Our atopic dermatitis development program is expected to target the treatment of adult and pediatric patients with moderate-to-severe AD, whose disease is not able to be controlled with topical prescription therapies. We initiated a Phase 2b dose-ranging trial in moderate-to-severe AD patients in August 2025 and are currently enrolling patients in the United States and plan to enroll patients in New Zealand. We expect to report initial results in the second half of 2026. The multi-center, randomized, double blind, placebo-controlled trial will evaluate the safety, tolerability and efficacy of EVO756 at three doses compared to placebo. Patients will be treated for 12 weeks and evaluated at several pre-specified time points. The primary endpoint will be percent change in EASI score and we also plan on assessing IGA, pruritus-NRS and safety. The results of the trial are expected to inform dose selection and other trial design considerations for Phase 3 EVO756 development in AD. The following figure depicts the trial design of our Phase 2b dose-ranging trial in AD:

Figure 33: Phase 2b Dose-Ranging Trial Design



Notes: EASI = Eczema Area and Severity Index; vIGA = Validated Investigator Global Assessment; Pruritus-NRS = Pruritus Numerical Rating Scale; BSA = Body Surface Area; BL = Baseline

In addition, if EVO756 demonstrates a positive treatment effect on itch associated with AD in the Phase 2b dose-ranging trial, we may pursue additional indications in which itch is a prominent feature in the future.

EVO756 for the Treatment of Migraine

Migraine Background

Migraine is a neurological disorder characterized by recurrent attacks of intense, often unilateral, throbbing headache lasting four to 72 hours often accompanied by symptoms including nausea, vomiting, and sensitivity to light or sound. It is estimated that migraine affects 40 million people in the United States and more than 10% of the global population. Migraine is the second leading cause of "years lived with a disability" worldwide, disproportionately impacting individuals during peak working years and contributing to an estimated $28 billion in annual United States healthcare costs, excluding broader productivity losses.

More than 10 million Americans are eligible for preventive therapy, yet current treatments are limited to only improving migraine days per month by approximately two days more than placebo. While acute therapies can provide symptomatic relief, they do not reduce underlying disease frequency. Preventive options — including calcitonin gene-related peptide (CGRP)-targeted therapies and neurotoxin approaches — have advanced care; however, approximately 45% of patients fail to achieve a ≥50% reduction in monthly migraine days, and many discontinue due to tolerability, durability, or access challenges. Despite recent innovation, migraine continues to impose significant clinical and economic burden, underscoring the need for differentiated preventive therapies capable of delivering sustained efficacy with demonstrated safety and convenience.

MRGPRX2 is expressed by both human trigeminal neurons and meningeal mast cells, positioning it as a potential key mediator of neurogenic inflammation in migraine. Activation of trigeminal afferents and meningeal mast cells is central to migraine initiation and propagation, and in vivo preclinical headache models support a pathogenic role for MRGPRX2 signaling in driving migraine-like pain behaviors.

Pituitary Adenylate Cyclase-Activating Polypeptide ("PACAP"), a well-established migraine trigger in humans, is a known ligand of MRGPRX2, directly linking this receptor to a clinically-validated migraine pathway. Clinical trials targeting PACAP have demonstrated efficacy in migraine prophylaxis, further reinforcing the relevance of this biology.

Given that MRGPRX2 can be activated by multiple endogenous and exogenous ligands, antagonism of this receptor represents a broader upstream approach to dampen aberrant trigeminal activation and mast cell–mediated neuroinflammation. We have shown that EVO756 blocks a range of relevant MRGPRX2 ligands, including PACAP, supporting its potential to reduce migraine frequency across a broad patient population, including individuals who do not achieve sufficient benefit with existing preventive therapies.

Clinical Development Plan and Status

Our Planned Phase 2b Trial in Migraine

We plan to initiate a Phase 2 trial in migraine in mid-2026. We expect the trial to be a Phase 2b dose ranging, randomized, double-blind, placebo-controlled trial assessing the efficacy and safety of EVO756 for the prevention of migraine patients.

EVO756 for the Treatment of Other Potential Indications

Overview

We believe EVO756 has the potential to address several additional chronic inflammatory diseases. Building on our ongoing research and nonclinical studies, we are exploring the potential for EVO756 in asthma, interstitial cystitis, irritable bowel syndrome and pruritus (itch) as potential expansion indications due to their large unmet patient needs along with the relevance of mast cells and sensory neurons in these diseases' pathology.

Background on Other Potential Indications

Asthma

Asthma is a chronic inflammatory disease of the airways characterized by variable airflow obstruction and bronchial hyperresponsiveness to triggers such as allergens, infections or environmental pollutants. It is one of the most common non-communicable respiratory diseases globally and in the United States, affecting both children and adults. The disease typically manifests through episodes of wheezing, coughing, chest tightness and shortness of breath, which may vary in frequency and severity. Asthma imposes a substantial burden on patients and health systems in terms of medical utilization (emergency department visits, hospitalizations), lost productivity and reduced quality of life. Current therapies, such as inhaled corticosteroids, bronchodilators and biologics, do not adequately control symptoms or prevent exacerbations in all patients, leaving a significant unmet need for new treatment modalities.

Interstitial Cystitis

Interstitial cystitis is a chronic condition causing bladder pressure, bladder pain and sometimes pelvic pain. The pain can range from mild discomfort to severe pain. The condition is a part of a spectrum of diseases known as painful bladder syndrome. The symptoms may vary over time, periodically flaring in response to common triggers, such as menstruation, sitting for a long time, stress, exercise and sexual activity. Epidemiological data in the United States suggest interstitial cystitis may affect approximately three to eight million women and one to four million men. Treatment options are limited, frequently palliative, and even if symptoms disappear, may return later. There is a substantial unmet need for therapies that address underlying pathophysiology, relieve pain, reduce urinary symptoms, improve function and offer durable benefit.

Irritable Bowel Syndrome

Irritable bowel syndrome is a common condition characterized by abdominal discomfort associated with altered bowel movement. Recent research has shown that many symptoms of irritable bowel syndrome are related to hypersensitivity of the nerves found in the wall of the gastrointestinal tract. Prevalence estimates vary depending on

diagnostic criteria, but some experts estimate that approximately 10% to 15% of adults in the United States have irritable bowel syndrome, and only about 5% to 7% of them see a provider and receive a diagnosis. This syndrome has a large impact on quality of life, psychological well-being and work productivity. Current treatments include dietary modification, cognitive behavioral therapy, laxatives and anti-diarrheals, which only often provide partial relief, creating an unmet need for novel agents targeting symptoms, visceral hypersensitivity and motility.

Pruritus (Itch)

Pruritus, commonly referred to as itch, is an unpleasant sensory sensation that provokes the desire to scratch. When pruritus persists for more than six weeks, it is defined as chronic pruritus. Pruritus can be painful or irritating and could be localized to one area of the body or spread throughout several areas. It is estimated that pruritus leads to more than seven million ambulatory visits annually in the United States and is among the 50 most prevalent conditions worldwide. Existing therapies, such as hydrocortisone, antihistamines, topical steroids and immunosuppressants, are often only partially effective, underscoring the need for treatments that more directly target itch sensory pathways and underlying immunologic or neuronal drivers.

Ongoing Nonclinical Translational Research

Our ongoing nonclinical translational research efforts are focused on elucidating the role of MRGPRX2 in human disease through a multifaceted approach. These activities include the characterization of MRGPRX2-expressing mast cells and the identification of MRGPRX2 agonists in human patient samples across relevant disease states. In parallel, we are also conducting functional studies in human-derived cell types and tissues to further define the biology of MRGPRX2 signaling. These include *in vitro* studies using primary human mast cells and neurons, as well as *ex vivo* studies in disease-relevant human tissues such as trigeminal neurons and meningeal mast cells for migraine and biopsies for other key indications. Lastly, we are utilizing sophisticated computational approaches to provide in silico validation of the critical role for MRGPRX2 in key disease indications.

Additionally, *in vivo* studies are underway using genetically modified mouse models, including Mrgprb2 knock-out and MRGPRX2 knock-in mice. These studies are complemented by established disease models, such as PACAP-induced migraine, to further assess the therapeutic potential of targeting MRGPRX2. Collectively, these nonclinical investigations are intended to support indication prioritization and inform our clinical development strategy of EVO756 in other potential indications.

We believe that continued interrogation of MRGPRX2's role across migraine, asthma, interstitial cystitis, irritable bowel syndrome and pruritus will provide critical insights into its role as a key neuronal mediator. These findings will guide our near-term indication expansion efforts and support the initiation of additional clinical trials in the future.

Clinical Development Plan

Initiation of a Phase 2 trial in any of these additional indications will be determined based on ongoing trials and corporate resources. To date, based on our data from the successful completion of our Phase 1 proof-of-concept trial of EVO756 in healthy volunteers, we believe there is a path to proceed to Phase 2 clinical development for these other indications, similar to our initiation of our Phase 2b trial in AD, subject to standard regulatory requirements. We are also currently exploring development of next-generation MRGPRX2 molecules that we believe can be optimized for select indications to bolster our intellectual property portfolio and potentially complement our product candidates to better manage the life cycle management of our development programs.

EVO301: Our SAFA IL-18BP Fusion Protein

Overview

Our second clinical-stage product candidate, EVO301, which is in Phase 2 development for the treatment of atopic dermatitis, is a long-acting biologic designed to neutralize the IL-18 inflammatory pathway, which plays a key role in various immune processes and is thought to be a key driver of immune dysregulation associated with chronic inflammatory diseases. In June 2024, we secured exclusive global rights to develop and commercialize EVO301 from AprilBio, which previously progressed EVO301 through a Phase 1 trial. In that study in healthy volunteers, EVO301 was well-tolerated across all doses evaluated, with no severe AEs observed or discontinuations due to AEs, and demonstrated a favorable PK profile. Importantly, EVO301 was well tolerated with no observed cases of conjunctivitis, which can be observed with other biologics in AD. We believe EVO301's differentiated profile may enable it to become a leading therapy for a broad range of chronic inflammatory diseases.

In February 2026, we announced positive top-line results from a randomized, double-blind, placebo-controlled Phase 2a trial evaluating EVO301 in adult patients with moderate-to-severe AD. The trial met its primary efficacy endpoint at week 12 and achieved highly statistically significant outcomes in adult patients with moderate-to-severe AD. The 70-patient trial was designed to evaluate the safety and efficacy of intravenous dosing of 5 mg/kg on day 1 and day 28 (n=48 active, n=22 placebo) over 12 weeks. The trial met its primary endpoint, demonstrating clinically meaningful activity in AD with statistical significance over placebo achieved at weeks 4, 8 and 12 at $p<0.01$. We believe demonstrating this activity with an IL-18 targeting therapy supports the relevance of this pathway in disease pathophysiology and reinforces that pathways beyond classic Th2 biology can contribute meaningfully to disease activity. Expanding therapeutics to target novel mechanisms like IL 18 could offer benefit for patients who remain uncontrolled on existing therapies and reinforces the urgent need to develop more options across the growing AD population. We plan to rapidly move a subcutaneous formulation of EVO301 into a Phase 2b trial in AD where we believe optimized and more frequent dosing of EVO301 could achieve potential best-in-class EASI activity.

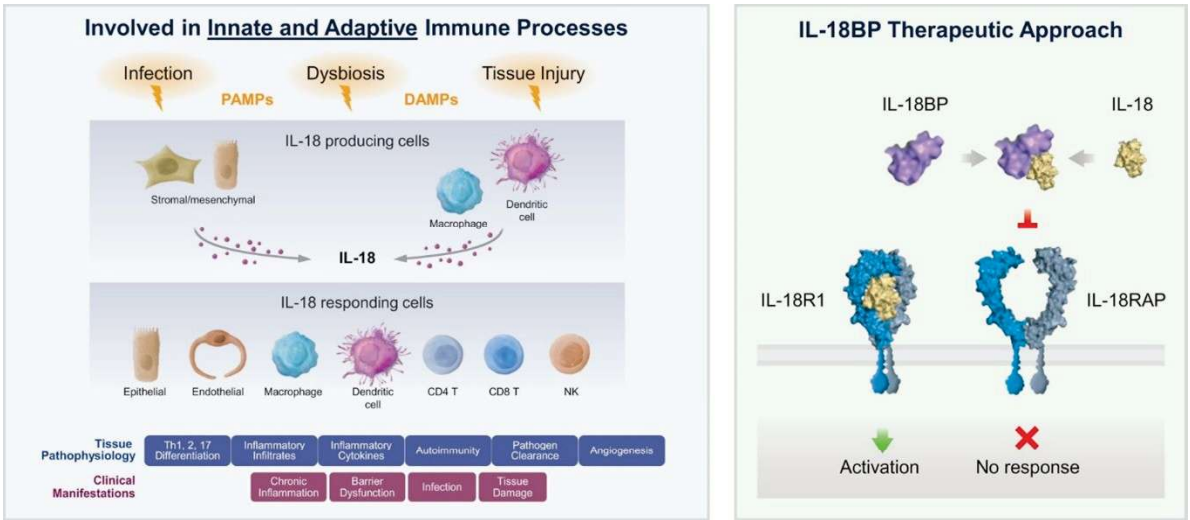
Beyond AD, we are evaluating a potential Phase 2 trial in moderate-to-severe UC patients. We may also evaluate EVO301 in Crohn's disease and other additional indications in which dysregulation of the IL-18 contributes to chronic inflammation and tissue damage driving disease pathology.

Although we are pursuing AD for both EVO301 and EVO756, we believe these approaches are sufficiently differentiated and complementary to each other given their distinct modalities and potential to be used together. In addition, based on the clinical data generated to-date, we believe each has the potential to transform the immunology and inflammation treatment landscape either as monotherapy or in combination with existing therapies.

IL-18 Mechanism of Action

IL-18, a pro-inflammatory cytokine of the IL-1 family, regulates various immune processes that drive inflammation. It plays an important role in the T-cell-helper type 1 inflammatory response and is a potent modulator of ongoing inflammation. An upregulated IL-18 pathway cyclically activates inflammatory mediators in an aberrant manner, resulting in tissue damage and other inflammatory and sensory disease pathology. We believe that targeting the IL-18 pathway differs from existing treatment options because this pathway impacts both innate and adaptive immune processes, a distinguishing feature that allows for broad applicability across multiple chronic inflammatory diseases. There are several large, heterogeneous chronic inflammatory diseases with significant numbers of uncontrolled patients including AD and inflammatory bowel diseases ("IBD") in which the IL-18 pathway is believed to play a key role. The following figures illustrate IL-18's role in both innate and adaptive immune processes, the IL-18BP therapeutic approach, a landscape of diseases that are regulated by the IL-18 pathway and the key role of IL-18 signaling in AD:

Figure 34: IL-18 Drives Various Innate and Adaptive Immune Processes Related to Infection, Inflammation and Autoimmunity



Notes: PAMPs: Pathogen-associated molecular patterns; DAMPs: Damage-associated molecular patterns.

Figure 35: IL-18 Pathways Regulate Many Diseases

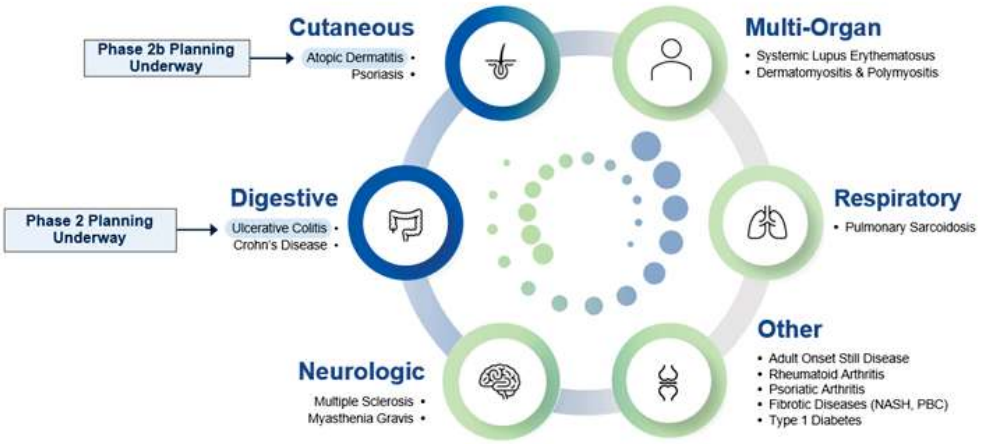
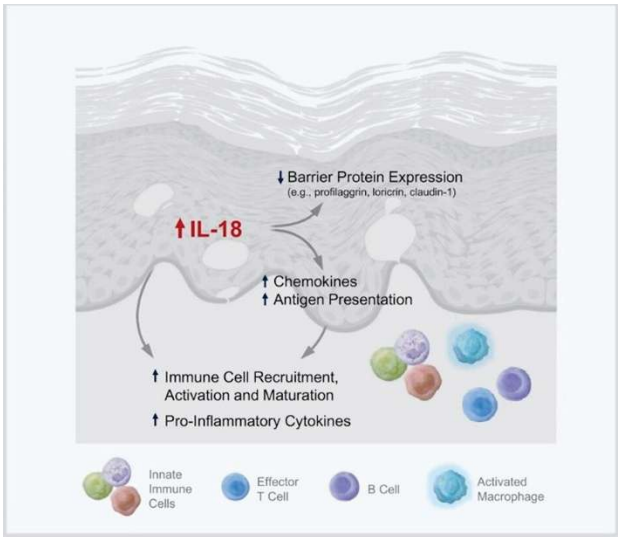


Figure 36: IL-18 Signaling in AD

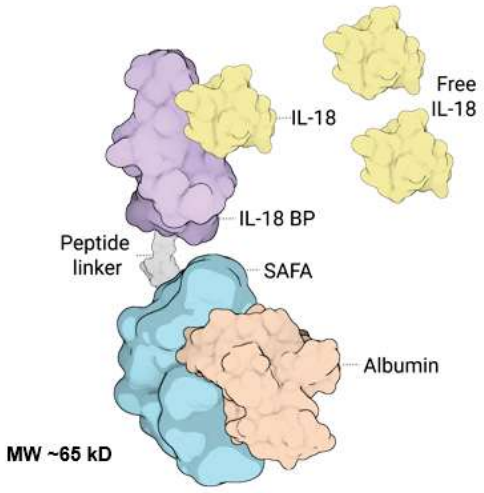


We are aware of one other IL-18 programs in clinical development for chronic inflammatory conditions, which involves a mAb approaches. As a result of its design, we see several potential advantages of the SAFA IL-18BP fusion protein relative to IL-18 mAbs, including tissue penetration and binding affinity. Thus, we believe there is substantial untapped therapeutic opportunity in AD and significant potential for improvement in the treatment landscape with our SAFA IL-18BP fusion protein, EVO301.

Our Solution: EVO301, an IL-18BP Fusion Protein

EVO301 is a long-acting injectable SAFA-IL-18BP fusion protein designed to neutralize aberrantly upregulated IL-18 activity. We believe this approach facilitates more efficient tissue distribution and improved binding affinity and specificity which presents an advantage over existing attempts to antagonize or inhibit the IL-18 pathway, including traditional mAbs. The following graphic depicts the molecular design of EVO301:

Figure 37: EVO301 Molecular Design



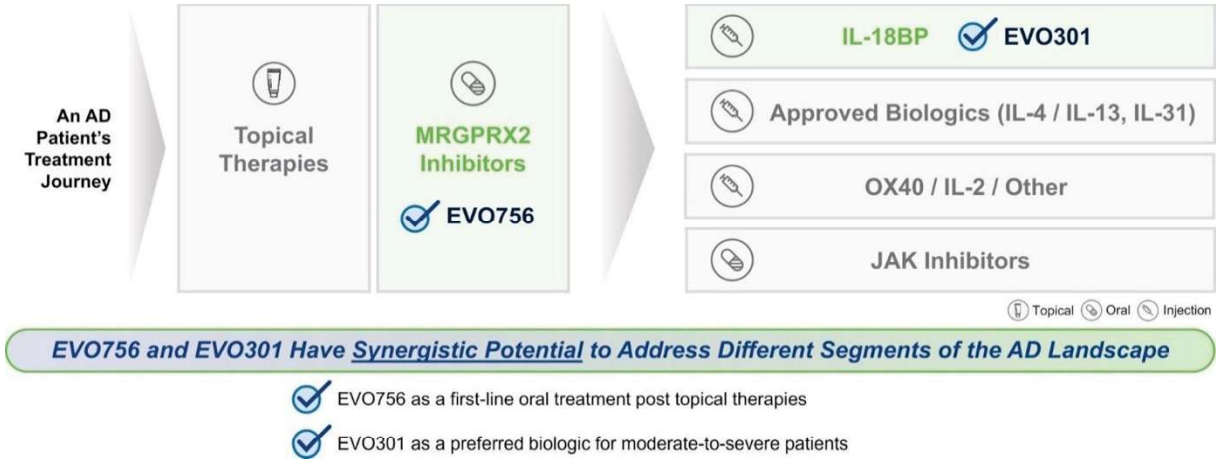
Notes: SAFA = Anti-Serum Albumin Fab-Associated.

EVO301 is designed specifically to neutralize upregulated IL-18 activity. Key distinguishing features of EVO301 include:

- **selective and high binding affinity of native human IL-18BP and binding to serum albumin**, allowing for specific inhibition of IL-18 pro-inflammatory activity and deeper penetration to inflamed tissues;
- **smaller molecular weight**, enabling improved targeting at the site of inflammation as EVO301 is only a fraction of the molecular weight compared to traditional antibodies;
- **extended half-life for the neutralization of IL-18**, conveyed by the SAFA, utilizing a body peptide linker which supports FcRn-mediated recycling of serum albumin; and
- **lower potential for immunogenicity**, as the use of native human IL-18BP, a naturally occurring inhibitor of IL-18, is expected to reduce immunogenicity risk and enhance durability of response.

Further, we believe the distinct mechanism and modality of EVO301 complement those of EVO756, providing us with multiple, potentially synergistic avenues to bring innovative therapeutics to the large, underserved and rapidly expanding population of patients suffering from chronic inflammatory diseases.

Figure 38: Potential for EVO756 and EVO301 Mechanism of Action Synergy in AD



EVO301 for the Treatment of Atopic Dermatitis

Atopic Dermatitis Background

Atopic dermatitis, commonly referred to as eczema, is one of the most prevalent chronic inflammatory diseases and is characterized by acute flares of itchy, red exudative papules (raised skin lesions that ooze fluid) and persistently dry, scaly skin. The hallmark of AD is intense inflammatory itch, known as pruritus, and episodic flares of rash and underlying chronic inflammation. For most moderate-to-severe AD patients, the disease significantly impacts patients' quality of life, driven primarily by relentless itch, sleep disruption and visible skin symptoms. The intense itch associated with AD often triggers an itch-scratch cycle, further compromising the epidermal barrier and exacerbating disease. While AD commonly begins in childhood, it is also highly and increasingly prevalent in adults, with about 15% to 20% of children and 1% to 3% of adults impacted.

IL-18 acts as a general amplifier of inflammation, capable of driving multiple inflammatory responses, including Th1, Th2, Th17/22 and innate pathways, all of which are highly implicated in AD. Broadly impacting these pathways is crucial for treating conditions with heterogeneous inflammation, where targeting a single pathway may not be optimal. When the IL-18 pathway is upregulated in a chronic, cyclical fashion, it can trigger a cascade of inflammatory mediators that ultimately lead to tissue damage and disease manifestations, including those we see in atopic dermatitis. IL-18 also directly disrupts essential skin barrier functions, positioning it as a pivotal pathogenic factor. Targeting IL-18 offers broader therapeutic utility with a novel approach, simultaneously reducing inflammation and restoring tissue integrity for patients with complex inflammatory conditions.

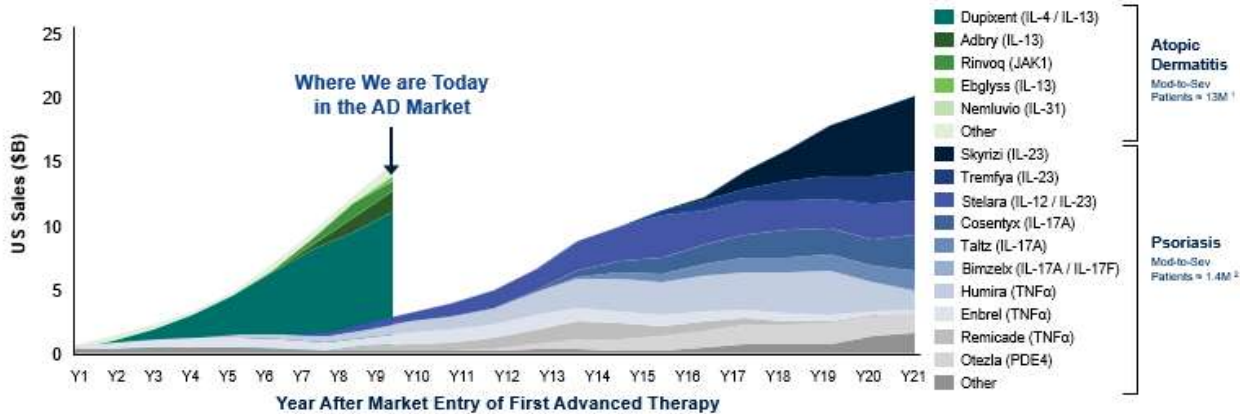
Current Treatment Paradigm

The current standard of care for first-line treatment of AD is primarily topical corticosteroids and targeted treatments (for example, topical JAK inhibitors). However, approximately 40% to 50% of AD patients have a moderate-to-severe form of the disease and are uncontrolled by topical therapies. For these patients, new systemic agents have emerged as advanced treatments that systemically target several different inflammatory mediators that contribute to underlying inflammation and flare-ups. Dupixent, an anti-IL-4 receptor alpha antagonist that inhibits the signaling of IL-4 and IL-13 cytokines, is currently the preferred biologic for moderate-to-severe AD. The initial dose is two injections followed by one injection every two weeks and is considered to have category-high efficacy with 36% of patients reaching EASI-90 in 16 weeks. While treatment with Dupixent has also been shown to reduce itch (as measured by peak pruritus-NRS) by up to approximately 50%, it typically takes 16 weeks to achieve this level of efficacy and plateaus thereafter. Despite Dupixent's efficacy, over 60% of AD patients remain uncontrolled and patients may be burdened with potential side effects, including conjunctivitis and injection site reactions, and the burden of twice-monthly injections. Two oral JAK inhibitors, Rinvoq and Cibinqo, have also been approved for the disease and offer improved efficacy with over 40% of patients exceeding EASI-90 at 16 weeks, but are reserved for later lines of treatment due to safety concerns including black box warnings for cardiac events and malignancies. Another biologic, Ebglyss (lebrikizumab), an IL-13 inhibitor, was recently approved by the FDA for the treatment of AD based on clinical results wherein approximately 33% to 43% of patients were observed to achieve IGA 0/1 with ≥2-point improvement from baseline to week 16. Several biologics are in development with differing mechanisms of action including product candidates that target IL-13, OX-40, IL-2R and IL-18, including our own EVO301.

Market Opportunity

We believe the market for AD therapeutics is in a nascent stage, particularly when compared to the growth observed in the market for psoriasis, which has grown meaningfully since the launch of Enbrel in 2004 as illustrated in the figure below:

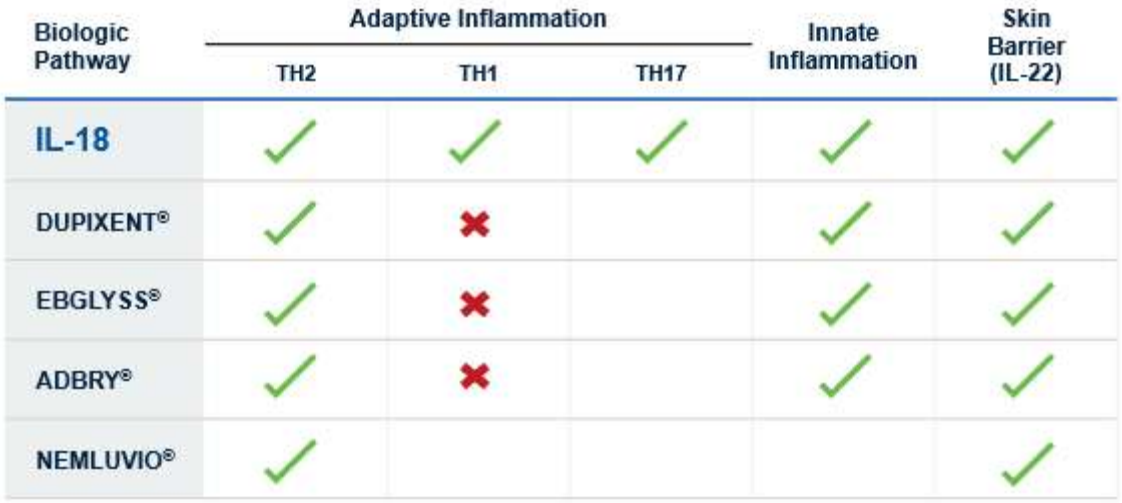
Figure 39: Expansion of AD Market Outpacing That of Psoriasis



Notes: "Year 1" for AD represents 2017 (year of Dupixent launch); "Year 1" for psoriasis represents 2004 (year of Enbrel launch in plaque psoriasis). May represent projections and not actual sales.

There is a substantial need for broad, safe treatments in AD, where approximately 16 million patients in the United States live with the disease, at least 40% of which are moderate-to-severe patients. Given that a significant number of patients with AD remain uncontrolled, we see the need for a biologic therapy with a competitive efficacy profile targeting a new mechanism of action and improved safety profile. We believe a treatment option with this product profile would have broad applicability, first-line potential in moderate-to-severe disease and could be utilized by a wider range of prescribers, expanding access. We believe IL-18 is the only target impacting broader immunological cascades of Th2, Th1, Th17, Innate Inflammation and IL-22, key factors underlying AD, as shown in the figure below:

Figure 40: IL-18 Impacts Multiple Inflammatory Pathways that Drive AD



Clinical Data

Completed Phase 1 Trial

EVO301 was observed to be well-tolerated at all doses, with no SAEs nor discontinuations due to AEs, in a Phase 1 randomized, placebo-controlled SAD trial in 31 healthy volunteers conducted by our licensor, AprilBio, with five cohorts that consisted of SAD ranging from 0.1 mg/kg up to 10 mg/kg administered intravenously.

The majority of reported AEs were determined to be mild in severity and included headache, nausea and reactions at the infusion site. No discontinuations were attributed to AEs, and there were no SAEs. In addition, there were no clinically significant ECG or lab abnormalities. No measurable impact on PK due to anti-drug antibody formation was observed.

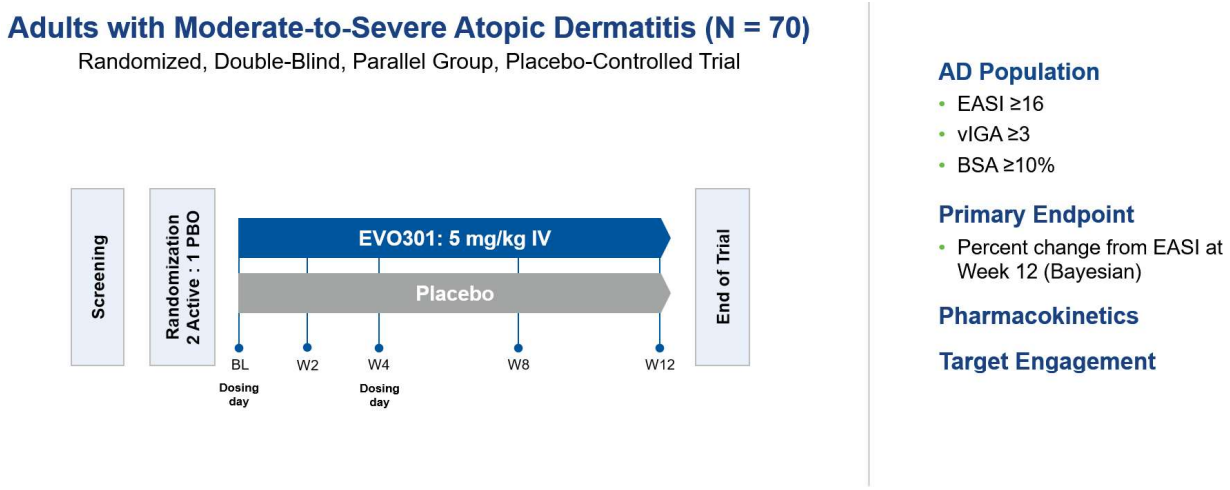
The pharmacokinetic profile of EVO301 supports the potential for monthly dosing. Serum concentrations exceeded the IC_{90} for more than four weeks after a single administration at dose levels of 0.3 mg/kg or greater.

Completed Phase 2a Trial for Moderate-to-Severe Atopic Dermatitis

We conducted a Phase 2a randomized, double-blind, placebo-controlled, parallel-group trial evaluating EVO301 in 70 adult patients with moderate-to-severe AD dosed on day 1 and day 29. The trial was conducted at sites in Australia and New Zealand and enrolled patients aged ≥18 years with moderate-to-severe AD for at least six months (with EASI score of ≥16, Validated IGA scale ≥3 and BSA of AD of ≥10%). The trial's primary endpoint was a Bayesian success criterion related to the difference between active and placebo in the percent improvement in baseline in EASI score at week 12. Secondary endpoints include vIGA response, percent change in BSA and change from baseline in pruritus-NRS.

The following figure shows the Phase 2a trial design:

Figure 41: EVO301 Phase 2a Trial Design



Notes: EASI = Eczema Area and Severity Index; vIGA = Validated Investigator Global Assessment; BSA = Body Surface Area.

A total of 70 patients were enrolled in the Phase 2a trial, with 48 patients assigned to the active cohort and 22 patients to the placebo cohort. Baseline EASI in the active and placebo cohorts was 30.0 and 29.8, respectively. A total of 65 patients completed the trial with 45 in the active cohort and 22 in the placebo cohort. There were no treatment related discontinuations in the trial. Baseline characteristics and patient dispositions for enrolled and treated patients are detailed in Figure 42 below:

Figure 42: Phase 2a EVO301 AD Trial Disposition

	EVO301	Placebo
N (treated)	48	22
N (completed)	45[1]	20[2]
Age	30.5 (11.1)	33.1 (11.8)
Gender (female, %)	29 (60.4%)	13 (59.1%)
Weight (kg)	78.5 (18.7)	76.4 (17.5)
BMI (kg/m^2)	27.4 (6.0)	28.1 (6.3)
EASI	30.0 (11.8)	29.8 (10.5)
IGA	3.3 (0.5)	3.5 (0.5)
Pruritus-NRS	6.3 (1.5)	6.7 (2.1)
% BSA	47.1 (21.2)	49.3 (16.1)

Notes: 1. Lost to follow-up. 2. Lost to follow-up and subject withdrawal

Efficacy Results

The trial met its primary endpoint, a Bayesian success criterion related to the difference between active and placebo in the percent improvement in baseline in the EASI. While the success criterion required at least 75% of the posterior distribution to be an improvement of at least 8% over placebo, the results of the trial demonstrated 99.8%

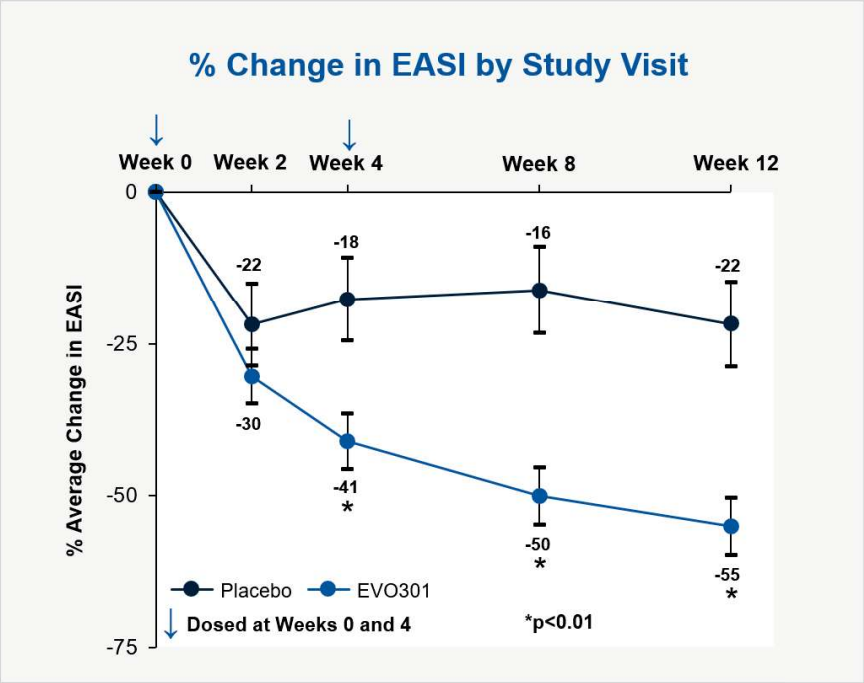
of the posterior distribution met that threshold. Furthermore, when analyzed by the more commonly used frequentist method, statistical significance was achieved at weeks 4, 8 and 12 at $p<0.01$.

After just two doses of EVO301 (administered on day 1 and at week 4), efficacy - measured by both % change in EASI and vIGA response - was already comparable to marketed AD biologics. Clinical separation emerged early and responses were durable, with sustained benefit observed 8 weeks after the final dose, as shown in the figures below:

Figure 43: Percent Reduction in EASI at Weeks 4, 8 and 12:

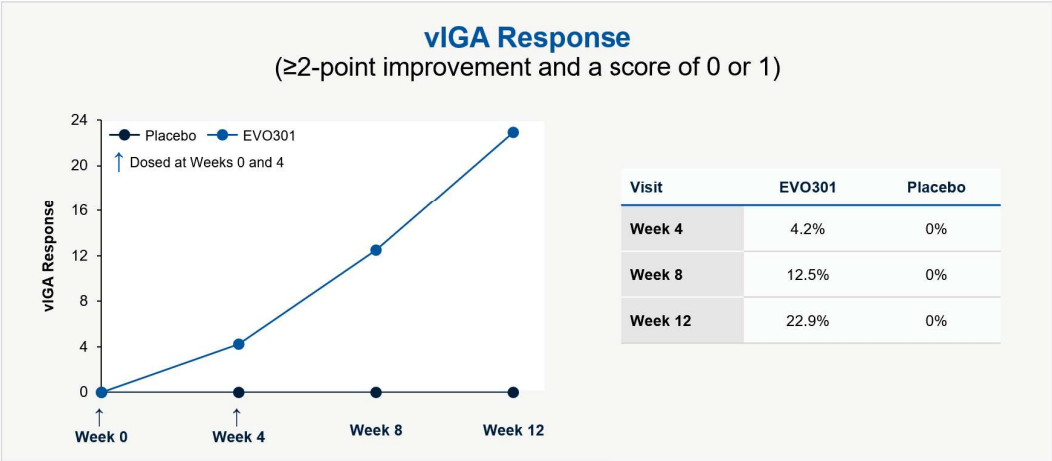
Visit	EVO301	Placebo	Placebo-adjusted Change	p-value
Week 4	-41	-18	-23	<0.01
Week 8	-50	-16	-34	<0.01
Week 12	-55	-22	-33	<0.01

Figure 44: Plotted Curves % Reduction in EASI, by Week:



Approximately 23% of patients treated with EVO301 (vs 0% placebo) achieved vIGA-AD 0/1 (percent of patients achieving a score of 0 or 1 on the vIGA for AD with ≥ 2-point reduction from baseline) at week 12.

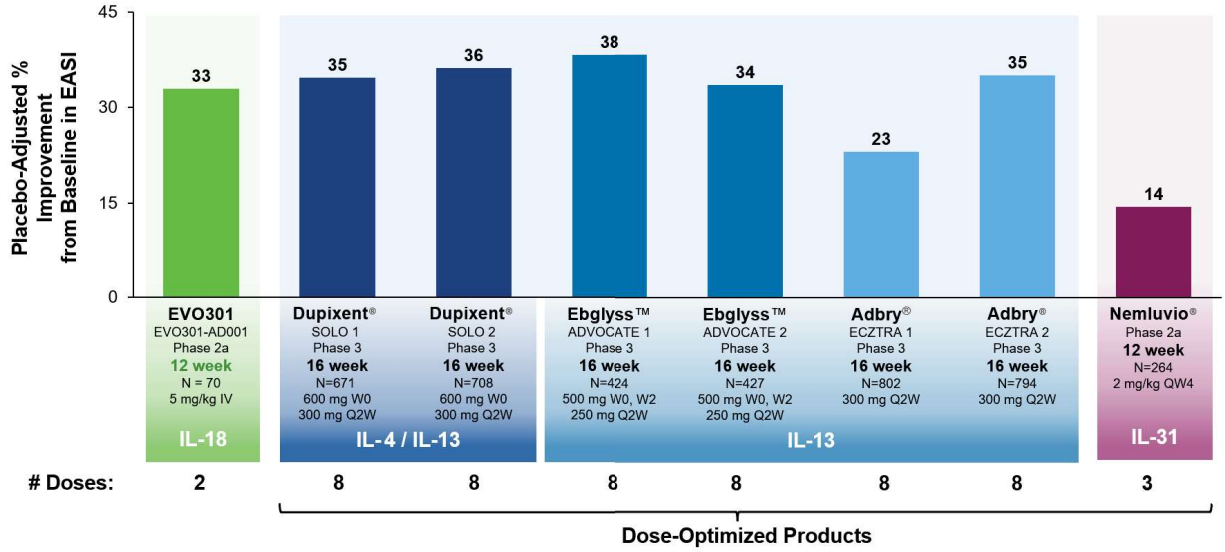
Figure 45: vIGA Response at Weeks 4, 8 and 12



Visit	EVO301	Placebo
Week 4	4.2%	0%
Week 8	12.5%	0%
Week 12	22.9%	0%

After only two administered doses (at day 1 and 28), EVO301 achieved comparable improvement in EASI from baseline to that of other approved biologics targeting alternate mechanisms of action, despite these agents administered under fully optimized dosing regimens.

Figure 46: Placebo-Adjusted Improvement from Baseline in EASI



Note: For illustrative purposes only. Not a head-to-head comparison. Differences exist between trial designs and study characteristics, and caution should be exercised when comparing across trials.

If this activity and safety profile observed to date are sustained or further enhanced in larger trials, we believe EVO301 has the potential to become an attractive first-line option for AD patients who are eligible for systemic therapy, as well as for patients who have experienced an inadequate response to existing therapies. Importantly, by targeting IL-18, EVO301 is designed to address underlying inflammatory drivers of disease more broadly, rather than focusing on a single downstream pathway.

As we advance EVO301 into a Phase 2b subcutaneous dose-ranging trial in moderate-to-severe AD, we will apply the insights from this proof-of-concept trial and leverage the team's extensive past experience optimizing dosing, to design a rigorous and efficient 16-week trial. With higher exposures delivered at an optimized dosing

cadence, we believe there is potential to further increase efficacy beyond the already robust responses observed in our Phase 2a trial.

In addition, EVO301 demonstrated PK and target engagement supportive of a Q4 week dosing regimen, accompanied by corresponding improvements in secondary endpoints and reductions in key Th2-associated biomarkers (CCL-17 (TARC), CCL-22) and non-Th2 associated biomarkers such as IL-22. Collectively, we believe this supports our thesis that IL-18 modulates AD disease pathology more broadly than just Th2 alone. These PK/PD results, combined with the clinical data, support our confidence in both the mechanism and the dosing strategy we plan to take forward.

Safety Results

EVO301 was well tolerated, with no related serious AEs or SAEs reported, no treatment-related discontinuations due to AEs and no meaningful differences in events between the active and placebo groups. There were no clinically significant lab abnormalities and no cases of conjunctivitis were reported.

Figure 47: EVO301 Phase 2a Safety Summary Table and Treatment Emergent Adverse Events in More than 5% of Subjects in Either Arm

	EVO301	Placebo	Total
	N=48	N=22	N=70
Patients with ≥1 Adverse Event (AE)	30 (62.5%)	16 (72.7%)	46 (65.7%)
Patients with ≥1 Treatment Related AE	5 (10.4%)	3 (13.6%)	8 (11.4%)
Patients with a Related Serious or Severe AE	0	0	0
AEs Leading to Study Discontinuation	0	0	0

AEs > 5% in Either Arm	EVO301	Placebo	Total
Upper respiratory tract infection	10 (20.8%)	4 (18.2%)	14 (20.0%)
Atopic dermatitis	10 (20.8%)	9 (40.9%)	19 (27.1%)
Headache	8 (16.7%)	3 (13.6%)	11 (15.7%)
Nasopharyngitis	4 (8.3%)	0	4 (5.7%)
Viral upper respiratory tract infection	3 (6.3%)	2 (9.1%)	5 (7.1%)
Dizziness	3 (6.3%)	1 (4.5%)	4 (5.7%)
Fatigue	3 (6.3%)	0	3 (4.3%)

Planned Phase 2b Trial for Moderate-to-Severe Atopic Dermatitis

Given the positive data from our Phase 2a trial, we are planning to advance EVO301 into a global Phase 2b trial using a subcutaneous formulation of EVO301, with results expected to support potential future Phase 3 registrational studies for EVO301 in moderate-to-severe AD.

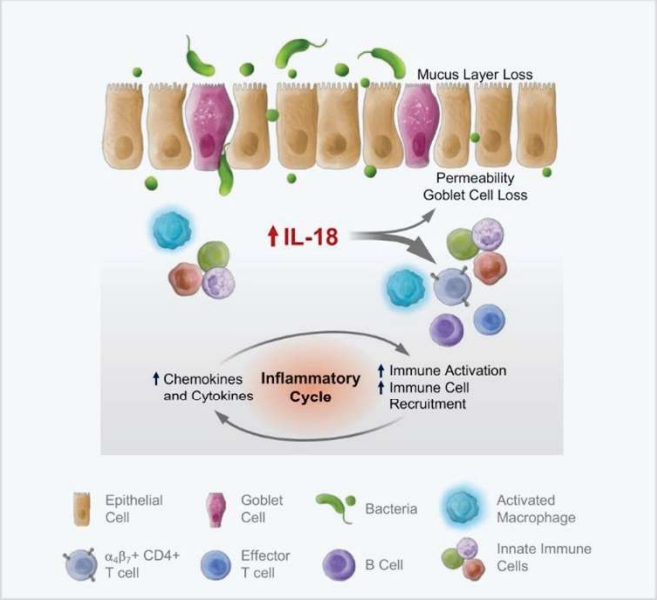
Clinical Development Plan and Status

EVO301 for the Treatment of Inflammatory Bowel Diseases

In the United States, over 2.2 million people live with inflammatory bowel diseases, which include UC and Crohn's disease. These diseases are characterized by relapsing and remitting inflammation of the gastrointestinal tract, leading to symptoms such as abdominal pain, diarrhea, bleeding and significant impacts on quality of life. Initial treatments often include aminosalicylates, corticosteroids or immunomodulators, yet a substantial portion of the patients require escalation to advanced therapies due to inadequate symptom control or adverse effects. Despite the availability of several advanced therapies including anti-TNF agents, anti-integrins, IL-12/23 inhibitors and JAK inhibitors, the landscape for IBD has no consistent treatment paradigm and continues to be marked by limitations, with up to 50% of patients failing to achieve or maintain meaningful clinical remission. As a result, many IBD patients cycle through multiple therapies without achieving durable disease control, leaving hundreds of thousands of patients in the United States inadequately managed, underscoring the need for new effective mechanisms of action.

Beyond AD, we are evaluating a potential Phase 2 trial in moderate-to-severe UC patients. The results of the trial are expected to inform dose selection and other trial design considerations for further clinical development in IBD. We believe that IL-18 signaling plays a key role in UC, as illustrated in the figure below:

Figure 48: Role of IL-18 in Ulcerative Colitis



Discovery Stage Programs

We are also selectively advancing discovery-stage programs to enable us to consistently deliver data on new product candidates. We are currently evaluating multiple preclinical molecules across various targets for possible nomination as lead development candidates for IND-enabling studies in 2026 and beyond.

We also intend to continue evaluating potential preclinical assets, including through in-licensing or partnerships, that we believe can be optimized for priority indications to broaden our portfolio.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, the expertise of our management team, clinical capabilities, research and development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including biotechnology and biopharmaceutical companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

There are several large biotechnology and biopharmaceutical companies that are currently pursuing the development of products for the treatment of chronic inflammation. Companies that we are aware of that are targeting the treatment of chronic inflammation and related diseases include large companies with revenues and significant financial resources. However, we know of one other company currently in clinical development with an MRGPRX2 antagonist and no other companies currently in clinical development with a serum albumin Fab-associated IL-18BP fusion protein.

Many of our competitors, either alone or with their collaborators, have significantly greater resources, established presence in the market and greater expertise across research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals, reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors.

The commercial potential of our product candidates could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive. Our competitors also may obtain FDA or regulatory approval from comparable foreign regulatory authorities for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of our product candidates are likely to be efficacy, safety, cost and convenience.

Intellectual Property

Our owned and exclusively licensed patents and patent applications relate to our compounds for treating certain chronic inflammation indications and include patents and patent applications directed to new compositions of matter and to methods of treating a variety of disorders. As we continue to develop our product candidates, we intend to seek additional patent protection in the United States, EU and in other key commercial markets worldwide.

EVO756

As of December 31, 2025, we exclusively license one patent family that includes one issued U.S. patent, two pending U.S. patent applications and issued and pending foreign counterpart patents and patent applications, relating to compositions of matter and methods of use for our product candidate, EVO756. If we continue to pursue patent protection, and if any patents issue based on our pending applications, we expect such patents to expire in November 2040, without taking into account possible patent term adjustments or extensions.

EVO301

As of December 31, 2025, we exclusively license three patent families that include two issued U.S. patents, two pending U.S. patent applications and issued and pending foreign counterpart patents and patent applications, relating to our product candidate, EVO301. One of these patent families includes U.S. Patent No. 9,879,077, relating to compositions of matter, and U.S. Patent No. 10,618,953, relating to methods of use, both of which are expected to expire in August 2034, absent any patent term extension. The second patent family includes two pending U.S. patent applications that are directed to, among others, compositions of matter and methods of use relating to EVO301. If we continue to pursue patent protection, and if any patents issue based on our pending applications in this patent family, we expect such patents to expire in September 2041 in the United States, absent any patent term adjustment and patent term extension. The third patent family includes one pending PCT application directed to methods of use. If we continue to pursue patent protection, and if any patents issue based on our pending applications in this patent family, we expect such patents to expire in June 2044 in the United States, without taking into account possible patent term adjustments or extensions.

The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the basic patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be extended by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date, or shortened due to an express disclaimer or abandonment. Additionally, the Drug Price Competition and Patent Term Restoration Act of 1984, permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review. Patent extensions of up to five years are also available in certain countries under certain circumstances as partial compensation for the regulatory review period in the respective jurisdictions.

For a discussion of the risks associated with our intellectual property, see "Risk Factors—Risks Related to Intellectual Property."

Strategic Collaborations and License Agreements

Dermira, Inc.

In December 2020, we entered into a License, Development and Commercialization Agreement with Dermira, pursuant to which Dermira granted us an exclusive, worldwide license to develop and commercialize certain compounds, including the compound in development by us known as EVO756 (the "Dermira License Agreement").

The Dermira License Agreement remains in effect on a product-by-product and a country-by-country basis until the expiration of the royalty term for such product in such country. The Dermira License Agreement may be terminated by either party due to the other party's uncured material breach or bankruptcy. Additionally, we may terminate the Dermira License Agreement for convenience upon a set number of days' prior notice.

In consideration for the licenses granted to us under the Dermira License Agreement, we paid to Dermira a $7.5 million upfront license fee. Additionally, in connection with our entry into the Dermira License Agreement, we issued to Dermira 3,227,805 shares of Series A Preferred Stock which was equal to approximately 5% of our fully diluted equity at the time of grant and was calculated by reference to the same per-share purchase price paid by the lead investor in the Series A Preferred Stock financing (as a completed qualified financing).

We are also obligated to pay to Dermira up to $45.0 million in development milestones for the development of EVO756 (or up to $135.0 million for the development of all licensed products), and up to $240.0 million in sales milestones for the development of EVO756 (or up to $720.0 million for the development of all licensed products) as well as tiered royalty payments in mid-single digit to low-tens percentages on worldwide sales of the licensed products.

As of December 31, 2025, we have paid a total of $11.0 million in upfront payments and development milestones under the Dermira License Agreement, which was recognized as research and development expense for the year in which they occurred. No milestones were achieved under the Dermira License Agreement during the year ended December 31, 2024. For the year ended December 31, 2025, we recorded $2.5 million as research and development expense upon achievement of a development milestone under the Dermira License Agreement. Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due.

Under the Dermira License Agreement, we may sublicense EVO756 to third parties. Dermira has consented to our sublicense of EVO756 to Maruho in Japan and certain Asian countries as described below.

Maruho Co., Ltd.

Maruho Japan Agreement

In September 2023, we entered into a sublicense agreement with Maruho and granted Maruho the exclusive license to develop and commercialize EVO756 in Japan (the "Maruho Japan Agreement"). Under the Maruho Japan Agreement, Maruho is responsible for the development and commercialization of EVO756 in Japan, except that we are required to use commercially reasonable efforts to develop EVO756 in CSU and to include a Japanese cohort in our Phase 1 clinical trial of EVO756.

Under the terms of the Maruho Japan Agreement, we received an upfront payment of $8.0 million in September 2023 and are eligible to receive up to $52.0 million in development, regulatory and commercial milestone payments upon the occurrence of specified events over the term of the agreement. In addition, we are eligible to receive low single digit royalty payments on future sales of EVO756 in Japan, on top of the royalty payments due to Dermira on such sales under the Dermira License Agreement. As of December 31, 2025, we have received a total of $18.0 million under the Maruho Japan Agreement.

The Maruho Japan Agreement remains in effect until the expiration of the royalty term for all licensed products in Japan, which continues until the expiration of all relevant patents and regulatory exclusivities and 10 years from the first commercial sale of the licensed product in Japan, whichever is the latest. The Maruho Japan Agreement may be terminated by either party due to the other party's uncured material breach or bankruptcy. In addition, we may terminate the agreement if Maruho challenges any licensed patent. Maruho may also terminate the agreement for convenience upon prior written notice to us.

Maruho Greater Asia Agreement

In March 2024, we entered into a separate sublicense agreement with Maruho (the "Maruho Greater Asia Agreement") and granted Maruho the exclusive license to develop and commercialize EVO756 in China, Taiwan, South Korea and the member states of the Association of Southeast Asian Nations (ASEAN) (the "Territory"). Under the Maruho Greater Asia Agreement, Maruho is responsible for the development and commercialization of EVO756 in the Territory, except that we are required to use commercially reasonable efforts to develop EVO756 in CSU.

Under the terms of the Maruho Greater Asia Agreement, we received an upfront payment of $7.0 million in March 2024 and are eligible to receive up to $54.5 million in development, regulatory and commercial milestone payments upon the occurrence of specified events over the term of the agreement. In addition, we are eligible to receive low single-digit royalty payments on future sales of EVO756 in the Territory, on top of the royalty payments due to Dermira on such sales under the Dermira License Agreement. As of December 31, 2025, we have received a total of $7.0 million under the Maruho Greater Asia Agreement.

The Maruho Greater Asia Agreement remains in effect until the expiration of the royalty term for all licensed products in the Territory, which continues until the expiration of all relevant patents and regulatory exclusivities and 10 years from the first commercial sale of the licensed product in the relevant country in the Territory, whichever is the latest. The Maruho Greater Asia Agreement may be terminated by either party due to the other party's uncured material breach or bankruptcy. In addition, we may terminate the agreement if Maruho challenges any licensed patent. Maruho may also terminate the agreement for convenience upon prior written notice to us.

AprilBio Co., Ltd.

In June 2024, we entered into a license agreement with AprilBio upon which AprilBio granted us an exclusive worldwide license to develop and commercialize EVO301 (the "AprilBio License Agreement"). Under the AprilBio License Agreement, we are responsible for the development and commercialization of the licensed product, except that AprilBio was responsible for completing the then ongoing Phase 1 clinical trial. We are required to use commercially reasonable efforts to develop and commercialize the licensed product in certain major market countries and to meet certain specified diligence milestones. In addition, AprilBio also granted us a right of first negotiation to license or acquire rights to other IL-18 products that may be developed by AprilBio if AprilBio completes certain development work for such product within a specified time period.

Under the AprilBio License Agreement, we paid an upfront payment of $15.0 million and are required to pay, upon achievement of specified milestones and the sale of the licensed product, development milestones of up to $82.5 million, sales milestones of up to $377.5 million, and tiered royalty payments in the mid to high-single digit percentage on worldwide sales of the licensed product. In addition, if we sublicense the licensed product, we are required to pay AprilBio a percentage of the sublicense revenue we received, which percentage depends on the timing of the sublicense grant. For the twelve months ended December 31, 2025, we recorded $1.5 million as research and development expense upon achievement of a development milestone under the AprilBio License Agreement. No development milestones were recorded as research and development expenses for the twelve months ended December 31, 2024. No other development or sales milestones have been achieved as of December 31, 2025. As of December 31, 2025, we have paid a total of $16.5 million under the AprilBio License Agreement.

The AprilBio License Agreement remains in effect on a product-by-product and country-by-country basis until the expiration of the royalty term for such product in such country, which continues until the expiration of all relevant patents and regulatory exclusivities and 12 years from the first commercial sale of such product in such country, whichever is the latest. The AprilBio License Agreement may be terminated by either party due to the other party's uncured material breach or bankruptcy. In addition, AprilBio may terminate the agreement if we challenge any licensed patent or if we cease active development of the licensed product. We may also terminate the agreement for convenience upon prior written notice to AprilBio.

Government Regulation

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs, such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling, export and import and record-keeping associated with all these functions, of our product candidates.

U.S. Government Regulation of Drug Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and its implementing regulations. The FDA also regulates biological products under the FDCA and the Public Health Service Act. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending New Drug Applications ("NDAs") or Biologics License Applications ("BLAs"), withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

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

- Completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's GLP regulations;

- Submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- Approval by an independent institutional review board ("IRB") at each clinical site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with GCP requirements to establish the safety and efficacy of the proposed drug product for each indication;
- Submission to the FDA of an NDA or BLA, including payment of application user fees;
- A determination by the FDA within 60 days of its receipt to accept the marketing application for review;
- Satisfactory completion of an FDA advisory committee review, if applicable;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice ("cGMP") requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- Satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data; and
- FDA review and approval of the NDA or BLA.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as *in vitro* and animal studies to assess potential safety and efficacy. The conduct of preclinical studies is subject to federal regulations and requirements, including good laboratory practice regulations for safety/toxicology studies.

An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some preclinical testing, such as animal tests of reproductive AEs and carcinogenicity, may continue even after the 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 related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to initiate.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial conducted in the United States and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it is initiated at that institution. The IRB also must review and approve the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completion.

Information about certain clinical trials must be submitted within specific timeframes to the Institutes of Health ("NIH") for public dissemination on their www.clinicaltrials.gov website. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Although sponsors are obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical trial or to submit trial results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government.

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

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval on an NDA or BLA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if SAEs occur. Written IND safety reports must be submitted to the FDA and 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.

Phase 1, Phase 2 and Phase 3 trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. 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 or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of 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 drug does not undergo unacceptable deterioration over its shelf life.

NDA or BLA Submission and Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. In most cases, the submission of an application is subject to a substantial user fee.

The FDA conducts a preliminary review of all applications within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an application to determine, among other things, whether the drug 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.

Under the Prescription Drug User Fee Act ("PDUFA") guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA or BLA to review and act on the submission and six months from the filing date of an application with priority review. Accordingly, this review process typically takes 12 months and eight months, respectively from the date the application is submitted to the FDA. The FDA does not always meet its PDUFA goal dates for standard or priority review, and the review process is often extended by FDA requests for additional information or clarification. The FDA reviews an NDA or BLA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to ensure the product's continued safety, quality and purity.

In addition, under the Pediatric Research Equity Act of 2003, as amended, certain applications or supplements to an approved application must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, 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. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan ("PSP"), within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials or other clinical development programs.

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

The FDA also may require the submission of a risk evaluation and mitigation strategy ("REMS") if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug. A REMS may include one or more elements, including medication guides, physician communication plans, patient package insert or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor must submit a proposed REMS. The FDA will not approve the application without a REMS, if required.

Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After evaluating the application and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter or, in some cases, a Complete Response Letter. A Complete Response Letter generally contains a statement of specific conditions that must be met in order to secure final approval of the application and may require additional clinical or preclinical testing in order for FDA to reconsider the application. If a Complete Response Letter is issued, the applicant may either resubmit the application within a year, addressing all of the deficiencies identified in the letter, or withdraw the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Expedited Development and Priority Review Programs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval, and the purpose of these programs is to either expedite the development or review of important new drugs to get them to patients earlier than under standard FDA development and review procedures.

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to both the product and the specific indication for which it is being studied. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as priority review, discussed below.

Additionally, a drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of Breakthrough Therapy designation include the same benefits as Fast Track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. A product may also be eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA determines at the time that the marketing application is submitted, on a case-by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review and to shorten the FDA's goal for taking action from ten months to six months from the date of filing of a marketing application.

A product may also be eligible for accelerated approval if it treats a serious or life-threatening disease or condition, generally provides a meaningful advantage over available therapies and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM"), that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of accelerated approval, the FDA requires that a sponsor perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Fast Track designation, Breakthrough Therapy designation and Priority Review designation do not change the standards for approval, but may expedite the development or review process. Drugs granted accelerated approval also must meet the same statutory standards for safety and effectiveness as those granted traditional approval. Based on current operating plans, we do not intend to pursue any expedited development and priority review programs.

U.S. Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain follow-on applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an Abbreviated New Drug Application for a generic version of the drug or a 505(b)(2) NDA for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, such a follow-on application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of market exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity period covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving follow-on applications that do not reference the protected clinical data. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods or listed patents. This six-month exclusivity may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

A seven-year period of orphan exclusivity is available for products (i) intended to treat a disease that affects fewer than 200,000 people in the U.S. or (ii) intended to treat a disease that affects more than 200,000 people, but for which there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States. A sponsor may request an orphan designation at any time before it submits a marketing application; if the designation is granted and the orphan-designated product is approved, the FDA will not approve another sponsor's marketing application for the same drug for the same use or indication before the expiration of seven years from the date of such approval, unless the orphan designation is revoked, the approval of the underlying application is revoked or the sponsor is unable to supply sufficient product to meet market demand.

For biologics, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic without such alteration or switch. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product. In addition, the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There are continuing, annual user fee requirements for any marketed products.

The FDA may impose a number of post-approval requirements as a condition of approval. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

FDA regulations require that products be manufactured in specific facilities (identified in the approved NDA or BLA) and in accordance with cGMP regulations which require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once approval of a drug 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 AEs of unanticipated severity or frequency, or with manufacturing processes or failure to comply with regulatory requirements, may result in mandatory 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. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Other potential consequences include, among other things:

- Restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- Fines, warning letters or holds on post-approval clinical trials;
- Refusal of the FDA to approve pending applications or supplements to approved applications or suspension or withdrawal of product approvals;
- Product seizure or detention or refusal to permit the import or export of products; and
- Injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted by a manufacturer and any third parties acting on behalf of a manufacturer only for the approved indications and in a manner consistent with the approved label for the product. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Other Healthcare Laws

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of drug products for which we obtain marketing approval. Arrangements with third-party payors, healthcare providers and physicians, in connection with the clinical research, sales, marketing and promotion of products, once approved, and related activities, may expose a pharmaceutical manufacturer to broadly applicable fraud and abuse and other healthcare laws and regulations. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency and patient data privacy and security laws and regulations, including but not limited to those described below:

- the Anti-Kickback Statute ("AKS"), which makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer or pay any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, that is intended to induce or reward, referrals including the purchase, recommendation, order or prescription of a particular drug for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The AKS has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers and formulary managers on the other. 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. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the AKS is violated. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal FCA;

- the federal civil and criminal false claims laws, including the FCA, which can be enforced by private citizens through "qui tam" or "whistleblower" actions, and civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Pharmaceutical and other healthcare companies have been, and continue to be, prosecuted under these laws, among other things, for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product and for causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses. Similar to the AKS, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation.

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created additional federal criminal provisions that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (for example, public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Like the AKS, the Patient Protection and Affordable Care Act (the "ACA") amended the intent standard for certain healthcare fraud provisions under HIPAA such that a person or entity no longer needs 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, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates and covered subcontractors that perform services for them that involve the creation, use, receipt, maintenance or disclosure of individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created four 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 HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services, under the Open Payments Program, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state, national and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of a pharmaceutical manufacturer's business activities could be subject to challenge under one or more of such laws. Efforts to ensure that business arrangements comply with applicable healthcare laws involve substantial costs. It is possible that governmental and enforcement authorities will conclude that a pharmaceutical manufacturer's business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions, which are costly to defend, are instituted against a pharmaceutical manufacturer, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, imprisonment, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reporting obligations and oversight if we become subject to integrity and oversight agreements to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect a pharmaceutical manufacturer's ability to operate its business and the results of operations. In addition, commercialization of any drug product outside the United States will also likely be subject to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Current and Future Healthcare Reform Legislation

In both the United States and certain foreign jurisdictions, there have been, and continue to be, a number of legislative and regulatory changes to the health care system. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In particular, in 2010, the ACA was enacted, which, among other things, 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 and provided incentives to programs that increase the federal government's comparative effectiveness research.

There have been judicial, administrative, executive and legislative challenges and amendments to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, on July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. It is possible that the ACA will be subject to additional challenges in the future. It is unclear whether the ACA will be overturned, repealed, replaced or further amended. We cannot predict what affect further changes to the ACA would have on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect until 2032 unless additional Congressional action is taken.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics.

The current administration is pursuing policies to reduce regulations and expenditures across government including at the U.S. Department of Health and Human Services ("HHS"), the FDA, the Centers for Medicare & Medicaid Services ("CMS") and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy and personnel changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions include, for example, (1) directives to reduce agency workforce program cuts, (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products and (3) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

HHS has revoked the Richardson Waiver, which required HHS and its subagencies to provide notice and an opportunity to comment on certain matters relating to agency management or personnel or to public property, loans, grants, benefits or contracts. This could result in modifications to HHS policies in these areas that could adversely affect our business. In addition, the Trump administration has issued an executive order directing agencies to examine all regulations, to repeal regulations that do not comply with statutes or are otherwise burdensome and to consider repealing such regulations without notice and comment, which may result in repeal or modification of regulations without significant advance notice. Congress may introduce and ultimately pass health care related legislation that could, among others, impact the drug approval process, modify the Medicare Drug Price Negotiation Program, expand the orphan drug exclusion under the IRA and reduce Medicaid enrollment and funding.

In addition, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Legislative and regulatory proposals and enactment of laws, at the foreign federal and state levels, directed at containing or lowering the cost of healthcare, will continue into the future. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare or impose price controls may adversely affect:

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

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

Regulation Outside the United States

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. The cost of establishing a regulatory compliance system for numerous varying jurisdictions can be very significant. Although many of the issues discussed above with respect to the United States apply similarly in the context of the EU and in other jurisdictions, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial authorization application ("CTA"), must be submitted for each clinical protocol to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is accepted in accordance with a country's requirements, the clinical trial may proceed.

The requirements and processes governing the conduct of clinical trials vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP, the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational medicinal product under EU regulatory systems, we must submit a marketing authorization application. The content of the application submitted in the United States is similar to that required in the EU, with the exception of, among other things, country-specific document requirements.

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing product development, the conduct of clinical trials, manufacturing, distribution, marketing approval, product licensing, pricing and reimbursement vary from country to country.

Countries that are part of the EU, as well as countries outside of the EU, have their own governing bodies, requirements and processes with respect to the approval of drug products. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Additionally, to the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

Authorization Procedures in the EU

In the U.K. and the EEA (the 27 EU member states plus Iceland, Liechtenstein and Norway), medicinal products must be authorized for marketing by using either the centralized authorization procedure or national authorization procedures.

- *Centralized procedure*—If pursuing marketing authorization of a product candidate for a therapeutic indication under the centralized procedure, following the opining of the EMA's Committee for Medicinal Products for Human Use ("CHMP"), the European Commission issues a single marketing authorization valid across the EEA. The centralized procedure is compulsory for human medicines derived from biotechnology processes or advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions, viral diseases and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned contains a new active substance not yet authorized in the EEA, or is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the EEA. Under the centralized procedure, the maximum timeframe for the evaluation of a marketing authorization application ("MAA"), by the EMA is 210 days, excluding "clock stops," when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, and which can add materially to the timeframe. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding clock stops.

- *National authorization procedures*—There are also two other possible routes to authorize products for therapeutic indications in several countries, which are available for products that fall outside the scope of the centralized procedure:

- *Decentralized procedure*—Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.

- *Mutual recognition procedure*—In the mutual recognition procedure, a medicine is first authorized in one EU member state, in accordance with the national procedures of that country. Following this, additional marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned recognize the validity of the original, national marketing authorization.

In the EEA, new products for therapeutic indications that are authorized for marketing (that is, reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of 11 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 their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

The criteria for designating an "orphan medicinal product" in the EEA are similar in principle to those in the United States. In the EEA, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five 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 investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten-year orphan market exclusivity period, no marketing authorization application shall be accepted, and no marketing authorization shall be granted for a similar medicinal product for the same indication. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies.

The ten-year market exclusivity 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, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

As in the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU member states govern the system for the approval of clinical trials in the EU. Under this system, an applicant must obtain prior approval from the competent national authority of the EU member states in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific trial site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an investigational medicinal product dossier (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC and, where relevant, the implementing national provisions of the individual EU member states and further detailed in applicable guidance documents.

In April 2014, the new Clinical Trials Regulation (EU) No 536/2014 or Clinical Trials Regulation, was adopted. It is expected that the Clinical Trials Regulation will apply following confirmation of full functionality of the Clinical Trials Information System, the centralized EU portal and database for clinical trials foreseen by the regulation, through an independent audit. The regulation becomes applicable six months after the European Commission publishes notice of this confirmation. The Clinical Trials Regulation will be directly applicable in all the EU member states, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the EU will continue to be bound by currently applicable provisions until the Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation

becomes applicable, the Clinical Trials Regulation will at that time begin to apply to the clinical trial. The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU.

The main characteristics of the regulation include (i) a streamlined application procedure via a single-entry point, the "EU portal," a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and (ii) a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is jointly assessed by the competent authorities of all EU member states in which an application for authorization of a clinical trial has been submitted (member states concerned). Part II is assessed separately by each member state concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU member state. However, overall related timelines will be defined by the Clinical Trials Regulation.

Should we utilize third-party distributors, compliance with such foreign government regulations would generally be the responsibility of such distributors, who may be independent contractors over whom we have limited control.

Coverage and Reimbursement

Successful commercialization of new drug products depends in part on the extent to which reimbursement for those drug products will be available from government health administration authorities, private health insurers and other organizations. In the United States, government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drug products. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. In addition, HHS has been empowered to negotiate the price of certain single-source drugs that have been on the market for at least 7 years and biologics that have been on the market for at least 11 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis.

Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not ensure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on its investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

In many countries, the prices of drug products are subject to varying price control mechanisms as part of national health systems. In general, the prices of drug products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for drug products but monitor and control

company profits. Accordingly, in markets outside the United States, the reimbursement for drug products may be reduced compared with the United States.

In the United States, the principal decisions about reimbursement for new drug products are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. 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 drug 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.

It is uncertain whether coverage or reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

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

Outside of the United States, the pricing of pharmaceutical products and medical devices is subject to governmental control in many countries. For example, in the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures.

Data Privacy and Security

In the ordinary course of business, we collect, receive, generate, make accessible, protect, secure, dispose, transmit, store, use, disclose, transfer, maintain and otherwise process sensitive information, including personal data. Accordingly, we are, and may become subject to various foreign, federal, state and local laws, rules, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations related to data privacy and security.

These data privacy and security obligations are evolving and may impose potentially conflicting obligations. Such obligations may include, without limitation, federal health information privacy laws, state information security and data breach notification laws, state health information privacy laws and federal and state consumer protection laws (for example, the Federal Trade Commission Act). In addition, in the past few years, numerous U.S. states have enacted comprehensive privacy laws, rules and regulations that impose certain obligations on covered businesses (including providing specific disclosures in privacy notices and affording individuals with certain rights concerning their personal data) and similar laws are being considered at the federal level. While certain of these laws do or may exempt some data processed in the context of clinical trials, these developments may further complicate compliance

efforts and are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing, as more fully discussed in the section titled "Risk Factors" included elsewhere in this Form 10-K.

Additionally, as we collect personal data from individuals outside of the United States, through clinical trials or otherwise, we are, and may become subject to foreign data privacy and security laws, such as Australia's Privacy Act, New Zealand's Privacy Act, Canada's Privacy Act, Japan's Act on the Protection of Personal Information and the European Union's General Data Protection Regulation. Such foreign data privacy and 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" included elsewhere in this Form 10-K.

Employees and Human Capital Resources

As of December 31, 2025, we had 48 full-time employees, who together hold 19 Ph.D. or M.D. degrees and 29 of whom are engaged in research and development activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

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

Facilities

We lease a facility containing 10,665 square feet of laboratory and office space, which is located in Palo Alto, California. The lease expired in July 2025 and has been extended until December 2025. In June 2025, we entered into a new lease agreement for our Palo Alto facility, which will include approximately 32,016 square feet and is expected to commence in March 2026 and expire in June 2031. We also lease offices in New York. We believe that our current facilities are sufficient to meet our current and near-term needs and that, should it be needed, suitable additional space will be available.

Corporate Information

We were incorporated under the laws of the State of Delaware in April 2020 under the name "Evommune, Inc." Our principal executive office is located at 1841 Page Mill Road, Suite 100, Palo Alto, California 94304. Our telephone number is (925) 247-4481. We completed our initial public offering in November 2025 and our common stock is listed on the New York Stock Exchange under the symbol "EVMN."

Available Information

Our website address is www.evommune.com and our investor relations website address is https://ir.evommune.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act are available free of charge on our investor relations website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is www.sec.gov.

Further corporate governance information, including our corporate governance guidelines and board committee charters, is also available on our investor relations website under the heading "Corporate Governance." The contents of our websites are not intended to be incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC, and any references to our websites are intended to be inactive textual references only.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Before deciding to invest in shares of our common stock, you should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and their related notes included elsewhere herein and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may materially and adversely affect our business, prospects, operating results and financial condition.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability. We have incurred net losses in every year since our inception. We expect to continue to incur net losses in the future.

We are a clinical-stage biotechnology company with a limited operating history. Since our inception in 2020, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, conducting business planning, organizing and staffing our company, raising capital, conducting preclinical studies and, more recently, clinical trials and providing general and administrative support for these operations. Biopharmaceutical product development is a highly speculative undertaking, involving substantial upfront capital expenditure and significant risk. Any product candidate may fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable, despite substantial investment on development or commercialization. To date, Evommune has not yet demonstrated its ability to successfully obtain regulatory approvals, manufacture a product on a commercial scale, or arrange for a third party to do so on its behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if Evommune had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each year since our inception. For the year ended December 31, 2025, we had a net loss of $68.9 million. As of December 31, 2025, we had an accumulated deficit of $221.1 million. We expect to continue to incur significant losses for the foreseeable future and expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our two clinical-stage product candidates, EVO756 and EVO301, along with any future product candidates we may develop.

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

- continue the research and development of our clinical- and preclinical-stage product candidates and discovery-stage programs, including the continued development of our most advanced product candidates, EVO756 and EVO301;
- increase the amount of research and development activities to identify and develop product candidates to advance into clinical trial development;
- make milestone, royalty or other payments under in-license or collaboration agreements;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts;
- establish sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;

- address any competing therapies and market developments;
- incur additional costs associated with operating as a public company;
- acquire or in-license other technologies; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies or trials, complex results, manufacturing challenges, safety issues or other regulatory challenges.

To become and remain profitable, we and any potential future collaborators must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, manufacturing our product candidates, either on our own or with contract development and manufacturing organizations ("CDMOs"), obtaining marketing approval for product candidates, marketing and selling any products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Our future results of operations will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

We will need substantial additional funding in order to maintain our operations and advance the development and commercialization of our product candidates, if approved. Failure to obtain this necessary capital when needed, or on acceptable terms, may force us to delay, reduce or eliminate certain of our research operations or development.

The development of biopharmaceutical product candidates, including conducting preclinical studies and clinical trials, is a time-consuming, capital-intensive and uncertain process. Our operations have consumed substantial amounts of cash since inception. To date, we have funded our operations primarily with proceeds from the sale of our convertible preferred stock and common stock. We expect our expenses to increase in connection with our ongoing activities, particularly as we advance our development of EVO756 and EVO301, and continue to research, develop and initiate clinical trials of any other future product candidates. In addition, if we successfully develop and obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or any future commercialization efforts.

As of December 31, 2025, we had cash, cash equivalents and investments of approximately $216.7 million. Based on current operating assumptions, we expect that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements through 2028. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Future capital requirements for EVO756 and EVO301 or any of our other product development programs will depend on many factors, including:

- the progress, timing and completion of preclinical studies and clinical trials for our current or any future product candidates, as well as the associated costs, including any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to disease outbreaks, epidemics and pandemics or other causes;
- the timing and amount of milestone and royalty payments we are required to make or are eligible to receive under our license agreements with Dermira, Inc. ("Dermira"), Maruho Co., Ltd. ("Maruho"), AprilBio Co. Ltd. ("AprilBio") and any future license or collaboration agreements;

- the number and characteristics of potential new product candidates we identify and decide to develop;
- the need for additional or expanded preclinical studies and clinical trials beyond those that we plan to conduct with respect to our current and future product candidates;
- the cost involved in growing the organization to the size needed to allow for the research, development and potential commercialization of our current or any future product candidates;
- the costs involved in filing patent applications, maintaining and enforcing patents or defending against infringement or other claims raised by third parties;
- the maintenance of our existing license and collaboration agreements and the entry into new license and collaboration agreements;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own;
- the cost associated with manufacturing and supply of our product candidates;
- the cost associated with operating as a public company;
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved; and
- market acceptance of any approved product candidates.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms or at all. Until we can generate sufficient product or other revenue to finance our cash requirements, which we may never achieve, we expect to finance our future cash requirements through a combination of equity offerings, debt financings or other capital sources, including potential collaborations, out-licenses or dispositions and other similar arrangements.

Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. Market volatility resulting from geopolitical and economic instability, including as a result of trade policy, inflation and the wars between Russia and Ukraine and in the Middle East or other factors could also adversely impact our ability to access capital as and when needed. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or product candidates or we may be unable to take advantage of future business opportunities.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, out-licenses or dispositions and other similar arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that may adversely affect the rights of our stockholders. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish certain valuable rights to our intellectual property, 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 capital when needed, we may be required to delay, limit, reduce or terminate our clinical development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential product candidates. These decisions may prove to have been wrong and may adversely affect our ability to develop our own programs, our attractiveness as a commercial partner and may ultimately have an adverse impact on our commercial success.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward our product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biotechnology industry, in particular for our most advanced product candidates, EVO756 and EVO301, our business, financial condition and results of operations could be materially adversely affected.

Risks Related to Discovery, Development and Regulatory Approval of Product Candidates

Preclinical and clinical drug development is a lengthy and expensive process, with uncertain timelines and outcomes. If preclinical studies or clinical trials of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our therapeutic candidates or any of our future therapeutic candidates on a timely basis or at all.

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

- clinical trial results may show the product candidates to be less effective than expected (for example, a clinical trial could fail to meet its primary or key secondary endpoint(s)) or have an unacceptable or unexpected safety 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 marketing application preparation, discussions with the U.S. Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA") or other comparable foreign regulatory authorities, including FDA, EMA or other comparable foreign regulatory authorities requesting additional preclinical or clinical data (such as long-term toxicology studies), or encountering unexpected safety or manufacturing issues;
- preclinical study results may show the product candidate to be less effective than desired or to have harmful on-target or off-target side effects; imposition of extensive post-marketing approval requirements; or
- the proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized.

Furthermore, 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 another and may be difficult to predict. Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations in the United States or country-specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform

measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced. Even if we are able to obtain coverage and adequate reimbursement for our products once approved, there may be features or characteristics of our products, such as dose preparation requirements, that prevent our products from achieving market acceptance by the healthcare or patient communities.

In addition, if any of our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration and will need to continue to comply (or ensure that our third-party providers comply) with current Good Manufacturing Practice ("cGMPs") and Good Clinical Practice ("GCPs") for any clinical trials that we conduct post-approval. In addition, there is 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 ("AEs") of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-approval could adversely affect our business, financial condition and results of operations.

Disruptions at the FDA and other government agencies caused by funding shortages or layoffs could hinder their ability to hire, retain or deploy key leadership and other personnel or otherwise prevent product candidates from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and approved by necessary government agencies, which would adversely affect our business. For example, over the last several years including on October 1, 2025, the U.S. government shut down several times and certain regulatory agencies, such as the FDA, furloughed or laid off critical employees and ceased critical activities. If a prolonged government shutdown or disruption occurs, it could significantly impact the ability of the FDA and applicable foreign authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. In addition, such issues could also prevent the FDA or applicable foreign authorities from conducting their regular inspections, reviews or other regulatory activities, which in turn could significantly impact the ability of such authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, including EVO756, EVO301 and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective for use in each targeted indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications, patient population and regulatory agency. Prior to obtaining approval to commercialize EVO756, EVO301 and any future product candidates in the United States or abroad, we or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses.

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or, if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

Even if the trials are completed to our satisfaction, clinical data are often susceptible to varying interpretations and analyses or may not provide a sufficient risk-benefit ratio, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do or find a risk-benefit ratio for a proposed indication acceptable, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA or comparable foreign regulatory authorities will view our product candidates as having efficacy even if we believe results observed in clinical trials are positive. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of EVO756, EVO301 and any future product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit our commercial potential.

The results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials or results in other indications. Initial positive results in our clinical trials may not be indicative of results obtained when these trials are completed or in later-stage trials.

The results of preclinical studies and early-stage clinical trials may not be predictive of the results of later-stage clinical trials, and results in one indication may not predict results for the same product candidate in another indication. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and any such setbacks in our clinical development could have a material adverse effect on our business and operating results. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials. 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 regulatory approval. Further, negative clinical trial results for a product candidate with respect to one indication may impact the potential or perceived potential of other indications. If our product candidates fail to demonstrate satisfactory characteristics in late-stage clinical trials, it could have a material adverse effect on our business, financial condition and results of operations.

Our product candidates may be associated with serious adverse, undesirable or unacceptable side effects or other properties or safety risks, which may delay or halt their clinical development, prevent their marketing approval or lead to limited market demand, if approved. If such side effects are identified during the development of our product candidates or following approval, we may suspend or abandon our development of such product candidates, the commercial profile of any approved label may be limited or we may be subject to other significant negative consequences following marketing approval.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. While our most advanced product candidates, EVO756 and EVO301, have generally been observed to be well tolerated in their preclinical studies and clinical

trials to date, the results from future preclinical studies and clinical trials, including our other product candidates, may identify safety concerns or other undesirable properties of our product candidates.

The results of our ongoing Phase 2 trials of EVO756 and planned Phase 2 trials of EVO301 and future clinical trials of these and other product candidates may show that our product candidates cause undesirable or unacceptable side effects or even death. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Furthermore, we may be required to expend time and incur costs to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Any of these occurrences may harm our business, financial condition and results of operations significantly.

Moreover, if our product candidates are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate, if approved.

Additionally, adverse developments in clinical trials of pharmaceutical and biopharmaceutical products conducted by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or to change the requirements for approval of any of our product candidates. For example, immunogenicity is a concern for all protein therapeutics in human clinical trials, and immunogenic reactions in patients in our trials may lead to adverse effects and impact exposure, which in turn may lead to protocol amendments, clinical holds or other actions that delay or significantly impact the prospects for our product candidates.

Additionally, if any of our product candidates receive marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product and require us to take such approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients or that we implement a risk evaluation and mitigation strategy ("REMS") plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- we may suspend or abandon our development of the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates, if approved.

Interim, top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could

result in material changes in the final data. Data from our clinical trials reported as of a measurement date may not be predictive of the effect, if any, of our product candidates at any later measurement date.

From time to time, we may publish interim, top-line or preliminary data from our clinical trials. Preliminary and interim data from our clinical trials may change as more patient data become available. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. Interim, top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary, top-line and interim data should be viewed with caution until the final data are available. Moreover, in connection with any data that is presented, caution should be exercised in drawing any conclusions from a comparison of data that does not come from head-to-head analysis. Material differences in the final data compared to the interim data could significantly harm our business prospects.

Additionally, data from a clinical trial as of any measurement date are only reflective of observations in such clinical trial at such date and should not be unduly used to predict any effect at a later measurement date. For example, in our Phase 2 trial of EVO756 in CIndU, we reported observations after four weeks of dosing. It is not possible to accurately predict what impact EVO756 would have had in this trial's subjects at any subsequent date.

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 delay or prevent regulatory approval of, or limit commercial prospects for, the particular product candidate and harm our business prospects. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to include in our public disclosure. If the preliminary and interim data that we report differ from actual results or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, which could adversely affect our business, operating results and prospects.

Patient enrollment and retention in clinical trials is a significant factor in the timing of clinical trials and depends on many factors, including the size and nature of the patient population, the eligibility criteria for the clinical trial, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number, nature and duration of competing treatments and ongoing clinical trials of competing drugs for the same indication and the proximity of patients to clinical trial sites. As we progress our programs, we may not be able to initiate or continue clinical trials for any product candidates we identify or develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, EMA or other comparable foreign authorities or as needed to provide appropriate statistical power for a given trial. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for such trials. We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for our planned clinical trials and monitoring such patients adequately during and after treatment. Other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials.

In addition, we compete for trial participants with other clinical trials for product candidates that are in the same areas as our product candidates, which could reduce the number and types of participants available to us and could affect the timing and cost of our clinical trials. For example, some participants who might have opted to enroll in our clinical trials may instead opt to enroll in a clinical trial being conducted by one of our competitors or to use currently marketed therapies. Delay in recruiting clinical trial participants could adversely affect our ability to bring a product to market prior to our competitors and increase trial costs. Further, research and discoveries by others may result in breakthroughs that render our product candidates obsolete even before they begin to generate any revenue.

The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If the actual number of patients that meet such criteria is smaller than we anticipate, we may encounter

difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our product candidates. Even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials.

Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. In addition, any negative results we may report in clinical trials of a product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate or other product candidates. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. Further, if patients drop out of our clinical trials, miss scheduled doses or follow-up visits or otherwise fail to follow clinical trial protocols, the integrity of data from our clinical trials may be compromised or not accepted by the FDA, EMA or other comparable foreign regulatory authorities, which would represent a significant setback for the applicable program. We have in the past and may in the future experience participant withdrawals or discontinuations from our clinical trials. Withdrawal of participants from our clinical trials may compromise the quality of our data. In addition, we may rely on contract research organizations ("CROs") and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance. Such delays or failures could adversely affect our business, operating results and prospects.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our therapeutics may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. 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 or the initiation of other clinical programs. All of these milestones are and will be based on numerous assumptions, 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, EMA 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 our product candidates;
- the securing of, costs related to and timing issues associated with, product manufacturing as well as sales and marketing activities; and
- securing product reimbursement.

The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our product candidates may be delayed or never achieved and, as a result, our stock price may decline.

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining marketing approval of our product candidates in other jurisdictions.

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, it does not mean that comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and

reimbursement of the product candidate in those countries. However, a failure or delay in obtaining marketing approval in one jurisdiction may negatively impact the marketing approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions.

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

Obtaining foreign marketing approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed, which would adversely affect our business, prospects, financial condition and results of operations.

Our product candidates are subject to extensive regulatory and compliance obligations, compliance with which is costly and time-consuming and which may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The research, clinical development, testing, quality control, safety, effectiveness, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, marketing, import, export, distribution, post-approval monitoring and post-approval reporting of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, neither we nor any future collaborators are permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, new relevant statutes or regulations may be enacted, and the FDA, EMA and other comparable foreign regulatory authorities have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA and other comparable foreign regulatory authorities, which could require us to delay or abandon clinical development plans.

In addition, regulatory authorities may require us to conduct further preclinical studies before evaluating our product candidate in a clinical trial. Once we initiate clinical trials, the FDA, EMA or other comparable foreign regulatory authorities may require additional clinical trials or suggest changes to our planned clinical trials, prior to and in support of the approval of a marketing application. Changes to data requirements by the FDA, EMA or other comparable foreign regulatory authorities during the development of our product candidates may cause the applicable regulatory authorities to require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or regulatory authorities may object to elements of our clinical development program.

The FDA, EMA or other comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our clinical trials;
- results from our clinical trials may not be sufficient for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;

- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we may be unable to demonstrate that a product candidate is safe and effective, and that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation or analysis of data from preclinical studies or clinical trials, such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support a submission to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling or the specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than what we apply for or with other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes, approval policies or facilities of our third-party manufacturers with which we or any of our current or future collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA, EMA and other comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing our product candidates.

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

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

We may develop our current or potential future product candidates in combination with one or more currently approved therapies or therapies in development. Even if any of our current or future product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

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

Furthermore, we cannot be certain that we will be able to obtain a steady supply of such therapies for use in developing combinations with our product candidates on commercially reasonable terms or at all. Any failure to

obtain such therapies for use in clinical development and the expense of purchasing therapies in the market may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If the FDA, EMA or other comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or, if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or future product candidates, we may be unable to obtain approval of or successfully market any one or all of the current or future product candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future product candidates, or, if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

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

Outside of the United States, we are presently conducting or plan to conduct clinical trials in Australia, New Zealand, Japan, Canada and the EU, and will likely choose to conduct additional international clinical trials in the future. The acceptance of trial data by the FDA or any comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions 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 (i) the data are applicable to the U.S. population and U.S. medical practice, (ii) the trials are performed by clinical investigators of recognized competence and pursuant to compliance with current GCP requirements and (iii) the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. 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 applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

- Conducting trials outside the United States also exposes us to additional risks, including risks associated with:
- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

Risks Related to Commercialization, Marketing and Competition of Our Product Candidates

We currently have no marketing, sales or distribution capabilities, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing, sales or distribution capabilities or enter into agreements with third parties to perform such activities, we may not be able to generate product revenue.

We currently have no marketing, sales or distribution capabilities, nor has Evommune as a company commercialized a product, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing, sales or distribution capabilities or enter into agreements with third parties to perform such activities, we may not be able to generate product revenue. If any of our product candidates ultimately receives marketing approval, we will be required to build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in the markets that we target, which will be expensive and time-consuming, or to collaborate with third parties that have direct sales forces and established

distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. Evommune has no prior experience as a company in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Furthermore, we are currently developing product candidates for multiple indications in different medical specialties, which will require us to build different sales and marketing capabilities that are tailored to a given product or medical specialty. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

If the market opportunities for any of our product candidates, if approved, are smaller than we estimate, our revenue may be adversely affected, and our business may suffer.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, third party reports, patient foundations and market research, and may prove to be incorrect. Further, new information may change the estimated incidence or prevalence of these diseases. The total addressable market across our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that our product candidates are also focused on treating. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the

development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

We anticipate that we will continue to face intense and increasing competition as new treatments enter the market and advanced technologies become available. There can be no assurance that our competitors are not currently developing, or will not in the future develop, products that are equally or more effective or are more economically attractive than any of our current or future product candidates. Competing products may gain faster or greater market acceptance than our products, if any, and medical advances or rapid technological development by competitors may result in our product candidates becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we or our product candidates do not compete effectively, we may suffer a material adverse effect on our business, financial condition and results of operations.

Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success. The revenues that we generate from our sales may be limited, and we may never become profitable.

As a company, we have never commercialized a product. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we could be prevented from, or significantly delayed in, achieving profitability. Market acceptance of our product candidates by the medical community, patients and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients to new treatments and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates are approved but do not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any product for which we receive marketing approval will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory authorities, including any limitations or warnings;
- the timing of market introduction of our product candidates in relation to other potentially competitive products;
- the cost of our product candidates in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage and adequate reimbursement from third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- the relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- the effectiveness of our sales and marketing efforts and distribution support; and
- the presence or perceived risk of potential product liability claims.

Even if we are able to commercialize any product candidate, the third-party payor coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors in the United States are essential for most patients to be able to afford treatments such as our products or product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for drug treatments by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our products and potentially attract additional collaboration partners to invest in the development of our product candidates. We cannot be sure that adequate coverage and reimbursement in the United States or elsewhere will be available for our products or any products that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products, medical devices and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug is available. For example, the U.S. Department of Health and Human Services ("HHS") imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. In addition, HHS has been empowered to negotiate the price of certain single-source drugs that have been on the market for at least 7 years and biologics that have been on the market for at least 11 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. In addition, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop, which could have an adverse effect on our operating results and our overall financial condition. It is possible that a third-party payor may consider our products or product candidates, if approved, and the generic or biosimilar parent drug as substitutable and only offer to reimburse patients for the generic drug. Even if we show improved efficacy or safety or improved convenience of administration with our products or product candidates, if approved, pricing of the existing parent drug may limit the amount we will be able to charge for such product. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products or product candidates and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs, biologics and medical devices will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs, biologics and medical devices. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products or product candidates.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our products and product candidates, if approved, and on related parent drugs. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Many countries, including the European Union ("EU") Member States, established complex and lengthy procedures to obtain price approvals, coverage and reimbursement. These procedures vary from country to country but are commonly initiated after grant of the related marketing authorization. More particularly, in the EU, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing systems. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced countries. Reductions in the pricing of our medicinal products in one EU Member State could affect the price in other EU Member States and, thus, have a negative impact on our financial results. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our

products or product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. As an example, many EU Member States review periodically their decisions concerning the pricing and reimbursement of medicinal products. The outcome of these reviews cannot be predicted and could have adverse effects on the pricing and reimbursement of our medicinal products in the EU Member States.

Moreover, increasing efforts by governmental and 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 new products approved and, as a result, they may not cover or provide adequate payment for our products or product candidates. We expect to experience pricing pressures in connection with the sale of our products and product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes or executive orders. The downward pressure on healthcare costs in general, particularly prescription drugs, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Even if we obtain any marketing approval for our current or any future product candidates, such approvals will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCPs, for any clinical trials that we may conduct post-approval. Any marketing approvals that we receive for our current or future product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval or contain requirements for potentially costly post-marketing testing, including Phase 4 trials and surveillance to monitor the quality, safety and efficacy of the drug.

In addition, biopharmaceutical manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the marketing application. If we or a regulatory authority discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of our current or future product candidates, a regulatory authority may, among other things:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending marketing authorization application or supplement submitted by us or our strategic partners;
- restrict or suspend the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

In addition, if any of our product candidates is approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees and imposed permanent injunctions under which specified promotional conduct is changed or curtailed.

The FDA's policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could cause changes to or delays in the drug review process or suspend or restrict marketing approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability, which would harm our business, financial condition, results of operations and prospects.

Our future growth may depend, in part, on our ability to commercialize products in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our product candidates. If we obtain regulatory approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

If our information technology systems or those of third parties with whom we work or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work process sensitive data, including personal data (such as health-related data). Cyber-attacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity and availability of our sensitive data and information technology systems and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties with whom we work, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain and ability to produce, sell and distribute our goods and services.

We and the third parties with whom we work are subject to a variety of evolving threats, including social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by AI and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, inability to provide our products or services, loss of sensitive data and income, reputational harm and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

It may be difficult and costly to detect, investigate, mitigate, contain and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain and remediate a security incident could result in outages, data losses and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment (or that of third parties with whom we work) to gain access to other parts of the relevant environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Remote work has increased risks to our information technology systems and data, as our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third parties to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work fail to satisfy their

privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and software, including that of third parties with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we have and may in the future experience delays in deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats have in the past and may in the future cause a security incident or other interruption that have in the past and may in the future result in unauthorized, unlawful or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of or access to our sensitive data or our information technology systems or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations have required us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators and investors, of security incidents or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and oversight, restrictions on processing sensitive data (including personal data), litigation (including class claims), indemnification obligations, negative publicity, reputational harm, monetary fund diversions, diversion of management attention, interruptions in our operations (including availability of data), financial loss and other similar harms. Security incidents and attendant material consequences may prevent or cause customers to stop using our services, deter new customers from using our services and negatively impact our ability to grow and operate our business.

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 data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect or infer sensitive data about us from public sources, data brokers or other means that reveal competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive data of us could be leaked, disclosed or revealed as a result of or in connection with our employees', personnel's or vendors' use of generative AI technologies.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation (including class claims) and mass

arbitration demands, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, "process") personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials and sensitive third-party data (collectively, "sensitive data").

Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security. In the United States, federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (for example, Section 5 of the Federal Trade Commission Act) and other similar laws (for example, wiretapping laws). For example, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), imposes specific requirements relating to the privacy, security and transmission of individually identifiable protected health information by covered entities, business associates and their covered subcontractors.

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 residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct or delete certain personal data and to opt-out of certain data processing activities, such as targeted advertising, profiling and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive data, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA") applies to personal data of consumers, business representatives and employees who are California residents and requires businesses that are subject to the law to provide specific disclosures in privacy notices and respond to requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties with whom we work. 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.

Outside the United States, an increasing number of laws, regulations and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR") (collectively, "GDPR"), New Zealand's Privacy Act and Australia's Privacy Act impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or 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.

Our employees and personnel may use generative artificial intelligence ("AI") and/or automated decision-making technologies to perform their work, and the disclosure and use of personal data in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws and regulations regulating AI and automated decision-making technologies. Our use of this technology could result in additional compliance costs, regulatory investigations and actions and lawsuits. If we are unable to use AI or automated decision-making technologies, it could make our business less efficient and result in competitive disadvantages.

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 United Kingdom ("UK") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent 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 standard contractual clauses, the UK's International Data Transfer Agreement / Addendum and the EU-U.S. Data Privacy 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 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 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 activist groups.

Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (for example, China, Russia and Iran) and covered individuals (individuals and entities located in or controlled by individuals or entities located in those jurisdictions) that impacts certain business activities such as vendor engagements, the sale or sharing of data, employment of certain individuals and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We also publish privacy policies, marketing materials and other statements concerning data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) 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, which 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 (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations.

If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (for example, investigations, fines, penalties, audits, inspections and similar), litigation (including class-action claims) and mass arbitration demands, additional reporting requirements or oversight, bans or restrictions on processing personal data, orders to destroy or not use personal data and imprisonment of company officials.

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 monumental 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 or financial condition, including: 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.

We are highly dependent on the services of our senior management team and if we are not able to retain members of our management team and recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

We are highly dependent on our senior management team. The employment agreements we have with these officers do not prevent such persons from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. In addition, we will need to attract, retain and motivate highly qualified additional management, clinical and scientific personnel. If we are not able to retain our management and to attract, on terms acceptable to us, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer operating history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to attract, retain and motivate high-quality personnel and consultants to accomplish our business objectives, the rate and success at which we can discover and develop product candidates, and our business will be limited and we may experience constraints on our development objectives.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions, including civil or criminal penalties, private litigation and adverse publicity and could negatively affect our operating results and business.

We and any current and future collaborators may be subject to federal, state/provincial, municipal and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, including Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal and administrative penalties if we violate HIPAA.

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

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

As of December 31, 2025, we had U.S. federal net operating loss carryforwards of approximately $44.1 million. The amount of net operating loss carryforwards that we are permitted to deduct is limited to 80% of taxable income in each such taxable year to which the net operating loss carryforwards are applied. In addition, our U.S. federal net operating losses and tax credits may be subject to limitations under Sections 382 and 383 of the Internal Revenue Code of 1986 (the "Code"), if we have undergone or undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a rolling three-year period. We may have experienced such ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. As a result, our ability to utilize our net operating loss carryforwards could be limited by an "ownership change," which could result in increased tax liability to us.

Legislation or other changes in U.S. tax law may have a material adverse effect on our business, cash flow, financial condition or results of operations.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service ("IRS") and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future. On July 4, 2025, the One Big Beautiful Bill Act (the "Act") was enacted into law. The Act includes significant changes to the U.S. tax code, including restoration of immediate recognition of domestic research and development expenditures and reinstatement of 100% bonus depreciation for qualifying property. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations.

It cannot be predicted whether, when, in what form or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. Investors should consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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

If earthquakes, fires, other natural disasters, terrorism and similar events beyond our control prevent us from using all or a significant portion of our headquarters or other facilities, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We have a disaster recovery plan in place and are in the process of implementing a business continuity plan. We may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which could have a material adverse effect on our business. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical manufacturing and distribution industry in particular are unclear, and changes in the supply, demand or available sources of energy and the regulatory and other costs associated with energy production and delivery may affect the availability or cost of goods and services, including raw materials and other natural resources, necessary to run our business. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

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

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

- decreased demand for any product candidate that we may develop;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- a diversion of management's time and our resources;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;

- the inability to commercialize any product candidate that we may develop;
- injury to our reputation and significant negative media attention; and
- a decline in our stock price.

We currently hold approximately $5.0 million in product liability insurance coverage in the aggregate. We may need to increase our insurance coverage as we expand our clinical trials and if we successfully commercialize any product candidate. Insurance coverage can be increasingly expensive. We may not be able to obtain or maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2025, we had 48 full-time employees. As we advance our research and development programs, we may need to further increase the number of our employees and the scope of our operations, particularly in the areas of clinical development, discovery biology, chemistry, manufacturing, general and administrative matters related to being a public company, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage any future growth, we must:

- identify, recruit, integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

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

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

We are exposed to the risk of fraud or other misconduct or improper activities by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include insider trading, intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting

our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

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

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

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Failure to comply with these laws, regulations and permitting requirements also may result in substantial fines, penalties or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. Currently, several of our suppliers are located outside of the United States, including in China. We also rely on specialized laboratory

equipment, supplies and materials, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts.

Current or future tariffs could result in increased research and development expenses, including with respect to increased costs associated with active pharmaceutical ingredients, raw materials, laboratory equipment and research materials and components. In addition, such tariffs could increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating entirely domestically or in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, results of operations and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects.

Risks Related to Government Regulatory and Legal Requirements

Our relationships with customers, physicians and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, other healthcare laws and regulations and health data privacy and security laws and regulations, contractual obligations and self-regulatory schemes. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws, the health care fraud provisions of HIPAA and the federal Physician Payments Sunshine Act and their implementing regulations. These laws will impact, among other things, our clinical research, as well as our proposed sales and marketing programs. In addition, we may be subject to health information privacy and security laws by the federal government, including HIPAA, as amended by HITECH, the states and other jurisdictions in which we may conduct our business.

Because of the breadth of these laws and the limited statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's

attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including the 2010 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), which substantially changed the way healthcare is financed by both the government and private insurers and significantly impacts the U.S. pharmaceutical industry. Since its enactment, there have been amendments and judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act, or the OBBBA, was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical and biologic products. In addition, 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.

We cannot be sure whether additional legislative changes will be enacted, whether FDA regulations, guidance or interpretations will be changed or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the CMS and related agencies. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug

manufacturers to offer, through a direct to consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions include, for example, (1) directives to reduce agency workforce program cuts, (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products, and (3) as part of the Make America Healthy Again (MAHA) Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager (PBM) payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could, among others, impact the drug approval process, modify the Medicare Drug Price Negotiation Program, expand the orphan drug exclusion and reduce Medicaid enrollment and funding.

In addition, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We cannot predict what healthcare reform initiatives may be adopted in the future. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act (the "FCPA") and similar anti-corruption and anti-bribery laws, as well as trade sanctions, embargoes and anti-money laundering laws and regulations. Compliance with these legal standards could hinder our ability to compete in certain markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

Our operations are subject to U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. The FCPA and these other laws generally prohibit us, our officers and our employees and intermediaries from, directly or indirectly, offering, authorizing or making improper payments to non-U.S. government officials for the purpose of obtaining or retaining business or other advantage. We engage third parties for clinical trials outside of the United States and may continue to do so in the future. We may also sell our products abroad if we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals for any product sales outside the United States. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. As our business expands, the applicability of the FCPA and other anti-bribery laws to our operations will increase. If our procedures and controls to monitor anti-bribery compliance fail to protect us from reckless or criminal acts committed by our employees or agents or if we, or our employees, agents, contractors or other collaborators, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

In addition, our products, if approved, may be subject to U.S. and foreign export controls, trade sanctions, embargoes and import laws and regulations. Governmental regulation of the import or export of our products or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in

international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations or in the countries, persons or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

There is substantial uncertainty regarding the new Administration's initiatives and how these might impact the FDA, its implementation of laws, regulations, policies and guidance and its personnel. Similar initiatives may also be directed toward other government agencies. These initiatives could prevent, limit or delay development and regulatory approval and impact commercialization, of our product candidates, which would impact our business.

FDA-regulated industries, such as ours, face substantial uncertainty regarding the regulatory environment we will face as we proceed with research and development, and possibly in future commercialization, efforts following the inauguration of President Trump in January 2025 (the "Administration"). Some of these efforts have manifested to date in the form of personnel measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays in or limitations on our ability to obtain guidance from the FDA on our product candidates in development and obtain the requisite regulatory approvals in the future. Moreover, the Administration has proposed action to freeze or reduce the budget of the National Institutes of Health ("NIH") related to its funding for medical research, which could decrease the ability of facilities that rely on NIH funding to enroll and conduct clinical trials or increase the costs to us of conducting clinical trials. There remains general uncertainty regarding future activities. The 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 and sale of new therapeutic products. For example, on January 20, 2025, the Administration announced an executive order establishing the Department of Government Efficiency to maximize government efficiency and productivity. Pressures on and uncertainty surrounding the U.S. federal government's budget and potential changes in budgetary priorities could adversely affect the funding for existing programs and grants and increase the costs to us of conducting clinical trials. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we or our collaborators become negatively impacted by future governmental orders, regulations, policies or guidance as a result of the Administration, there could be a material adverse effect on us and our business.

Risks Related to Third Party Relationships

We rely on third-party manufacturers, CROs, CDMOs and suppliers to supply, develop and test components of our product candidates. The loss of our third-party manufacturers, CROs, CDMOs or suppliers, their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, or changes in methods of product candidate manufacturing, development or formulation would materially and adversely affect our business.

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing. We currently rely exclusively, and may continue to rely exclusively, on third-party contract manufacturers, to manufacture and test bulk drug substances, biologic and drug products, raw materials, samples, components or other materials and reports. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, terminated or of satisfactory quality or continue to be available at acceptable prices. In addition, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a product candidate is subject to FDA, EMA and foreign regulatory authority review. In some cases, we, and our suppliers and manufacturers, some of which may be our sole source of supply, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA, EMA and other comparable foreign regulatory authorities. If our contract

manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA and other comparable foreign regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our product candidates. Moreover, we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all, or the clinical development of our product candidates may be delayed. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party.

These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines; and we may be required to repeat some of the development program. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. We will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our products will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the FDA or foreign regulatory authorities could adversely affect our business in a number of ways, including:

- delay in the progress on certain research programs;
- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications or receiving regulatory approvals for product candidates;
- loss of the cooperation of existing or future collaborators;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our therapeutics.

Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our contract manufacturers were to encounter any of these difficulties, our ability to provide our product candidates to patients in preclinical and clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

In addition, we currently rely on foreign CROs and CDMOs, for manufacturing and development activities and will likely continue to rely on foreign CROs and CDMOs in the future. Foreign CDMOs may be subject to U.S. legislation, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies.

For example, the BIOSECURE Act, which was recently enacted as part of the Fiscal Year 2026 National Defense Authorization Act and signed by the President on December 18, 2025, prohibits U.S. federal agencies from entering into or renewing a contract with any company that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" in the performance of that contract, which may impact one of

our CDMOs. It also prohibit loans or grant funding from U.S. federal agencies to entities that use any biotechnology equipment or services produced or provided by a "biotechnology company of concern" in the performance of the government grant or loan. This legislation could have the downstream effect of restricting the ability of pharmaceutical companies that enter into contracts with or receive funding from U.S. federal agencies from purchasing services or equipment from certain Chinese biotechnology companies, including those that are specifically named in the proposed BIOSECURE Act, as well as supply chain disruptions or delays. In addition to the BIOSECURE Act, any additional executive action, legislative action or potential sanctions with China could materially impact our work. U.S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties.

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

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

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, contracted laboratories and third-party CROs, to conduct our preclinical studies and clinical trials in accordance with applicable regulatory requirements, to validate our assays and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with good laboratory practices ("GLPs"), as applicable, and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GLPs and GCPs through periodic inspections of laboratories conducting GLP studies, trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs or contracted laboratories fail to comply with applicable GLPs and 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 preclinical studies or clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical studies or clinical trials comply with applicable GLP or GCP regulations. In addition, our clinical trials must be conducted with product, including biologic product, produced in compliance with applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat preclinical studies or clinical trials, which would delay the regulatory approval process.

Further, these laboratories, investigators and CROs are not our employees, and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent laboratories, investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if we can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. If any of our relationships with these third-party laboratories, CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, CROs or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, CROs or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements or for other reasons, our preclinical or clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional laboratories or CROs (or investigators) involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory or CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our contracted laboratories and CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and results of operations.

In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest or the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidate or any future product candidates.

The manufacturing of our product candidates is complex, and our third-party manufacturers may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval or our ability to provide supply of our products for patients, if approved, could be delayed or stopped.

The process of manufacturing pharmaceuticals is complex, time-consuming, highly regulated and subject to multiple risks. Our contract manufacturers must comply with legal requirements, cGMPs and guidelines for the manufacturing of pharmaceuticals used in clinical trials and, if approved, marketed products. Our contract manufacturers may have limited experience in the manufacturing of cGMP batches.

Manufacturing pharmaceuticals is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at our third-party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business.

In addition, there are risks associated with large-scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. Even if we or our future collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

Scaling up a pharmaceutical manufacturing process is a difficult and uncertain task, and our third-party manufacturers may not have the necessary capabilities to complete the implementation, manufacturing and development process. If we are unable to adequately validate or scale-up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

We cannot assure that any stability or other issues relating to the manufacture of any of our current or future product candidates will not occur in the future. If our third-party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, prospects, financial condition and results of operations.

As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our current or future product candidates to perform differently and affect the results of our current or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

Our existing collaborations are, and our future collaborations may be, important to our business. If we are unable to enter into new collaborations, or if our collaborations are not successful, our business could be adversely affected.

A part of our strategy is to systematically evaluate and, as deemed appropriate, enter into strategic collaborations when strategically attractive, including potentially with major biotechnology or pharmaceutical companies. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we have entered into, and may enter into, collaborations with other companies to provide us with important technologies and funding for our programs and technology. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates could be delayed, the commercial potential of our product candidates could change and our costs of development and commercialization could increase. Furthermore, we may find that our programs require the use of intellectual property rights held by third parties, and the growth of our business may depend in part on our ability to acquire or in-license these intellectual property rights.

Our existing collaborations and any future collaborations we may enter into may pose a number of risks, including, but not limited to, the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic

focus or available funding or external factors, such as a strategic transaction that may 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 a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products, if approved, and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates 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;
- if a collaborator of ours is involved in a business combination, the collaborator might de-emphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our future collaborations do not result in the successful discovery, development and commercialization of product candidates or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborative partners. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon an 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 relating to our business. These factors may include the design or results of preclinical studies or clinical trials, the likelihood of regulatory approval, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of any uncertainty with respect to our ownership of technology (which can exist if there is a challenge to such ownership regardless of the merits of the challenge) and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

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

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Reliance on third parties to manufacture or commercialize our current or any future product candidates and on collaborations with additional third parties for the development of our current or any future product candidates, requires us to share trade secrets with these third parties. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, services agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any third-party collaborators. A competitor's discovery of our trade secrets could harm our business.

Risks Related to Intellectual Property

We have licensed intellectual property rights from third parties and may do so in the future. Such licenses may be subject to early termination if we fail to comply with our obligations in our licenses with third parties, which could result in the loss of rights or technology that are material to our business.

We are a party to licenses that give us rights to third-party intellectual property or technology that is necessary or useful for our business, and we may enter into additional licenses in the future. For example, we depend on licenses from Dermira and AprilBio for certain intellectual property relating to the development and commercialization of our clinical-stage product candidates, EVO756 and EVO301, respectively. Under these license agreements, we are or may become obligated to pay the licensor fees, which may include annual license fees, upstream license obligations, milestone payments, royalties, a percentage of revenues associated with the licensed technology and a percentage of sublicensing revenue. These fees may be significant, which could make it difficult for us to achieve or maintain profitability. In addition, under certain of such agreements, we are or may become required to diligently pursue the development of products using the licensed technology. If we fail to comply with these obligations, including due to our use of the intellectual property licensed to us in an unauthorized manner, and fail to cure our breach within a specified period of time, the licensor may have the right to terminate the applicable license, in which event we could lose valuable rights and technology that are material to our business, harming our ability to develop, manufacture and commercialize our product candidates.

In addition, the agreements under which we license intellectual property or technology to or from third-parties can be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. The failure to obtain or in-license any compositions, methods of use, processes or other third-party intellectual property rights at a reasonable cost or on reasonable terms, could harm our business. If we fail to obtain licenses to necessary third-party intellectual property rights, we may need to cease use of the compositions or methods covered by such third-party intellectual property rights. Furthermore, we may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

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

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, formulations, combination therapies, and methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected. The patenting process is expensive and time-consuming, and we may not be able to file, prosecute and maintain or in-license, all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue, obtain or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications or to maintain the patents, covering technology that we license from or license to third parties, and are reliant for such purposes on our licensors or licensees. In addition, we cannot guarantee that patent applications or patents that we initially believe to be owned by the company or a licensor will not be found to be encumbered by third party ownership or other third party rights that may not have been evident to us at the time of preparation, filing or in-licensing. For instance, such rights could arise from the intellectual contributions of company employees who were previously employed by third parties, such as universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors, or from the intellectual contributions of company consultants, advisors or independent contractors with current or previous relationships with such third parties. Therefore, these patents and applications may not be prepared, filed, prosecuted or enforced in a manner consistent with the best interests of our business. Furthermore, licenses from such third parties may be required or desirable but may not be available on reasonable terms, or at all.

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

We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim, and we may be subject to a third-party submission of prior art to the United States Patent and Trademark Office ("USPTO") in connection with pending patent applications, and any analogous procedures outside the United States. There also may be prior art of which we are aware, but which we believe does not affect the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be found by a court to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities and conclude that we are free to operate in relation to our product candidates, but our competitors may ultimately obtain issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which compete with our products on an independent basis which do not infringe our patents or other intellectual property rights or will design around the claims of patents to which we have rights that cover our products.

The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available or the availability of patent protection in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents that have already issued. Depending on actions 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 patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of patent term adjustment ("PTA") for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in the future and whether patent expiration dates, or even patent validity, may be impacted. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which has significantly impacted European patents, including those granted before June 1, 2023. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the Unitary Patent Court ("UPC"). Additionally, certain non-Unitary Patents that are European patents may also be subject to the jurisdiction of the UPC. As the UPC is a new court system, there is only a limited established body of substantive and procedural precedents, which increases the uncertainty of any litigation. Proprietors of certain European patents granted before the implementation of the UPC have the option of opting such patents out of the jurisdiction of the UPC and designating such patents as being subject to the jurisdiction of national courts. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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

- others may be able to make or use compounds or proteins that are similar to our product candidates but that are not covered by the claims of patents to which we have rights;
- biologic drugs that are among our current product candidates may eventually become commercially available in biosimilar drug products. Patent protection for our products may not be available at all or may only be available with regard to the formulation of such products or methods of using such products, which are considered to provide limited protection;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights and exclusivity;

- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions and, as a result, may be unable to obtain any patent protection for such inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our patents or licensors' patents;
- it is possible that others may circumvent our owned or in-licensed patents without infringing them;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to our own;
- the laws of foreign countries may not protect ours or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed 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;
- we have engaged in scientific collaborations in the past and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop, or may not be able to develop, additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates we develop may be covered by third parties' patents or other exclusive rights; and
- the patents of others may have an adverse effect on our business.

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and technologies and to prevent third parties from copying and further developing our inventions and intellectual property, thus eroding our competitive position in our markets. Our success depends in large part on our ability to obtain and maintain patent protection for our product candidates and their intended uses, maintain trade secret protection of our product candidates, as well as our ability to operate without infringing the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel inventions and technologies that are important to our business or by in-licensing such patent rights. Our pending and future patent applications, including in-licensed patent applications, may not result in patents being issued or may not result in issued patents that will afford sufficient protection of our product candidates or their intended uses nor can there be any assurance that any patents that issue will be infringed, not designed around and not invalidated by third parties, or that they will effectively prevent others from commercializing competitive technologies or products.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain or enforce patents that may issue based on our patent applications, or in-license any similar rights, at a reasonable cost or in a timely manner, including due to delays as a result of global pandemics impacting our or our licensors' operations. Further, we may decide to not pursue or seek patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek and obtain patent protection. If we delay in filing a patent application, and a competitor files a patent application on the same or a similar technology before we do, we may face a limited ability to secure patent rights, or we may not be able to obtain a patent on such technology at all. Even if we are able to obtain a patent covering such technology, we may only be able to obtain a narrow scope of protection, and such narrow scope may be inadequate to protect our product candidates, or to block competitor products or product candidates that are similar to ours.

Composition of matter patents for pharmaceutical product candidates are considered to provide a strong form of intellectual property protection, because such patents provide protection for all uses of the product candidate. The claims in our pending patent applications, including in-licensed applications, that are directed to composition of matter coverage of our product candidates may not be found to be patentable by the USPTO or by patent offices in foreign countries. The courts in the United States or foreign countries may find that such patents are not valid and enforceable. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although products distributed pursuant to off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain and involves complex legal and factual questions that are governed by laws and regulations that are subject to change. In recent years, patent rights have been the subject of much litigation, and such high rates of litigation may continue into the future. The issuance, scope, validity, enforceability and commercial value of our patent rights are subject to many factors including such litigation and, as a result, are subject to great uncertainty. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patent rights or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and we or any of our potential future collaborators may not be successful in protecting our product candidates by obtaining and successfully defending and enforcing patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and, as a result, the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, including in-licensed patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other foreign jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in patents or pending patent applications to which we have rights or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. We or any of our potential future collaborators may not be successful in protecting our product candidates by obtaining and defending patents. Although we have rights to U.S. and foreign patent applications, we cannot predict:

- if and when patents may issue based on our or our licensors' patent applications;

- the scope of protection of any patent issuing based on our or our licensors' patent applications;
- whether the claims of any patent issuing based on our or our licensors' patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our or our licensors' patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce or defend our patent rights which will be costly, time-consuming and require us to expend resources, whether we win or lose;
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; and
- whether we may experience patent office interruption or delays to our ability to timely secure patent rights covering our product candidates.

The claims in our or our licensors' pending patent applications directed to our product candidates or technologies may not be considered patentable by the USPTO or by patent offices in foreign countries. Any such patent applications may not be issued as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," which is information that was or is deemed available prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our or our licensors' patent application claims or, if issued, affect the validity or enforceability of a patent claim. There may be disallowed double patenting among patents to which we have rights, which the patent examiner(s) fail to raise during prosecution. Even if the patents do issue based on our or our licensors' patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio (including in-licensed patents) may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, this could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates.

Our and our licensors' pending patent applications may be challenged in the USPTO or in patent offices in foreign countries. Also, because the issuance of a patent is not conclusive as to its scope, validity or enforceability, even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our and our licensors' pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or patent offices in foreign countries, or our issued patents may be subject to post-grant review ("PGR") proceedings, oppositions, derivations, reexaminations or *inter partes* review ("IPR") proceedings, in the United States or elsewhere, challenging our patent rights. An adverse determination in any such challenges may result in loss of exclusivity or in our patent rights being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technologies and products or limit the duration of the patent protection of our technologies and product candidates. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, only limited protection may be available and our patent rights may not provide us with sufficient rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

In addition to seeking patent protection for our product candidates and technologies, we may rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents or that may alternatively be covered by trade secret protection or through measures of confidentiality. Elements of our product candidates,

including processes for their preparation and manufacture, may involve proprietary know-how, information or technology that is not covered by patents, or that is more advantageously protected by trade secrets or confidentiality, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. We expect to rely on CROs and third parties to generate chemical molecules and important research data. Any disclosure, either intentional or unintentional, by our employees or third-party consultants and vendors or CROs that we engage to perform research, clinical trials or manufacturing activities or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know-how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own technology or know-how, and if the license is not available on commercially viable terms, then we may not be able to complete development of, or commercialize, our products. Although we require all of our employees, consultants, collaborators, CROs, contract manufacturers, advisors and any third parties who have access to our proprietary know-how, information or technologies to enter into confidentiality agreements, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. We cannot be certain that our trade secrets and other confidential proprietary information may not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party unlawfully disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Furthermore, the laws of some foreign countries do not protect proprietary rights, such as trade secrets rights, to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, and this scenario could materially adversely affect our business, financial condition and results of operations.

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

Changes in either the patent laws or interpretation of the patent laws in the United States and other foreign countries could increase uncertainties and costs and may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our patent rights or narrow the scope of our patent rights. The Leahy-Smith America Invents Act of 2011 (the "Leahy-Smith Act") included several significant changes to U.S. patent law that impacted how patent rights could be prosecuted, enforced and defended. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a patent claim

invalid even though the same evidence would be insufficient to invalidate the patent claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our or our licensors' patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, under the Leahy-Smith Act, the United States transitioned from a "first-to-invent" system to a "first-to-file" system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we or our licensors file an application covering the same invention, could therefore be awarded a patent covering an invention to which we have rights even if we or our licensors made the invention before it was made by such third party. This will require us and our licensors to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

These and future changes in patent law could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our and our licensors' issued patents, all of which could have a negative effect on our business.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, already obtained. Depending on actions 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 and our licensors' ability to obtain new patents or to enforce patents that we have licensed or that we might obtain or license in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our and our licensors' ability to obtain new patents or to enforce patents that we have licensed or that we may obtain or license in the future.

We may be involved in lawsuits or proceedings to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may infringe or otherwise violate our patents, trademarks or other intellectual property or the patents of our licensors. To stop infringement or unauthorized use, we or our licensors may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our or licensors' patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more patents to which we have rights at risk of being invalidated, held unenforceable or interpreted narrowly and could place patent applications to which we have rights under the risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the foreign patent offices. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result

at the USPTO or other patent office then we may be exposed to litigation by a third party alleging that the patent is infringed by our product candidates or proprietary technologies.

In addition, because (i) some patent applications in the United States may be maintained in secrecy until the patents are issued, (ii) other patent applications in the United States and patent applications in many foreign jurisdictions are typically not published until 18 months after filing and (iii) publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned or in-licensed issued patents or our owned or in-licensed pending applications, or that we or, if applicable, a licensor, was the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering products or technology similar to ours before we or our licensors do so. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to eventually seek to obtain rights to issued patents covering such technologies from third parties. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor, may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. We or our licensors may lose patent rights as a result. If we or one of our licensors is a party to an interference proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, unduly occupy our management's time in connection with legal proceedings, divert management from its usual duties and substantially expend other resources, even if we are successful.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our or our licensors' current patent rights and could require us to cease using the related technology or to attempt to license rights to it from a prevailing third party or other third party. Our business could be harmed if the prevailing party or the other third party does not offer us a license on commercially reasonable terms or at all. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during intellectual property litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our or our licensors' issued patent, or any patents that may be issued as a result of our or our licensors' pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in- license needed technologies or other product candidates or enter into development partnerships that would help us bring our product candidates to market.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed trade secrets or other confidential information of their current or former employers or claims asserting inventorship or ownership of what we regard as our own intellectual property.

Many of our employees, consultants and advisors are currently or were previously employed at universities or other healthcare, biotechnology or pharmaceutical companies, including our competitors or potential competitors and our licensors. Although we try 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 used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer or client without authorization. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs, the expenditure of other resources and be a distraction to management.

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

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

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

Rights to improvements to our product candidates may be held by third parties.

In the course of testing our current or future product candidates, we may enter into agreements with third parties to conduct clinical testing, which may provide that improvements to our product candidates may be owned solely by a third party or jointly between the parties. If we determine that rights to such improvements owned solely by a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing the product candidates. 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 granted on non-exclusive terms, thereby potentially giving our competitors and other third parties access to the same technologies licensed to us. Failure to obtain a license on commercially reasonable terms or at all, or to obtain an exclusive license, could prevent us from commercializing our current or future product candidates or force us to cease some of our business operations, which could materially harm our business. If we determine that rights to improvements jointly owned between us and a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such improvements, such co-owners may be able to license their rights to other parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our intellectual

property in order to enforce such intellectual property against other parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration date of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any patent searches or analyses that are performed, including the identification of relevant patents, the scope of patent claims or the expiration dates of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our current or future product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the language of the claim, the written disclosure in the relevant patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our future products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our future products.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

While we seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our current or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering

the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce and defend such patents or patent applications or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our current or future product candidates that are subject of such licensed rights could be adversely affected.

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

It is possible that we may be unable to obtain necessary licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates or future methods or products resulting in either an injunction prohibiting our manufacture or future sales or, with respect to our future sales, an obligation on our part to pay royalties or other forms of compensation to third parties, which could be significant.

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- when and under what conditions the license agreement may be terminated and the consequences thereof;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

In spite of our best efforts, our future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors might have the freedom to seek

regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

From time to time, we may be required to license technologies relating to our programs from additional third parties to further develop or commercialize our current or future product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

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

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, 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 exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to our product candidates and programs. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third-party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

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

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

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the United States is protected under the Safe Harbor exemption as set forth in 35 U.S.C. § 271, and there are similar laws in some foreign jurisdictions. If any of our

product candidates are approved by the FDA, that certain third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. Even if we believe that any claims of such patent that could otherwise materially adversely affect commercialization of our product candidates, if approved, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign its infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Even if such a license is available, it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Lastly, we may need to indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our product candidates, including EVO756 and EVO301. Third parties may assert infringement claims against our customers or distributors. Our agreements with our customers or distributors may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors or may be required to obtain licenses for the product candidates or services they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products or services.

Our intellectual property licensed from third parties may be subject to retained rights.

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

Government agencies may provide funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may have retained rights in such intellectual property. The United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (the "Bayh-Dole Act"), including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize licensed products. While we currently are not engaging with university partners, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent offices in several stages over the lifetime of the patent. Certain foreign jurisdictions also require the payment of periodic annuity payments to maintain patent applications and avoid their abandonment. The USPTO and various foreign governmental patent agencies require compliance with a number of other procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, we or our licensors may fail to obtain patent protection, and our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business. The following examples are illustrative:

- others may be able to make compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents that we own or control;
- we or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or control, which may cause such patents to be invalidated;
- we or our licensors might not have been the first to file patent applications covering certain of the inventions we own or control, which may prevent the patent applications from being granted or, if already granted, might cause them to be invalidated;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process or technology export can result in abandonment or lapse of a patent or patent application and partial or complete loss of patent rights in the relevant jurisdiction;
- pending patent applications that we own or control may not lead to issued patents;
- issued patents that we own or control may be held invalid or unenforceable as a result of legal challenges;

- our competitors might conduct research and development activities in the United States and other foreign countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive product candidates for sale in our major commercial markets;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims directed to our product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public health policy;
- countries other than the United States may have patent laws that are less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages or may be challenged by third parties;
- if enforced, a court may find that our patents are invalid, unenforceable or not infringed;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our current and any future product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can have a different scope and strength than do those in the United States. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States or from selling or importing products made using our or our licensors' inventions in and into the United States or other countries. Competitors may use our or our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own product candidates and, further, may export otherwise infringing product candidates to territories where we or our licensors may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These product candidates may compete with our product candidates in jurisdictions where we and our licensors do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patent rights or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patent rights at risk of being invalidated, held unenforceable or interpreted narrowly, could put our or our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse.

Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In addition, certain developing countries, including China and India, have compulsory licensing laws

under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

Our current or future trademarks or trade names may be challenged, opposed, infringed, circumvented, invalidated, cancelled, declared generic, determined to be not entitled to registration or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Any trademark litigation could be expensive. In addition, we could be found liable for significant monetary damages, including treble damages, disgorgement of profits and attorneys' fees, if we are found to have willfully infringed a trademark. We may not be able to protect our exclusive right to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential collaborators or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

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

We may seek additional in-licenses from third parties. If we are unable to acquire these rights, our business may be materially adversely affected, and if disputes arise with future licensors, we may be subject to future litigation as well as the potential loss of or limitations on our ability to develop and commercialize products and technologies covered by these license agreements.

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations at a reasonable cost or on reasonable terms, if at all, which would adversely affect our business. We may need to cease use of the technology covered by such third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive and may allow our competitors access to the same technologies licensed to us. The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive for commercializing our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We

may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates and technology that we may seek to acquire.

Even if we successfully enter into license agreements with third parties under which we receive rights to intellectual property that are important to our business, our continued rights to use the technology we license would be subject to the continuation of and compliance with the terms of those agreements. These intellectual property license agreements may require of us various development, regulatory or commercial diligence obligations, payment of milestones or royalties and other obligations. If we fail to comply with our obligations under these agreements, we use the licensed intellectual property in an unauthorized manner or we are subject to bankruptcy-related proceedings, the terms of the license agreements may be materially modified, such as by rendering currently exclusive licenses non-exclusive, or it may give our licensors the right to terminate their respective agreement with us, which could limit our ability to implement our current business plan and materially adversely affect our business, financial condition, results of operations and prospects.

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

In some cases, we may not control the prosecution, maintenance or filing of the patents to which we hold licenses, or the enforcement of those patents against third parties. Hence, our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed in a manner consistent with the best interests of our business. Even if patents are issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Further, we may have limited control over these activities or any other intellectual property that may be in-licensed. For example, we cannot be certain that such activities by licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves. In the event our licensors fail to adequately pursue and maintain patent protection for patents and applications they control and to timely cede control of such prosecution to us, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Moreover, disputes may arise with respect to our licensing or other upstream agreements, including:

- the scope of rights granted under the agreements and other interpretation-related issues;
- whether and the extent to which our systems and consumables, technologies and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under any collaborative development relationships;
- our diligence obligations under the license and sub-license agreements and what activities satisfy those diligence obligations;
- our right to transfer or assign the sublicense;
- when and under what conditions the sublicense agreement may be terminated and the consequences thereof;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our upstream licensors and us and our partners; and

- the priority of invention of patented technology.

In spite of our efforts to comply with our obligations under our in-license agreements, our licensors might conclude that we have materially breached our obligations under our license agreements and might therefore terminate the relevant license agreement, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If any such in-license is terminated, or if the licensed patents fail to provide the intended exclusivity, competitors or other third parties might have the freedom to market or develop products similar to ours. In addition, absent the rights granted to us under such license agreements, we may infringe the intellectual property rights that are the subject of those agreements, we may be subject to litigation by the licensor, and, if such litigation by the licensor is successful, we may be required to pay damages to such licensor, or we may be required to cease our development and commercialization activities which are deemed infringing, and, in such event, we may ultimately need to modify our activities or products to design around such infringement, which may be time- and resource-consuming, and which may not be ultimately successful. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Risks Related to Ownership of Our Common Stock

We do not know whether an active, liquid and orderly trading market will be sustained for our common stock or what the market price of our common stock will be, and, as a result, it may be difficult for you to sell your shares of our common stock.

Prior to our IPO in November 2025, there was no public trading market for our common stock. If a liquid market for our common stock is not sustained, it may be difficult for you to sell your shares of our common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall. 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 market price of our common stock may be volatile, which could result in substantial losses for investors.

The stock market in general, and the market for pharmaceutical 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. The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and many others, some of which may include:

- results of clinical trials and preclinical studies of our product candidates or those of our competitors or existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;

- if securities or industry analysts do not publish research or reports about our business or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of our securities by us or other securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations or continued development of our product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- the introduction of technological innovations or new therapies that compete with our product candidates;
- period-to-period fluctuations in our financial results; and
- the other factors described in this "Risk Factors" section.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

As of December 31, 2025, our executive officers, directors and stockholders beneficially owning 5% or greater of our common stock, in the aggregate, beneficially owned a significant percentage of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

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

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

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an

acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

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

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- do not permit stockholders to cumulate votes at any election of directors;
- expressly authorize our board of directors to make, alter, amend or repeal our amended and restated bylaws; and
- require majority votes of all holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated bylaws.

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

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the 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.

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

Our amended and restated certificate of incorporation contains exclusive forum provisions, which may limit a stockholder's ability to bring a claim in a judicial forum it finds favorable and may discourage lawsuits with respect to such claims.

Our amended and restated certificate of incorporation provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of or based on a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (3) any action asserting a claim against us or any of our current or former directors, officers, employees or stockholders arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine. In addition, our amended and restated certificate of incorporation designate the federal district courts of the United

States as the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act; however, such exclusive forum provision does not apply to claims brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The validity and enforceability of such provision is uncertain in a number of courts other than Delaware Supreme Court and certain other state courts.

We recognize that these provisions may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, these forum selection clauses in our amended and restated certificate of incorporation 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. Section 22 of the Securities Act creates a concurrent jurisdiction for state and federal courts over all suits brought concerning a duty or liability created by the securities laws, rules and regulations thereunder. While the Delaware Supreme Court and other state courts have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our federal selection provision. The federal selection provision may also impose additional litigation costs on stockholders who assert the provision is unenforceable, and, if the provision is found to be unenforceable, we may incur additional costs with resolving such matters. The Court of Chancery of the State of Delaware 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.

General Risk Factors

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. 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 (the "Sarbanes-Oxley Act"), as well as rules subsequently adopted by the SEC and NYSE to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, the Dodd-Frank Wall Street Reform and Consumer Protection Act includes significant corporate governance and executive compensation related provisions that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. Emerging growth companies ("EGCs") and smaller reporting companies are exempted from certain of these requirements, but we may be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Shareholder 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.

We expect the rules and regulations applicable to public companies to substantially 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 a material adverse effect on our business, financial condition and results of operations. The increased costs will 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, we expect these rules and regulations to 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.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). For as long as we continue to be an EGC, we may take advantage of certain exemptions from various

public company reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm under Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, being required to provide only two years of audited financial statements and two years of selected financial data, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may take advantage of these exemptions until the last day of the fiscal year ending after the fifth anniversary of our IPO or until we are no longer an emerging growth company, whichever is earlier. We will cease to be an EGC prior to the end of such five-year period if certain earlier events occur, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, our annual gross revenues equal or exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period prior to such time. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

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

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our 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 experience material weaknesses in our internal control over financial reporting in the future or otherwise fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

We may in the future discover material weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

We, and our independent registered public accounting firm, were not required to perform an evaluation of our internal control over financial reporting as of December 31, 2024 in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we will not in the future identify material weaknesses. Material weaknesses may exist when we become required to report on the effectiveness of our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably ensure that information we must disclose in reports we file or submit pursuant to the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls

and procedures, or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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

We may not be able to satisfy listing requirements of NYSE or obtain or maintain a listing of our common stock on the NYSE.

If, after listing, we fail to satisfy NYSE's continued listing requirements, such as the corporate governance requirements or the minimum closing bid price requirement, the NYSE may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again on the NYSE or any other securities exchange, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NYSE minimum bid price requirement or prevent future non-compliance with NYSE's listing requirements.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

While we maintain commercial insurance at a level we believe is appropriate against certain risks commonly insured in the industry in which we operate, there is no guarantee that our insurer will cover costs or that we will be able to obtain the desired level of coverage on acceptable terms in the future. Some of the policies we currently maintain include general liability, crime insurance, products liability, workers' compensation, cyber, directors' and officers', employment practices and fiduciary liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Changes in the market conditions and our business operations may necessitate the addition of new insurance policies or change of our existing insurance policies. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

We also expect that operating as a U.S. public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, on our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would negatively affect our business, financial condition and results of operations.

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

From time to time we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal data, contractual relations with collaborators and licensors and intellectual property rights. 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.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and clinical trial data ("Information Systems and Data").

Our Information Technology department helps identify, assess and manage our cybersecurity threats and risks. The Information Technology department identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example, automated tools, conducting scans of the threat environment, evaluating our and our industry's risk profile, evaluating threats reported to us, certain internal and/or external audits, conducting threat assessments for internal and external threats, third party threat assessments, and conducting vulnerability assessments to identify vulnerabilities.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: an incident response plan, incident detection and response measures, disaster recovery/business continuity plans, risk assessments, encryption of certain data, network security controls, segregation of certain data, access controls, physical security, asset management, tracking, and disposal, systems monitoring, employee training, penetration testing, and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management program. For example: (1) cybersecurity risk is addressed as a component of our enterprise risk management program and (2) the Information Technology department works with management to evaluate material risks from cybersecurity threats against our overall business objectives.

We use third-party service providers to assist us from time to time in an effort to identify, assess, and manage material risks from cybersecurity threats, including, for example, cybersecurity software providers, dark web monitoring services, and penetration testing firms.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, contract research organizations, and contract manufacturing organizations. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment, including conducting audits, designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including If our information technology systems or those of third parties with whom we work or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits and other adverse consequences.

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The board of directors is responsible for overseeing our cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management including the Senior Director of Information Technology, who has over 15 years of experience leading cybersecurity programs across a variety of industries, including life sciences.

The Senior Director of Information Technology is responsible for hiring appropriate personnel relevant to mitigating cybersecurity risks, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. The Senior Director of Information Technology is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response processes and plan are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including senior management. Senior management works with our incident response team to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response processes and plan include reporting to the board of directors for certain cybersecurity incidents.

The board of directors receives annual reports from management concerning our significant cybersecurity threats and risks and the processes we have implemented in an effort to address them. The board also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation as relevant.

Item 2. Properties.

We lease a facility containing 10,665 square feet of laboratory and office space, which is located in Palo Alto, California. The lease expired in July 2025 and has been extended until April 2026. In June 2025, we entered into a new lease agreement for our Palo Alto facility, which will include approximately 32,016 square feet and is expected to commence in March 2026 and expire in June 2031. We also lease offices in New York with an expiration date in October 2030. We believe that our current facilities are sufficient to meet our current and near-term needs and that, should it be needed, suitable additional space will be available.

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock trades under the symbol "EVMN" on the New York Stock Exchange and began trading on November 6, 2025. Prior to that date, there was no public trading market for our common stock.

Holders of Our Common Stock

As of March 3, 2026, there were approximately 113 stockholders of record of our common stock. This number does not include beneficial owners whose shares are held by brokers or other nominees in street name. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

We currently expect to retain all future earnings, if any, for use in the operation and expansion of our business and paying any debts. We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our capital stock. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from our Public Offering of Common Stock

On November 6, 2025, we completed the initial public offering ("IPO") of our common stock pursuant to which we issued and sold 10,781,250 shares of our common stock at a price to the public of $16.00 per share.

All shares issued and sold in the initial public offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-290793), as amended (the "Registration Statement"), which became effective on November 5, 2025.

We received net proceeds of approximately $157.0 million after deducting underwriting discounts and commissions of $12.1 million and offering expenses of $3.4 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates. Morgan Stanley & Co. LLC, Leerink Partners LLC, Evercore Group L.L.C. and Cantor Fitzgerald & Co. acted as joint book-running managers for the offering.

The net proceeds from our IPO have been invested primarily in U.S. Treasury securities, corporate bonds and money market accounts. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our Prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on November 6, 2025.

Issuer Purchases of Equity Securities

None.

Securities Authorized for Issuance Under Equity Compensation Plans

Our equity plan information required by this Item is incorporated by reference to the information in Part III, Item 12 of this Annual Report on Form 10-K.

Item 6. Reserved

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

In this Annual Report on Form 10-K, unless otherwise stated or the context otherwise requires, references to the "Company," "Evommune," "we," "us" and "our" refer to Evommune, Inc. and its consolidated subsidiaries. You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

Evommune is a clinical-stage biotechnology company developing innovative therapies that target key drivers of chronic inflammatory diseases, with initial clinical development programs focusing on chronic spontaneous urticaria ("CSU"), atopic dermatitis ("AD") and ulcerative colitis ("UC"). Chronic inflammation is a significant healthcare problem in the world, substantially impacting patients' quality of life and leading to life-threatening conditions.

Our mission is to improve patients' daily lives and prevent the long-term effects of uncontrolled inflammation that are a consequence of the limitations of existing therapies. To achieve this, we are advancing a portfolio of differentiated product candidates that target key drivers of chronic inflammation.

Among our portfolio of programs, we currently have two product candidates, EVO756 and EVO301, in Phase 2 development. We are initially developing EVO756 for the treatment of CSU and AD, and EVO301 for the treatment of AD and UC. We see broad expansion potential for both programs across additional chronic inflammatory diseases. We also intend to advance additional preclinical programs into clinical development.

We were incorporated under the laws of the State of Delaware in April 2020 under the name "Evommune, Inc." We have two wholly owned subsidiaries: Evommune Research, LLC and Evommune Biologics, LLC.

We have incurred significant operating losses in each year since our inception. As of December 31, 2025, we had an accumulated deficit of $221.1 million. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses and capital expenditures will continue to increase. In particular, we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, as well as hire additional personnel, pay fees to outside consultants, lawyers and accountants, and incur other increased costs associated with being a public company. In addition, if and when we seek and obtain regulatory approval to commercialize any product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We expect to continue to incur significant and increasing net operating losses for the next several years as we:

- continue the research and development of our clinical- and preclinical-stage product candidates and discovery-stage programs, including the continued development of our most advanced product candidates, EVO756 and EVO301;
- increase the amount of research and development activities to identify and develop product candidates;
- make milestone, royalty or other payments under in-license or collaboration agreements;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts;
- establish sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;

- address any competing therapies and market developments;
- incur additional costs associated with operating as a public company;
- invest in or in-license other technologies; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies or trials, complex results, manufacturing challenges, safety issues or other regulatory challenges.

As a result, we will require substantial additional funding to further develop our product candidates and support our continuing operations. To date, we have not had any products approved for sale and, therefore, have not generated any approved product-related revenue. We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which will not be for at least the next several years, if ever. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash requirements through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on commercially acceptable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Strategic Collaborations and License Agreements

Dermira, Inc.

In December 2020, we entered into a License, Development and Commercialization Agreement with Dermira, pursuant to which Dermira granted us an exclusive, worldwide license to develop and commercialize certain compounds, including the compound in development by us known as EVO756 (the "Dermira License Agreement").

The Dermira License Agreement remains in effect on a product-by-product and a country-by-country basis until the expiration of the royalty term for such product in such country. The Dermira License Agreement may be terminated by either party due to the other party's uncured material breach or bankruptcy. Additionally, we may terminate the Dermira License Agreement for convenience upon a set number of days' prior notice.

In consideration for the licenses granted to us under the Dermira License Agreement, we paid to Dermira a $7.5 million upfront license fee. Additionally, in connection with our entry into the Dermira License Agreement, we issued to Dermira 3,227,805 shares of Series A Preferred Stock which was equal to approximately 5% of our fully diluted equity at the time of grant and was calculated by reference to the same per-share purchase price paid by the lead investor in the Series A Preferred Stock financing (as a completed qualified financing).

We are also obligated to pay to Dermira up to $45.0 million in development milestones for the development of EVO756 (or up to $135.0 million for the development of all licensed products), and up to $240.0 million in sales milestones for the development of EVO756 (or up to $720.0 million for the development of all licensed products) as well as tiered royalty payments in mid-single digit to low-tens percentages on worldwide sales of the licensed products.

As of December 31, 2025, we have paid a total of $11.0 million in upfront payments and development milestones under the Dermira License Agreement, which was recognized as research and development expense for the year in which they occurred. No milestones were achieved under the Dermira License Agreement during the year ended December 31, 2024. For the year ended December 31, 2025, we recorded $2.5 million as research and development expense upon achievement of a development milestone under the Dermira License Agreement. Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due.

Under the Dermira License Agreement, we may sublicense EVO756 to third parties. Dermira has consented to our sublicense of EVO756 to Maruho in Japan and certain Asian countries as described below.

Maruho Co., Ltd.

Maruho Japan Agreement

In September 2023, we entered into a strategic collaboration with Maruho and granted Maruho an exclusive license to develop and commercialize EVO756 in Japan (the "Maruho Japan Agreement"). Under the Maruho Japan Agreement, we are eligible to receive up to $60.0 million in upfront and customary milestone payments and royalty payments on future sales of EVO756 in Japan. As of December 31, 2025, we have received a total of $18.0 million in upfront payments and development milestones under the Maruho Japan Agreement. No other development or sales milestones have been achieved as of December 31, 2025.

Maruho Greater Asia Agreement

In March 2024, we entered into a second strategic collaboration with Maruho (the "Maruho Greater Asia Agreement") and granted Maruho the exclusive license to develop and commercialize EVO756 in Greater China and certain other Asian countries. Under the Maruho Greater Asia Agreement, we are eligible to receive up to $61.5 million in upfront and customary milestone payments. As of December 31, 2025, we have received a total of $7.0 million in upfront payments under the Maruho Greater Asia Agreement. No other development or sales milestones have been achieved as of December 31, 2025.

AprilBio Co., Ltd.

In June 2024, we entered into a license agreement with AprilBio (the "AprilBio License Agreement") under which AprilBio granted us an exclusive worldwide license to develop and commercialize EVO301. Under the AprilBio License Agreement, we paid an upfront payment of $15.0 million and may be required to pay milestone payments up to $460.0 million upon achievement of future milestones and royalties on future sales of EVO301. For the year ended December 31, 2025, we recorded $1.5 million as research and development expense upon achievement of a development milestone under the AprilBio License Agreement. No development milestones were recorded as research and development expenses for the year ended December 31, 2024. No other development or sales milestones have been achieved as of December 31, 2025.

Components of Operating Results

Revenue

Our revenue since inception has consisted exclusively of license revenue. We have not generated any revenue from the sale of products and do not expect to generate any revenue from the sale of products in the foreseeable future, if at all. If our development efforts for our current product candidates and any future product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales, payments from existing or potential future collaboration or license agreements with third parties or any combination thereof.

Operating Expenses

Our operating expenses since inception have consisted primarily of research and development expenses and general and administrative costs**.**

Research and Development

Our research and development expenses consist primarily of external and internal costs incurred for the development of our product candidates and our drug discovery efforts, which include:

- personnel costs, which include salaries, benefits and equity-based compensation expense;
- expenses incurred under agreements with consultants and third-party contract organizations that conduct research and development activities on our behalf, such as contract research organizations ("CROs");
- costs related to research and license agreements;
- costs related to production of preclinical and clinical materials, including fees paid to contract development and manufacturing organizations ("CDMOs");
- costs related to compliance with regulatory requirements;
- laboratory and vendor expenses related to the execution of preclinical studies and planned clinical trials; and

- laboratory supplies and equipment used for internal research and development activities.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers. Non-refundable advance payments for goods and services that will be used over time for research and development are deferred and capitalized as prepaid expenses on our consolidated balance sheets. The capitalized amounts are recognized as an expense as the goods are delivered or as the related services are performed. Since our inception, substantially all of our external costs were related to the development of product candidates. We use internal resources for platform development, early pipeline discovery, preclinical development, management of clinical development activities, technical operations and oversight of manufacturing partners. Our third-party research and development expenses consist primarily of fees paid to outside consultants, CROs, CDMOs and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. Our other research and development costs are internal costs primarily associated with our discovery efforts, laboratory supplies and facilities, including depreciation, that are deployed across multiple programs.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in conducting clinical trials, manufacturing and otherwise advancing our programs. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain.

Because of the numerous risks and uncertainties associated with product development and the current stage of development of our product candidates and programs, we cannot reasonably estimate or know the nature, timing and estimated costs necessary to complete the remainder of the development of our product candidates or programs. We are also unable to predict if, when or to what extent we will obtain regulatory approval and generate revenues from the commercialization and sale of our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- enrollment in our Phase 2b dose-ranging trials for EVO756 in CSU and AD, any future clinical trials of EVO756 or EVO301, and any clinical trials for future product candidates;
- data from our clinical programs that support an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- acceptance by the FDA or other comparable foreign regulatory authorities, of the Investigational New Drug ("IND") applications, clinical trial applications and other regulatory filings for EVO756, EVO301, our other current product candidates and any future product candidates;
- expansion and maintenance of a workforce of experienced scientists and others to continue to develop our product candidates;
- successful application for and receipt of marketing approvals from applicable regulatory authorities;
- obtainment and maintenance of intellectual property protection and regulatory exclusivity for our product candidates;
- arrangements with third-party manufacturers for, or establishment of, manufacturing capabilities;
- maintenance, enforcement, defense and protection of our rights in our intellectual property portfolio; and
- avoidance of infringement, misappropriation or other violations with respect to others' intellectual property or proprietary rights.

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

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to increase for the foreseeable future as we continue to implement our business strategy, which includes advancing EVO756 and EVO301 through clinical development and other product candidates further into clinical development, expanding our research and development efforts, including hiring additional personnel to support our research and development efforts and seeking regulatory approvals for our product candidates that successfully complete clinical trials. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be predicted.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs, depreciation expense and other expenses for outside professional services, including legal, human resources, audit and accounting services and facility-related fees. Personnel costs consist of salaries, benefits and equity-based compensation expense for our personnel in executive, finance and accounting, business operations and other administrative functions. We expect our general and administrative expenses to increase over the next several years to support our continued research and development activities, manufacturing activities, increased costs of expanding our operations and operating as a public company. These increases will likely include increases related to the hiring of additional personnel and legal, regulatory and other fees and services associated with maintaining compliance with NYSE listing rules and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company.

Other Income, Net

Our other income, net consists primarily of interest earned on our invested cash, cash equivalents and short-term investment balances, interest expense, foreign exchange gains and losses and other insignificant amounts.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following sets forth our results of operations:

	Year ended December 31,		Change	
	2025	2024	Amount	Percent
Revenue	$ 13,000	$ 7,000	$ 6,000	86%
Operating expenses:				
Research and development	74,042	64,244	9,798	15%
General and administrative	20,029	12,769	7,260	57%
Total operating expenses	94,071	77,013	17,058	72%
Loss from operations	(81,071)	(70,013)	(11,058)	14%
Other income, net	12,201	3,205	8,996	281%
Net loss	$ (68,870)	$ (66,808)	$ (2,062)	295%

Revenue

For the years ended December 31, 2025 and 2024, we recognized $13.0 million and $7.0 million, respectively, in revenue through our license agreements. The increase was due to higher license revenue recognized under the Maruho Japan Agreement in 2025. License revenue of $3.0 million was recognized upon the satisfaction of the performance obligation and $10.0 million was recognized upon completion of development milestones under the Maruho Japan Agreement for the year ended December 31, 2025, compared to $7.0 million recognized under the Maruho Greater Asia Agreement for the year ended December 31, 2024.

Operating Expenses

Research and Development

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

	Year ended December 31,		
	2025	2024	Change
EVO756	$ 35,184	$ 24,662	$ 10,522
EVO301	7,137	19,669	(12,532)
Discovery research	19,936	10,314	9,622
Personnel costs	11,785	9,599	2,186
Total research and development expenses	$ 74,042	$ 64,244	$ 9,798

Research and development expenses were $74.0 million and $64.2 million for the years ended December 31, 2025 and 2024, respectively. The increase was primarily attributable to an increase in clinical trial expenses for EVO756 and additional preclinical research expenses for undisclosed discovery programs, which is classified as discovery research expense in the table above, partially offset by a decrease for EVO301, primarily related to our in-licensing which included an upfront license fee payment of $15.0 million, which was expensed as incurred in 2024.

General and Administrative

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

	Year ended December 31,		
	2025	2024	Change
Personnel costs	$ 8,011	$ 5,958	$ 2,053
Stock-based compensation	4,534	1,017	3,517
Professional fees	2,842	2,496	346
Other general and administrative expenses	4,642	3,298	1,344
Total general and administrative expenses	$ 20,029	$ 12,769	$ 7,260

General and administrative expenses were $20.0 million and $12.8 million for the years ended December 31, 2025 and 2024, respectively. The increase was primarily driven by higher personnel-related costs, including increased headcount and higher stock-based compensation expense, reflecting the recognition of $0.3 million of restricted stock unit expense and $1.8 million of stock appreciation right expense following the completion of our initial public offering. The increase in other general and administrative expenses of $1.3 million was primarily driven by expenses related to our initial public offering.

Other income, net

Other income, net was $12.2 million and $3.2 million for the years ended December 31, 2025 and 2024, respectively. The increase was primarily due to a decrease in the fair value of convertible preferred stock forward of $8.9 million prior to settlement of the stock forward in June 2025.

Liquidity and Capital Resources

Sources of Liquidity

Our operations to date have been financed primarily by aggregate net proceeds from the issuance of convertible preferred stock and common stock. As of December 31, 2025, we maintained $216.7 million in cash, cash equivalents and investments. In November 2025, we completed our IPO, pursuant to which we issued and sold an aggregate of 10,781,250 shares of common stock at a price to the public of $16.00 per share, including 1,406,250 shares issued upon the exercise in full of the underwriters' over-allotment option to purchase additional shares. We received aggregate net proceeds of $157.0 million after deducting underwriting discounts and commissions of $12.1 million and offering expenses of $3.4 million. In February 2026, we sold shares of our common stock pursuant to a securities purchase agreement in exchange for gross proceeds of approximately $125.3 million, before deducting any transaction-related expenses. We expect that our cash, cash equivalents, and investments as of December 31, 2025 will enable us to fund our operating expenses and capital expenditures requirements into the second half of 2028, based on our current business plan.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Year ended December 31,		
	2025	2024	Change
Net cash used in operating activities	$ (76,441)	$ (58,195)	$ (18,246)
Net cash used in investing activities	(115,307)	(3,993)	(111,314)
Net cash provided by financing activities	220,763	49,419	171,344
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 29,015	$ (12,769)	$ 41,784

Operating Activities

Cash used in operating activities of $76.4 million during the year ended December 31, 2025 was attributable to our net loss of $68.9 million, a net decrease of $4.1 million in our working capital, and non-cash income upon settlement of preferred stock forward of $8.9 million, partially offset by non-cash items, including stock-based compensation, accretion of discount on investments and depreciation and amortization expense totaling $5.5 million.

Cash used in operating activities of $58.2 million during the year ended December 31, 2024 was attributable to our net loss of $66.8 million, partially offset by items, including stock-based compensation, accretion of discount on short-term investments and depreciation and amortization expense totaling $1.2 million and a net increase of $7.4 million in our working capital.

Investing Activities

Cash used in investing activities in the year ended December 31, 2025 comprised purchases of investments of $199.2 million and property and equipment of $0.2 million, partially offset by maturities of investments of $84.1 million.

Cash used in investing activities in the year ended December 31, 2024 comprised purchases of short-term investments of $90.3 million and property and equipment of $0.1 million, partially offset by maturities of short-term investments of $86.4 million.

Financing Activities

Cash provided by financing activities for the year ended December 31, 2025 was $220.8 million, which comprised net proceeds of $157.0 million received from our IPO and net proceeds from the sale and issuance of our Series C Preferred Stock of $65.2 million, partially offset by taxes paid for net share settlement of equity awards of $1.2 million and principal payments on finance leases and financing obligations of $0.5 million.

Cash provided by financing activities for the year ended December 31, 2024 was $49.4 million, which comprised net proceeds from the sale and issuance of our Series C Preferred Stock in October 2024 of $49.8 million, partially offset by principal payments on finance leases and financing obligations of $0.4 million.

Future Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses; costs related to third-party clinical research, manufacturing and development services; costs relating to the build-out of our headquarters and other offices, our laboratories and our manufacturing facility; license payments or milestone obligations that may arise; laboratory expenses and costs for related supplies; clinical costs; manufacturing costs; legal and other regulatory expenses and general overhead costs. We expect that our research and development expenses, general and administrative expenses and capital expenditures will continue to increase. Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future.

We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds, which may be through equity offerings, debt financings or other capital sources, including potential collaborations, out-licenses or dispositions and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through offerings of equity or equity-linked securities, the ownership interest of our existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that may adversely affect our stockholders' rights. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, timing and completion of preclinical studies and clinical trials for our current or any future product candidates, as well as the associated costs, including any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to disease outbreaks, epidemics and pandemics or other causes;
- the timing and amount of milestone and royalty payments we are required to make or are eligible to receive under our license agreements with Dermira, Maruho, AprilBio and any future license or collaboration agreements;
- the number and characteristics of potential new product candidates we identify and decide to develop;
- the need for additional or expanded preclinical studies and clinical trials beyond those that we plan to conduct with respect to our current and future product candidates;
- the cost involved in growing the organization to the size needed to allow for the research, development and potential commercialization of our current or any future product candidates;
- the costs involved in filing patent applications, maintaining and enforcing patents or defending against infringement or other claims raised by third parties;
- the maintenance of our existing license and collaboration agreements and the entry into new license and collaboration agreements;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;

- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own;
- the cost associated with manufacturing and supply of our product candidates;
- the cost associated with operating as a public company;
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved; and
- market acceptance of any approved product candidates.

A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities.

Contractual Obligations and Commitments

As of December 31, 2025, we had commitments of $0.4 million related to our operating leases with non-cancelable terms of less than 12 months. In June 2025, we executed a sixty-three month lease agreement to lease approximately 32,016 square feet of office space in Palo Alto, California. The lease is expected to commence in March 2026 and includes annual lease payments during each of the first three years of approximately $1.5 million, with increases of approximately 3% each year thereafter for the remainder of the lease.

We enter into contracts in the normal course of business with third-party service providers for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. We may also enter into additional research, manufacturing, supplier and other agreements in the future, which may require up-front payments and even long-term commitments of cash.

Critical Accounting Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reporting amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to investments, goodwill, fair value of warrant liabilities, share-based compensation and accrued expenses. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. If actual results for the critical accounting estimates listed below varied from our estimates, it could significantly impact our financial results. We believe that full consideration has been given to all relevant circumstances that we may be subject to, and the consolidated financial statements accurately reflect our best estimate of the results of operations, financial position and cash flows for the periods presented. While our significant accounting policies are more fully described in Note 2, "Summary of Significant Accounting Policies" of the notes to our consolidated financial statements in Part IV, Item 15 of this Annual Report on Form 10-K, we believe the following accounting policies to be most critical to the judgements and estimates used in the preparation of our financial statements.

Revenue Recognition

We recognize revenue in accordance with Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers. Our revenue is generated through research collaboration and license agreements with pharmaceutical partners. The terms of these agreements contain multiple goods and services which may include (i) licenses, (ii) research and development activities and (iii) participation in joint research and development steering committees. The terms of these agreements may include non-refundable upfront license or option fees, payments for research and development activities, milestone payments and royalty payments based on product sales derived from the collaboration. Under ASC 606, we evaluate whether the license agreement, research and development services and participation in research and development steering committees represent separate or combined performance obligations. We have determined that these services within our existing contracts represent multiple performance obligations.

The research collaboration and license agreements typically include contingent milestone payments related to specified preclinical and clinical development milestones and regulatory milestones. These milestone payments represent variable consideration that are not initially recognized within the transaction price as they are fully constrained under the guidance in ASC 606. We will continue to assess the probability of significant reversals for any amounts that become likely to be realized prior to recognizing the variable consideration associated with these payments within the transaction price.

Revenue is recognized ratably over our expected performance period or as these performance obligations are fulfilled under each respective arrangement. We make our best estimate of the period over which we expect to fulfill our performance obligations, which includes access to technology through the license agreement and research activities. Given the uncertainties of these collaboration arrangements, significant judgment is required to estimate the duration of the performance period.

For the years ended December 31, 2025 and 2024, transaction price allocated to the performance obligations identified under the agreements was recognized as these performance obligations were fulfilled under each respective arrangement.

Our contracts may also call for certain sales-based milestone and royalty payments upon successful commercialization of a target. In accordance with ASC 606-10-55-65, we recognize revenues from sales-based milestone and royalty payments at the later of (i) the occurrence of the subsequent sale or (ii) the performance obligation to which some or all of the sales-based milestone or royalty payments has been allocated has been satisfied (or partially satisfied). We anticipate recognizing these milestone and royalty payments if and when subsequent sales are generated by the customer from the use of the technology. To date, no revenue from these sales-based milestone and royalty payments has been recognized for any periods.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets.

Research and Development Costs

Research and development expenses are recognized as services are performed and as costs occur. As part of our process of preparing our consolidated financial statements, we are required to estimate our research and development expenses as of each balance sheet date. Research and development expense accruals are estimated based on the level of services performed, progress of the work orders, including the phase or completion of events, and contracted costs. This process involves reviewing open contracts and purchase orders along with preparation of financial models taking into account communications with our key personnel to identify the level of services that have been performed. We then make estimates of levels of service performed when we have not yet been invoiced or otherwise notified of actual costs incurred as of the balance sheet date. We make significant judgments and estimates in determining the accrual balance at each reporting period based on the facts and circumstances known to us at that time.

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

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the level of services and timing of services performed differ from actual status and timing of services

performed, it could result in us reporting amounts that are too high or too low in any particular reporting period. To date, there have been no material differences between estimates of such expenses and the amounts actually incurred.

Convertible Preferred Stock Forward

Certain provisions of the Series C Preferred Stock Purchase Agreement ("Series C SPA") obligated us to sell, and the investors to purchase, an additional tranche of shares of Series C Preferred Stock, par value $0.0001 per share ("Series C Preferred Stock"), at a future date and specified price (the "tranche closings forward") if certain clinical performance milestones are met. The tranche closings forward represented freestanding instruments as they were legally detachable and separately exercisable and, therefore, were accounted for separately from Series C Preferred Stock as convertible preferred stock forwards (liability or asset).

These derivatives were recorded at fair value at inception and were subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recognized in change in the fair value of convertible preferred stock forward in the statements of operations. (see Note 3 and Note 7 to our audited consolidated financial statements).

Recently Adopted Accounting Pronouncements

Refer to Note 2, "Summary of Significant Accounting Policies," in the accompanying notes to our audited consolidated financial statements for the years ended December 31, 2025 and 2024 for a discussion of recent accounting pronouncements.

Emerging Growth Company and Smaller Reporting Company Status

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

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

We may remain classified as an emerging growth company until the end of the fiscal year following the fifth anniversary of our IPO or such earlier time that we are no longer an emerging growth company. If the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of June 30 of any year, or if we have annual gross revenues of $1.235 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year. We also would cease to be an emerging growth company if we issue more than $1.0 billion of non-convertible debt over a three-year period.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures until the fiscal year following the determination that (i) our voting and non-voting common stock held by non-affiliates is at least $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is at least $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is at least $700.0 million measured on the last business day of our second fiscal quarter.

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

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data.

Our financial statements, together with the report of our independent registered public accounting firm, appear in Part IV, Item 15 of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

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

Evaluation of Disclosure Controls and Procedures

As of December 31, 2025, management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of December 31, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) or an attestation report of our independent registered accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

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

Item 9B. Other Information.

During the three months ended December 31, 2025, none of our directors or officers adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are 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 by this item (other than the information set forth in the next paragraph in this Item 10) will be included in our definitive proxy statement with respect to our 2026 Annual Meeting of Shareholders to be filed with the SEC, which will be filed no later than 120 days after the end of our fiscal year ended December 31, 2025 and is incorporated herein by reference.

We have adopted a written code of conduct and business ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer, or persons performing similar functions, and third-party consultants. We have posted a current copy of the code on our website, *www.evommune.com*. In addition, we intend to post on our website all disclosures that are required by law or the New York Stock Exchange listing standards concerning any amendments to, or waivers from, any provision of the code. The reference to our website does not constitute incorporation by reference of the information contained at or available through our website.

We have adopted insider trading policies and procedures governing the purchase, sale, and/or other dispositions of our securities by directors, officers and employees. In addition, it is our intent to comply with the applicable laws and regulations relating to insider trading.

Item 11. Executive Compensation.

The information required by this item will be included in our definitive proxy statement with respect to our 2026 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

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

The information required by this item will be included in our definitive proxy statement with respect to our 2026 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

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

The information required by this item will be included in our definitive proxy statement with respect to our 2026 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be included in our definitive proxy statement with respect to our 2026 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) *Consolidated Financial Statements*

Our consolidated financial statements are listed in the "Index to Consolidated Financial Statements" under Part IV, Item 15 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

All financial statement schedules have been omitted because they are not applicable, not material, or the required information is shown in Part IV, Item 15 of this Annual Report on Form 10-K.

(3) Exhibits

The exhibits listed below are filed as part of this Annual Report on Form 10-K, or are incorporated herein by reference, in each case as indicated below:

Exhibit Index

Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-42938	3.1	11/7/2025	
3.2	Amended & Restated Bylaws of the Registrant	S-1	333-290793	3.4	10/9/2025	
4.1	Form of Common Stock Certificate	S-1	333-290793	4.1	10/9/2025	
4.2†	Third Amended and Restated Investors' Rights Agreement, dated October 30, 2024, by and among the Registrant and the investors party thereto	S-1	333-290793	4.2	10/9/2025	
4.3	Description of Registrant's Securities					X
10.1+	Form of Indemnification Agreements	S-1	333-290793	10.1	10/9/2025	
10.2+	Evommune, Inc. 2020 Stock Plan	S-1	333-290793	10.2(a)	10/9/2025	
10.3+	Forms of Stock Option Grant Notice, Option Agreement, Notice of Exercise, Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice under the 2020 Plan	S-1	333-290793	10.2(b)	10/9/2025	
10.4+	Evommune, Inc. 2025 Equity Incentive Plan	S-8	333-291386	99.3	11/7/2025	
10.5+	Forms of Stock Option Grant Notice, Option Agreement, Notice of Exercise, Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice under the 2025 Plan.	S-1/A	333-290793	10.3(b)	10/17/2025	
10.6+	Evommune, Inc. 2025 Employee Stock Purchase Plan	S-1/A	333-290793	10.4	10/17/2025	
10.7+†	Employment Agreement, dated November 1, 2024, by and between the Registrant and Luis Peña	S-1	333-290793	10.5	10/9/2025	
10.8+†	Employment Agreement, dated November 1, 2024, by and between the Registrant and Eugene A. Bauer	S-1	333-290793	10.6	10/9/2025	
10.9+†	Amendment to Employment Agreement, dated September 22, 2025, by and between the Registrant and Eugene A. Bauer	S-1	333-290793	10.7	10/9/2025	
10.10+†	Employment Agreement, dated November 1, 2024, by and between the Registrant and Kyle B. Carver	S-1	333-290793	10.8	10/9/2025	
10.11+†	Employment Agreement, dated November 1, 2024, by and between the Registrant and Janice Drew	S-1	333-290793	10.9	10/9/2025	

10.12+†	Employment Agreement, dated November 1, 2024, by and between the Registrant and Gregory S. Moss	S-1	333-290793	10.10	10/9/2025	
10.13+†	Employment Agreement, dated November 1, 2024, by and between the Registrant and Jeegar P. Patel	S-1	333-290793	10.11	10/9/2025	
10.14+	Stock Appreciation Right Agreement, dated January 17, 2025, by and between the Registrant and Luis Peña	S-1	333-290793	10.12	10/9/2025	
10.15†	License, Development and Commercialization Agreement, dated December 17, 2020, by and between the Registrant and Dermira, Inc.	S-1	333-290793	10.13	10/9/2025	
10.16†	Sublicense Agreement, dated September 26, 2023, by and between the Registrant and Maruho Co., Ltd.	S-1	333-290793	10.14	10/9/2025	
10.17†	Sublicense Agreement, dated March 19, 2024, by and between the Registrant and Maruho Co., Ltd.	S-1	333-290793	10.15	10/9/2025	
10.18†	License Agreement, dated June 20, 2024, by and between the Registrant and AprilBio Co., Ltd.	S-1	333-290793	10.16	10/9/2025	
10.19†	Lease Agreement, dated June 29, 2025, by and between the Registrant and Hudson Page Mill Hill, LLC	S-1	333-290793	10.17	10/9/2025	
10.20	Form of Securities Purchase Agreement, dated February 12, 2026, by and among the Registrant and the investors thereunder	8-K	001-42938	10.1	2/12/2026	
10.21	Form of Registration Rights Agreement, dated February 12, 2026, by and among the Registrant and the investors thereunder	8-K	001-42938	10.2	2/12/2026	
19.1	Insider Trading Policy					X
21.1	List of Subsidiaries of the Registrant					X
23.1	Consent of BDO USA, P.C., Independent Registered Public Accounting Firm					X
24.1	Power of Attorney (included on signature page)					X
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.					X
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.					X

32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
97	Incentive Compensation Recoupment Policy	X
101.INS	Inline XBRL Instance Document	X
101.SCH	Taxonomy Extension Schema With Embedded Linkbase Documents	X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibits 101)	X

+ Indicates management contract or compensatory plan.

† Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

* This certification is deemed not filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

Item 16. Form 10-K Summary

None.

EVOMMUNE, INC.
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
Evommune, Inc.
Palo Alto, CA

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Evommune, Inc. (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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/ BDO USA, P.C.

We have served as the Company's auditor since 2022.

New York, NY

March 5, 2026

EVOMMUNE, INC.
Consolidated Balance Sheets
(in thousands, except share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 44,063	$ 16,255
Short-term investments	105,137	55,785
Prepaid expenses and other current assets	4,278	1,948
Total current assets	153,478	73,988
Operating lease right-of-use assets, net	1,469	472
Property and equipment, net	994	1,326
Long-term investments	67,489	—
Restricted cash	1,415	208
Other non-current assets	101	61
Total assets	$ 224,946	$ 76,055
Liabilities, Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 7,756	$ 8,264
Accrued liabilities	9,547	6,729
Operating lease liability, current portion	242	487
Convertible preferred stock forward	—	8,928
Deferred revenue	—	3,000
Other current liabilities	364	573
Total current liabilities	17,909	27,981
Operating lease liability, non-current portion	1,290	—
Financing lease liability	181	535
Total liabilities	19,380	28,516
Commitments and contingencies (Note 6)		
Convertible preferred stock: $0.0001 par value — 10,000,000 and 157,657,729 shares authorized at December 31, 2025 and December 31, 2024, and 0 and 116,716,142 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively, (liquidation preference $0 and $210,328 at December 31, 2025 and December 31, 2024, respectively)	—	191,776
Stockholders' equity (deficit):		
Common stock, par value $0.0001 — 500,000,000 and 223,593,879 shares authorized at December 31, 2025 and December 31, 2024, respectively; 31,524,093 and 1,551,420 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	3	—
Additional paid-in capital	426,652	7,982
Accumulated deficit	(221,089)	(152,219)
Total stockholders' equity (deficit)	205,566	(144,237)
Total liabilities, convertible preferred stock, and stockholders' equity	$ 224,946	$ 76,055

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

EVOMMUNE, INC.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	**2024**
Revenues:		
License revenue	$ 13,000	$ 7,000
Total revenue	13,000	7,000
Operating expenses:		
Research and development	74,042	64,244
General and administrative	20,029	12,769
Total operating expenses	94,071	77,013
Loss from operations	(81,071)	(70,013)
Other income, net:		
Change in fair value of convertible preferred stock forward	8,928	—
Interest income	3,323	3,242
Other expense, net	(50)	(37)
Total other income, net	12,201	3,205
Net loss	(68,870)	(66,808)
Deemed dividend	—	(1,500)
Net loss attributable to common stockholders	(68,870)	(68,308)
Basic and diluted net loss per share of common stock	$ (11.22)	$ (45.29)
Weighted average basic and diluted shares of common stock outstanding	6,136,636	1,508,284

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

EVOMMUNE, INC.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)

	Convertible Preferred stock		Common stock		Additional paid-in	Accumulated	
	Shares	Amount	Shares	Amount	capital	Deficit	Total
Balance, January 1, 2024	85,222,619	$ 149,374	1,545,137	$ —	$ 6,197	$ (83,911)	$ (77,714)
Issuance of common stock on exercise of options	—	—	6,283	—	13	—	13
Issuance of Series C convertible preferred stock, net of transaction costs and tranche liability (Note 7)	31,493,523	42,402	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,722	—	1,722
Vesting of early exercised options	—	—	—	—	50	—	50
Deemed dividend	—	—	—	—	—	(1,500)	(1,500)
Net loss	—	—	—	—	—	(66,808)	(66,808)
Balance, December 31, 2024	116,716,142	$ 191,776	1,551,420	$ —	$ 7,982	$ (152,219)	$ (144,237)
Issuance of common stock on exercise of options	—	—	3,545	—	6	—	6
Issuance of Series C convertible preferred stock, net of transaction costs	40,941,587	65,228	—	—	—	—	—
Conversion of redeemable convertible preferred stock upon initial public offering	(157,657,729)	(257,004)	19,147,559	2	257,003	—	257,005
Issuance of common stock upon initial public offering	—	—	10,781,250	1	156,989	—	156,990
Vesting of restricted stock units	—	—	109,436	—	—	—	—
Shares withheld related to net share settlement of equity awards	—	—	(69,117)	—	(1,224)	—	(1,224)
Stock-based compensation	—	—	—	—	5,856	—	5,856
Vesting of early exercised options	—	—	—	—	40	—	40
Net loss	—	—	—	—	—	(68,870)	(68,870)
Balance, December 31, 2025	—	$ —	31,524,093	$ 3	$ 426,652	$ (221,089)	$ 205,566

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

EVOMMUNE, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Years End December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (68,870)	$ (66,808)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	5,856	1,722
Accretion of discount on investments	(1,769)	(1,820)
Depreciation and amortization	1,389	1,287
Change in fair value of convertible preferred stock forward	(8,928)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,370)	(1,017)
Accounts payable	(837)	6,506
Accrued liabilities	2,818	2,704
Operating lease liabilities	(730)	(769)
Deferred revenue	(3,000)	—
Net cash used in operating activities	(76,441)	(58,195)
Cash flows from investing activities:		
Purchases of investments	(199,172)	(90,255)
Maturities of investments	84,100	86,350
Purchase of property and equipment	(235)	(88)
Net cash used in investing activities	(115,307)	(3,993)
Cash flows from financing activities:		
Proceeds from the sale of common stock in initial public offering, net of offering costs paid	157,284	—
Proceeds from issuance of convertible preferred stock, net of issuance costs	65,228	49,829
Proceeds from exercise of stock options	6	13
Principal payments of finance lease liability	(373)	(208)
Principal payments of financing obligation	(158)	(215)
Taxes paid related to net share settlement of equity awards	(1,224)	—
Net cash provided by financing activities	220,763	49,419
Net increase (decrease) in cash, cash equivalents and restricted cash	29,015	(12,769)
Cash, cash equivalents and restricted cash, beginning of year	16,463	29,232
Cash, cash equivalents and restricted cash, end of year	$ 45,478	$ 16,463
Components of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	44,063	16,255
Restricted cash	1,415	208
Total cash, cash equivalents, and restricted cash	45,478	16,463
Supplemental cash flow disclosures:		
Cash paid for interest	$ 7	$ 34
Non-cash investing and financing activities:		
Issuance of common stock upon conversion of convertible preferred stock	257,005	—
Unpaid fixed asset purchases	35	—
Vesting of early exercised stock options	40	50
Assets acquired under finance leases	10	1,032
Deferred offering costs in accounts payable	294	—
Operating lease liabilities arising from obtaining right-of-use assets	1,775	—
Deemed dividend from trigger of anti-dilution provision feature	—	1,500

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

1. Organization and Description of the Business

Business and Organization

Evommune, Inc. and its subsidiaries ("Evommune" or the "Company") is a Delaware corporation headquartered in Palo Alto, California. Evommune is a clinical stage biotechnology company developing innovative therapies that target key drivers of chronic inflammatory diseases.

Liquidity

The Company has incurred significant operating losses since inception and has relied primarily on equity financing and license revenue to fund its operations. As of December 31, 2025, the Company had an accumulated deficit of $221.1 million. The Company expects to continue to incur substantial losses, and its ability to achieve and sustain profitability will depend on the successful development, approval, and commercialization of product candidates and on the achievement of sufficient revenue to support its cost structure. The Company may never achieve profitability and, unless and until it does, the Company will need to continue to raise additional capital.

As previously disclosed in the Company's consolidated financial statements for the year ended December 31, 2024, management identified conditions that raised substantial doubt about the Company's ability to continue as a going concern. During the year ended December 31, 2025, management implemented plans that alleviated the substantial doubt. The principal factor leading to this conclusion is additional capital raised through the issuance of preferred stock (Note 7), and the issuance of common stock in the Company's initial public offering ("IPO") in November 2025 (Note 7), through which the Company raised gross proceeds of $237.8 million. As of December 31, 2025, management expects that existing cash, cash equivalents and short-term investments will be sufficient to fund the Company's current operating plan for at least twelve months from the issuance date of these financial statements.

Significant Risks and Uncertainties

The Company operates in a dynamic and highly competitive industry and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations, or cash flows: its ability to obtain future financing; its ability to continue research and development of its product candidates; payment obligations under license or collaboration agreements; advances and trends in new technologies and industry standards; results of clinical trials; regulatory approval and market acceptance of the Company's product candidates; development of sales, marketing and distribution infrastructure; competing therapies and marketing development; investment in or in-license other technologies; certain strategic relationships; competition from pharmaceutical or other biotechnology companies with greater financial resources or expertise; litigation or claims against its intellectual property portfolio, patent, product, regulatory, or other factors; operational, financial and management systems; and the Company's ability to attract and retain employees necessary to support its growth.

Product candidates being developed by the Company require approvals from the U.S. Food and Drug Administration ("FDA") or other international regulatory agencies prior to commercial sales. There can be no assurance that any product candidates will receive the necessary approvals. If the Company is denied approval, approval is delayed or the Company is unable to maintain approval, it could have a material adverse impact on the Company.

The Company has expended and expects to continue to expend substantial funds to complete the research, development and pre-clinical and clinical testing of product candidates. The Company also will be required to expend additional funds to establish commercial-scale manufacturing arrangements and to provide for the marketing and distribution of product candidates that may receive regulatory approval. If adequate funds are unavailable from operations or additional sources of financing, the Company may have to delay, reduce the scope of or eliminate one or more of its research or development programs which would materially and adversely affect its business, financial condition and results of operations.

The Company is currently operating in a period of economic uncertainty and capital markets disruption, which has been impacted by domestic and global monetary and fiscal policy, geopolitical instability, a recessionary environment and high domestic and global inflation. The U.S. Federal Reserve and other central banks may be unable to contain inflation through more restrictive monetary policy, and inflation may increase or continue for a prolonged period of time. Inflationary factors, such as increases in the cost of clinical supplies, interest rates, overhead costs and transportation costs may adversely affect the Company's operating results. The Company continues to monitor these events and the potential impact on its business. Although the Company does not believe that inflation has had a material impact on its financial position or operations to date, it may be adversely affected in the future due to domestic and global monetary and fiscal policy, supply chain constraints, and other factors, and such factors may lead to increases in the cost of manufacturing for and initiation of studies in the Company's product candidates.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements, which include the accounts of Evommune, Inc. and its subsidiaries, all of which are wholly owned by Evommune, Inc., have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") as defined by the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of income and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to revenue recognition, stock-based compensation, including the fair value of common stock and related assumptions, accrued expenses, and the valuation of convertible preferred stock forwards. Management bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from those estimates.

Reverse Stock Split

On October 17, 2025, the Company effected a 1-for-8.5180 reverse stock split of its common stock. 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 the reverse stock split. There was no effect on the number of shares of common stock or preferred stock authorized for issuance under the Company's certificate of incorporation or the par value of such securities. The shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. In addition, the conversion ratios for each series of the Company's convertible preferred stock were proportionally adjusted (Note 7).

Segments

The Company operates in one segment considering the nature of the Company's products and services, class of customers, methods used to distribute the products and the regulatory environment in which the Company operates. The Company's chief operating decision maker ("CODM"), its Chief Executive Officer, manages and allocates resources to the operations of the company on a total company basis by assessing the overall level of resources available and how to best deploy these resources across functions and research and development projects that are in line with its long-term company-wide strategic goals. In making these decisions, the CODM uses consolidated financial information for purposes of evaluating performance, and forecasting future period financial results. The CODM performs this assessment based on the Company's consolidated net loss. Through this analysis, the CODM assesses performance by comparing actual net loss versus the budget, and then decides how to allocate resources to invest in the Company's research and development programs. The following is a breakdown of net loss by category for the years ended December 31, 2025 and 2024 as managed by the CODM (in thousands).

	December 31, 2025	December 31, 2024
License revenue	$ 13,000	$ 7,000
Operating expenses:		
EVO756	35,184	24,662
EVO301	7,137	19,669
Other research and development	19,936	10,314
Total external research and development	$ 62,257	$ 54,645
Research and development personnel costs	11,785	9,599
Total research and development operating expenses	74,042	64,244
General and administrative operating expenses	12,018	6,811
General and administrative personnel costs	8,011	5,958
Total general and administrative operating expenses	20,029	12,769
Total operating expenses	$ 94,071	$ 77,013
Other income, net	12,201	3,205
Net loss	$ (68,870)	$ (66,808)

Other research and development consists of discovery research, pre-clinical programs and other early-stage development programs. The measure of segment assets, all of which are held in the United States, is reported on the condensed consolidated balance sheets as total assets.

Revenue Recognition

The Company recognizes revenue in accordance with FASB Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers ("ASC 606"), the core principle of which is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to receive in exchange for those goods or services. To achieve this core principle, five basic criteria must be met before revenue can be recognized: (1) identify the contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to performance obligations in the contract; and (5) recognize revenue when or as the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it determines that it is probable it will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in the Company's consolidated balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, non-current portion. Since inception, the Company's only revenues have been generated through license agreements.

License Revenue

The terms of the Company's license agreements typically may include payment to the Company of one or more of the following: non-refundable, up-front license fees; research, development and commercial milestone payments; royalties and other contingent payments due based on the activities of the counterparty. Each of these types of revenue are recorded as license revenues in the Company's consolidated statements of operations. See Note 5 for additional details regarding the Company's license arrangements.

As part of the accounting for these arrangements, the Company allocates the transaction price to each performance obligation on a relative stand-alone selling price basis. The stand-alone selling price may be, but is not presumed to be, the contract price. In determining the allocation, the Company maximizes the use of observable inputs. When the stand-alone selling price of a good or service is not directly observable, the Company estimates the stand-alone selling price for each performance obligation using assumptions that require judgment. Acceptable estimation methods include, but are not limited to: (i) the adjusted market assessment approach, (ii) the expected cost plus margin approach, and (iii) the residual approach (when the stand-alone selling price is not directly observable and is either highly variable or uncertain). In order for the residual approach to be used, the Company must demonstrate that (a) there are observable stand-alone selling prices for one or more of the performance obligations and (b) one of the two criteria in ASC 606-10- 32-34(c)(1) and (2) is met. The residual approach cannot be used if it would result in a stand-alone selling price of zero for a performance obligation as a performance obligation, by definition, has value on a stand-alone basis.

An option in a contract to acquire additional goods or services gives rise to a performance obligation only if the option provides a material right to the customer that it would not receive without entering into that contract. Factors that the Company considers in evaluating whether an option represents a material right include, but are not limited to: (i) the overall objective of the arrangement, (ii) the benefit the collaborator might obtain from the arrangement without exercising the option, (iii) the cost to exercise the option (for example, priced at a significant and incremental discount) and (iv) the likelihood that the option will be exercised. With respect to options determined to be performance obligations, the Company recognizes revenue when those future goods or services are transferred or when the options expire.

The Company's revenue arrangements may include the following:

Up-front License Fees: If a license is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of an agreement that includes research and development milestone payments, the Company evaluates whether each milestone is considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation 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 the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the Company's estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license revenues and earnings in the period of adjustment.

Royalties: If the Company is entitled to receive sales-based royalties from its licensees, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, provided the reported sales are reliably measurable, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its license arrangements.

The Company receives payments from its licensees based on schedules established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

Transaction Price Allocated to Future Performance Obligations

ASC 606 requires that the Company disclose the aggregate amount of transaction price that is allocated to performance obligations that have not yet been satisfied as of December 31, 2025. The guidance provides certain practical expedients that limit this requirement. The Company has various contracts that meet the following practical expedients provided by ASC 606:

1. The performance obligation is part of a contract that has an original expected duration of one year or less.

2. Revenue is recognized from the satisfaction of the performance obligations in the amount billable to the customer.

3. The variable consideration is allocated entirely to a wholly unsatisfied performance obligation or to a wholly unsatisfied promise to transfer a distinct good or service that forms part of a single performance obligation.

Concentration of Credit Risk

Cash equivalents are financial instruments that potentially subject the Company to concentrations of credit risk. The Company has less than $3 million maintained in cash balance in excess of federally insured limits as of December 31, 2025. The Company has not experienced any losses on its cash and cash equivalents. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Cash, Cash Equivalents, Short-term and Long-term Investments

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of December 31, 2025 and 2024, cash and cash equivalents consisted of cash and money market mutual funds.

The Company has invested its excess cash in U.S. government securities and corporate bonds. The Company intends and has the ability to hold these investments to maturity. Securities with original maturity dates of more than three months are reported as held-to-maturity investments and are recorded at amortized cost, which approximates fair value measured using a combination of Level 1 and Level 2 inputs due to the negligible risk of changes in value due to interest rates. The Company determines the appropriate classification of its investments at the time of purchase. All of the Company's investments are classified as held to maturity and are reported as short-term or long-term based on maturity dates.

The Company reviews investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the consolidated statements of operations if the Company experienced a credit loss and has the intent to sell the investment or if it is more likely than not that the Company will be required to sell the investment before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with the Company's investment policy, the severity and the duration of the impairment and changes in value subsequent to the end of the period. There was no impairment of the Company's investments as of December 31, 2025 and 2024.

The following tables summarize the Company's short-term and long-term investments (in thousands):

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
Held-to-maturity securities	$ 105,137	$ —	$ —	105,137
Total short-term investments	105,137	—	—	105,137
Long-term investments:				
Held-to-maturity securities	67,489	—	—	67,489
Total long-term investments	67,489	—	—	67,489
Total investments	$ 172,626	$ —	$ —	$ 172,626

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments				
Held-to-maturity securities	$ 55,785	$ —	$ —	$ 55,785
Total short-term investments	$ 55,785	$ —	$ —	$ 55,785

As of December 31, 2025, the Company had 30 securities with a fair value of $105.1 million with a contractual maturity of less than 12 months and 14 securities with a fair value of $67.5 million with a contractual maturity of greater than 12 months. As of December 31, 2024, the Company had 42 securities with a fair value of $55.8 million with a contractual maturity of less than 12 months.

Restricted Cash

Restricted cash is defined as cash and cash equivalents that cannot be withdrawn or used for general operating activities. As of December 31, 2025 and 2024, the Company's restricted cash was $1.4 million and $0.2 million, respectively, and was associated with a letter of credit issued in connection with office leases.

Property and Equipment, Net

Property and equipment are recorded at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally three to five years, and leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset. Repairs and maintenance expenditures, which are not considered improvements and do not extend the useful life of property and equipment, are expensed as incurred. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the consolidated balance sheets and the resulting gain or loss is reflected in the consolidated statements of operations in the period realized.

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

	Useful Lives Years	December 31, 2025	December 31, 2024
Leasehold improvements	Shorter of life of lease or remaining lease term	$ 528	$ 458
Office equipment and furniture	3-5	684	544
Machinery and laboratory equipment	3-5	149	125
Lab and office equipment under finance right-of-use asset	3	1,157	1,147
Construction-in-progress	—	35	—
		$ 2,553	$ 2,274
Less accumulated depreciation and amortization		(1,559)	(948)
Property and equipment, net		$ 994	$ 1,326

Depreciation and amortization expense of property and equipment, net totaled $0.6 million and $0.5 million for the years ended December 31, 2025 and 2024, respectively.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount to the future undiscounted net cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows generated by the assets. There have been no such impairments of long-lived assets during the years ended December 31, 2025 and 2024.

Leases

Contractual arrangements that meet the definition of a lease are classified as operating or finance leases and are recorded on the consolidated balance sheets as both a right-of-use asset ("ROU asset") and lease liability, calculated by discounting fixed lease payments over the lease term at the Company's incremental borrowing rate ("IBR"). Lease ROU assets and lease obligations are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The Company currently has operating leases for office space and equipment and a finance lease related to lab and office equipment.

ROU assets are adjusted for (i) payments made at or before the commencement date, (ii) initial direct costs incurred, and (iii) tenant incentives under the lease. As the implicit rates for the operating leases are not determinable, the Company uses an IBR based on the information available at the respective lease commencement dates to determine the present value of future payments. IBR represents the interest rate that the Company would expect to incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis with similar terms and payments, in an economic environment where the leased asset is located. The Company considers a lease term to be the non-cancelable period that it has the right to use the underlying asset, including any periods where it is reasonably certain the Company will exercise any option to extend the contract.

Lease costs for minimum lease payments for operating leases are recognized on a straight-line basis over the lease term. Lease liabilities are increased by interest and reduced by payments each period, and the ROU asset is amortized over the lease term. Variable lease payments that do not depend on an index or rate are recognized as lease costs when incurred. In measuring the ROU assets and lease liabilities, the Company has elected to combine lease and non-lease components.

A finance lease ROU asset is recorded within property and equipment, net within the Company's consolidated balance sheets, and is amortized on a straight-line basis over the shorter of estimated useful lives of the asset or the lease term. Finance lease liability is recorded within other current liabilities and other non-current liabilities within the Company's consolidated balance sheets. Interest expense from fixed payments on finance leases is recognized using the effective interest method. Finance lease ROU asset amortization and interest expense are recorded within operating expenses and interest expense, respectively, within the Company's consolidated statements of operations.

The Company does not recognize ROU assets or lease liabilities for short-term leases, if any, having initial terms of 12 months or less at lease commencement as an accounting policy election, and recognizes rent expense on a straight-line basis over the lease term for these types of leases.

Fair Value Measurements

The Company follows the provisions of FASB ASC Topic 820, "Fair Value Measurements and Disclosures" ("ASC 820"). This pronouncement defines fair value, establishes a framework for measuring fair value under GAAP and requires expanded disclosures about fair value measurements. ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement, and defines fair value as the price to sell an asset or transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow) and the cost approach (cost to replace the service capacity of an asset or replacement cost). These valuation techniques are based upon observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect the Company's market assumptions. ASC 820 utilizes a fair value hierarchy that prioritizes inputs to fair value measurement techniques into three broad levels. The following is a brief description of those three levels:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. The carrying amounts reflected in the consolidated balance sheets for cash, cash equivalents, restricted cash, short-term investments, accounts payable and accrued liabilities approximate their fair values due to their short-term nature.

Convertible Preferred Stock

Prior to the completion of the Company's IPO, the convertible preferred stock was recorded outside of permanent equity because while it was not mandatorily redeemable, in certain events considered not solely within the Company's control, such as a merger, acquisition, or sale of all or substantially all of the Company's assets (each, a "deemed liquidation event"), the convertible preferred stock would have become redeemable at the option of the holders of at least a majority of the then outstanding shares of convertible preferred stock. The Company did not adjusted the carrying values of the convertible preferred stock to its liquidation value prior to the IPO, because a deemed liquidation event obligating the Company to pay the liquidation preferences to holders of shares of convertible preferred stock was not probable. In connection with the closing of the Company's initial public offering on November 6, 2025, all outstanding shares of convertible preferred stock automatically converted into shares of common stock.

Convertible Preferred Stock Forward

Certain provisions of the Series C Preferred Stock Purchase Agreement ("Series C SPA") obligated the Company to sell, and the investors to purchase, additional tranches of the Series C Convertible Preferred Stock ("Series C Preferred Stock") at a future date and specified price (the "tranche closings forward") if certain clinical performance milestones were met. The tranche closings forward represented freestanding instruments as they are legally detachable and separately exercisable and, therefore, were accounted for separately from Series C Preferred Stock as convertible preferred stock forwards (liability or asset).

These derivatives were recorded at fair value at inception and were subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recognized in change in the fair value of convertible preferred stock forward in the statements of operations (Note 3 and Note 7). The Company had $8.9 million of forward contracts related to shares of Series C Preferred Stock outstanding as of December 31, 2024. The tranche closings forward were settled in June 2025. See Note 7 for additional details regarding the Company's convertible preferred stock.

Research and Development

Research and development costs are expensed as incurred. Research and development costs include salaries and benefits, consultants' fees, process development costs, stock-based compensation, laboratory supplies, preparation of regulatory submission expenses, and allocated facilities related expenses as well as fees paid to third parties that conduct certain preclinical research and development activities on the Company's behalf. Payments made to third parties under these arrangements in advance of the performance of the related services by the third parties are recorded as prepaid expenses until the services are rendered.

The Company has entered into agreements with third parties to acquire technologies and product candidates for development (Note 5). Such agreements generally require an initial payment by the Company when the contract is executed, and additional payments upon the occurrence of certain events. Additionally, the Company may be obligated to make future royalty payments in the event the Company commercializes the product candidate. In accordance with FASB ASC Topic 730-10-55, Research and Development, expenditures for research and development, including upfront licensing fees and milestone payments associated with products that have not yet been approved by the FDA and do not have alternative commercial use, are charged to research and development expense as incurred. Future contract milestone payments will be recognized as expense when achievement of the milestone is determined to be probable. Once a product candidate receives regulatory approval, subsequent license payments are recorded as an intangible asset.

The Company's accruals for research and development activities performed by third parties are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued liabilities on the consolidated balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company intends to adjust the accruals accordingly.

Stock-Based Compensation

The Company maintains a stock-based compensation plan as a long-term incentive for employees, certain consultants and advisors, and directors of the Company. Stock-based compensation is measured at the date of grant, based on the estimated fair value of the award, and recognized as an expense over the employee's requisite service period (usually the vesting period) on a straight-line basis. The Company estimates the grant date fair value of restricted stock units ("RSUs") using the common stock fair value as determined by the board of directors with the assistance of management and an independent third-party valuation specialist. The Company has issued RSUs and stock appreciation rights ("SARs") with service and performance-based vesting conditions and records the expense for these awards if the Company concludes that it is probable that the performance condition will be achieved. The Company estimates the grant date fair value of the stock options, and the resulting stock-based compensation, using the Black-Scholes option pricing model. The Company accounts for forfeitures as they occur.

The Black-Scholes model considers several variables and assumptions in estimating the fair value of each stock option that requires judgment. Changes in these variables and assumptions can materially affect the resulting estimates of fair value. These variables and assumptions include the per unit fair value of the underlying common units, exercise price, expected term, risk-free interest rate, expected dividend rate, and the expected unit and stock price volatility over the expected term as follows:

- *Expected term.* The expected term represents the period that the options granted are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term) as the Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate expected term.
- *Expected volatility*. The Company derives the expected volatility from the average historical volatilities over a period approximately equal to the expected term of comparable publicly traded companies within its peer group that were deemed to be representative of future stock price trends as the Company does not have any trading history for its common stock. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.
- *Risk-free interest rate*. The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term equivalent to the expected term of a stock award.
- *Expected dividend rate*. The Company has not paid and does not anticipate paying any dividends in the near future. Accordingly, the Company has estimated the dividend yield to be zero.
- *Common stock fair value.* Prior to having a public common stock price available, the grant date fair value of the Company's common stock has been determined by the board of directors with the assistance of management and an independent third-party valuation specialist. The grant date fair value of the Company's common stock was determined using valuation methodologies that utilize certain assumptions including probability weighting of events, volatility, time to liquidation, a risk-free interest rate and an assumption for a discount for lack of marketability (Level 3 inputs). In determining the fair value of the Company's common stock, the methodologies used to estimate the enterprise value of the Company were performed using methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

The fair values of SARs are estimated at the grant date using a Monte Carlo simulation model. Compensation expense is recognized for the number of SARs expected to be earned after assessing the probability that certain performance criteria will be met and the targeted payout level associated with the performance criteria expected to be achieved. Cumulative adjustments are recorded each quarter to reflect the estimated outcome of the performance-related conditions until the date results are determined and settled.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires deferred tax assets and liabilities to be recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts and respective tax bases of existing assets and liabilities, as well as for net operating loss carryforwards and research and development credits. Valuation allowances are provided if it is more likely than not that some portion or all of the deferred tax assets will not be realized. The impact of a change in the tax laws is recorded in the period in which the law is enacted.

Net Loss Per Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the convertible preferred stock, common stock subject to repurchase, stock options, restricted stock units ("RSUs"), and stock appreciation rights ("SARs") are considered to be potentially dilutive securities. Basic and diluted net loss per share is presented in conformity with the two-class method required for participating securities as the convertible preferred stock is considered a participating security. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss is attributed entirely to common stockholders. Because the Company has reported a net loss for the reporting periods presented, the diluted net loss per common share is the same as basic net loss per common share for those periods.

The following table sets forth the computation of the basic and diluted net loss per share (in thousands, except share and per share amounts):

	Year ended December 31,	
	2025	**2024**
Numerator:		
Net loss	$ (68,870)	$ (66,808)
Adjust: deemed dividend	—	(1,500)
Net loss attributable to common stockholders	$ (68,870)	$ (68,308)
Denominator:		
Weighted-average common shares outstanding	6,148,223	1,546,467
Less: weighted-average unvested founder shares	—	(10,011)
Less: weighted-average unvested early-exercised options	(11,587)	(28,172)
Weighted-average common shares outstanding used to compute net loss per share, basic and diluted	6,136,636	1,508,284
Net loss per share, basic and diluted	$ (11.22)	$ (45.29)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	December 31,	
	2025	**2024**
Convertible preferred stock	—	14,341,090
Stock options outstanding	6,598,693	3,715,207
Restricted stock options outstanding	328,318	437,754
Stock appreciation rights outstanding	444,992	444,992
Common stock subject to repurchase	5,503	19,055
Total	7,377,506	18,958,098

The amounts above represent common stock equivalents, where applicable.

JOBS Act Accounting Election

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date the Company (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09 "Improvements to Income Tax Disclosures" ("ASU 2023-09"), which will require incremental income tax disclosures on an annual basis for all public entities. The amendments require that public business entities disclose specific categories in the rate reconciliation and provide additional information for reconciling items meeting a quantitative threshold. The amendments also require disclosure of income taxes paid to be disaggregated by jurisdiction, and disclosure of income tax expense disaggregated by federal, state and foreign. The Company adopted this ASU on January 1, 2025, with retrospective application. The adoption of this ASU resulted in expanded disclosures as shown in Note 10.

In November 2024, the FASB issued ASU 2024-03 "Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures" ("ASU 2024-03"), which will require additional expense disclosures for all public entities. The amendments require that at each interim and annual reporting period, an entity will disclose certain disaggregated expenses included in each relevant expense caption, as well as the total amount of selling expenses and, in annual periods, an entity's definition of selling expenses. ASU 2024-03 is effective for annual reporting periods beginning with the fiscal year ending December 31, 2027, and interim periods thereafter, with early adoption permitted. The Company is currently evaluating the incremental disclosures that will be required in its future consolidated financial statements.

3. Fair Value Measurements and Fair Value of Financial Instruments

The following table sets forth the Company's consolidated financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	Fair Value Measurements at December 31, 2025			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets:				
Cash equivalents				
Money market funds	$ 44,063	$ 44,063	$ —	$ —
Total fair value of assets	$ 44,063	$ 44,063	—	$ —

	Fair Value Measurements at December 31, 2024			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets:				
Cash equivalents				
Money market funds	$ 14,227	$ 14,227	$ —	$ —
Total fair value of assets	$ 14,227	$ 14,227	$ —	$ —
Liabilities:				
Convertible preferred stock forward	$ (8,928)	—	—	(8,928)
Total fair value of liabilities	$ (8,928)	$ —	$ —	$ (8,928)

Items classified as Level 1 within the valuation hierarchy consist of the Company's cash equivalents held in money market funds. The Company measures these investments at fair value determined based on Level 1 observable quoted price market inputs. The Company's money market funds are included in cash and cash equivalents in the consolidated balance sheets.

Items classified as Level 3 within the valuation hierarchy consist of the Company's convertible preferred stock forward (Note 7). The fair value of the convertible preferred stock forward has been estimated at the date of inception, and re-measured at the end of each reporting period until the forwards expired. The Company used a standard forward pricing valuation model to estimate the fair value of the forward contracts with the following significant assumptions:

	June 26, 2025	**December 31, 2024**
Fair value per share of Series C Tranche II	$ 1.59	$ 0.22
Strike Price	$ 1.59	$ 1.59
Expected term	0.1 years	0.6 years
Discount rate	4.11%	4.32%

The following table is a roll-forward of Level 3 assets (liabilities) for the periods indicated (in thousands):

	Series C Tranche Two Forward
Balance at January 1, 2024	$ —
Issuance of convertible preferred stock forward	(8,928)
Balance at December 31, 2024	(8,928)
Change in fair value of convertible preferred stock forward	8,928
Balance at December 31, 2025	$ —

In June 2025, the Company issued 40,941,587 shares of Series C Preferred Stock and settled the convertible preferred stock forward.

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued research and development	$ 3,981	$ 2,828
Accrued compensation	4,934	3,634
Other	632	267
Total	$ 9,547	$ 6,729

5. Strategic Collaborations and License Agreements

Dermira

In December 2020, the Company entered into an exclusive license agreement with Dermira, Inc., a wholly owned subsidiary of Eli Lilly and Company ("Dermira") to develop and commercialize EVO756 and two other development programs for the treatment of various inflammatory diseases (the "Dermira License Agreement").

The Dermira License Agreement remains in effect on a product-by-product and a country-by-country basis until the expiration of the royalty term for such product in such country. The Dermira License Agreement may be terminated by either party due to the other party's uncured material breach or bankruptcy.

Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due. Under the Dermira License Agreement, the Company paid certain upfront and milestone fees that were recognized as research and development expense between 2020 and 2022, and may be required to pay up to $285.0 million upon achievement of specified development, regulatory and sales milestones, as well as tiered royalty payments in the mid-single digit to low-double digit percentage on worldwide sales of the licensed products. For the year ended December 31, 2025, the Company has recorded $2.5 million as research and development expense upon achievement of a development milestone under the Dermira License Agreement. No milestones were achieved under the Dermira License Agreement during the year ended December 31, 2024.

Maruho Co., Ltd.

Maruho Japan Agreement

In September 2023, the Company entered into a strategic collaboration with Maruho Co., Ltd. ("Maruho") and granted Maruho an exclusive license to develop and commercialize EVO756 in Japan (the "Maruho Japan Agreement").

Under the Maruho Japan Agreement, the Company received an upfront payment of $8.0 million in September 2023 and is eligible to receive up to $52.0 million in additional milestone payments and also eligible to receive low single-digit royalty payments on future sales of EVO756 in Japan.

The potential development, regulatory and commercial milestone payments and sales-based royalties that the Company is eligible to receive represent variable consideration under the Maruho Japan Agreement. The development and regulatory milestone amounts were excluded from the transaction price and were fully constrained based on their probability of achievement and the fact that the Company cannot reasonably conclude that a significant reversal of revenue related to these milestones would not occur. Any future sales-based royalties, including commercial milestone payments based on the level of sales, will be included in the transaction price and recognized as revenue when the related sales occur and the milestones are achieved. The Company will reevaluate the transaction price at the end of each reporting period as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price.

The recognition of revenue related to the Maruho Japan Agreement requires significant judgment and estimates. As discussed in Note 2, the Company is required to identify distinct performance obligations and subsequently allocate a portion of the transaction price to each performance obligation. The Company identified the following two performance obligations under the arrangement: (1) an exclusive license to develop and commercialize EVO756 in Japan ("Exclusive License 1") and (2) to conduct a Phase 1 clinical trial including a Japanese cohort (the "R&D Activity Deliverable"). The Company will recognize such revenue or expense, as applicable, as these performance obligations are fulfilled. The Company allocated the transaction price to the two performance obligations based on the estimated stand-alone selling price (R&D Activity Deliverable) and residual approach (Exclusive License 1) at contract inception. The Company determined the residual approach was appropriate, consistent with ASC 606-10-32-34(c)(1) and (2), as a standalone selling price has not previously been established for Exclusive License 1. Significant estimates were used in the determination of the stand-alone selling prices. The stand-alone selling price of the R&D Activity Deliverable was based on an expected cost approach, and considered several factors including, but not limited to, contract research organization costs and project management. The Company reevaluates the transaction price and the total estimated costs expected to be incurred to satisfy the performance obligations and adjust the deferred revenue at the end of each reporting period, if necessary. Such changes will result in a change to the amount of collaboration revenue recognized and deferred revenue.

As of December 31, 2024, the Company had recorded short term deferred revenue of $3.0 million, attributable to the Company's ongoing performance obligations. The Company recognized $3.0 million in license revenue for the year ended December 31, 2025 upon the satisfaction of the performance obligation. There was no deferred revenue recorded as of any other period and no outstanding performance obligations remain under the agreement. In addition, in July 2025, the Company received payment from Maruho of $10.0 million upon the achievement of a development milestone, which is recognized as license revenue for the year ended December 31, 2025. No other milestone or royalty revenues related to this agreement have been earned as of December 31, 2025.

Maruho Greater Asia Agreement

In March 2024, the Company entered into a second strategic collaboration with Maruho (the "Maruho Greater Asia Agreement") and granted Maruho an exclusive license to develop and commercialize EVO756 in Greater China and other Asian countries (the "Territory"). Under the Maruho Greater Asia Agreement, the Company received an upfront payment of $7.0 million in March 2024 and is eligible to receive up to $54.5 million in additional milestone payments and is also eligible to receive low single-digit royalty payments on future sales of EVO756 in the Territory.

The potential development, regulatory and commercial milestone payments and sales-based royalties that the Company is eligible to receive represent variable consideration under the Maruho Greater Asia Agreement. The development and regulatory milestone amounts were excluded from the transaction price and were fully constrained based on their probability of achievement and the fact that the Company cannot reasonably conclude that a significant reversal of revenue related to these milestones would not occur. Any future sales-based royalties, including commercial milestone payments based on the level of sales, will be included in the transaction price and recognized as revenue when the related sales occur and the milestones are achieved. The Company will reevaluate the transaction price at the end of each reporting period as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price.

The recognition of revenue related to the Maruho Greater Asia Agreement requires significant judgment and estimates. As discussed in Note 2, the Company is required to identify distinct performance obligations and subsequently allocate a portion of the transaction price to each performance obligation. The Company identified the following performance obligation under the arrangement: an exclusive license to develop and commercialize EVO756 in the Territory ("Exclusive License 2"). The Company recognized $7.0 million in license revenue in March 2024 related to the Maruho Greater Asia Agreement. No other milestone or royalty revenues related to Maruho Greater Asia Agreement have been earned as of December 31, 2025.

AprilBio

In June 2024, the Company entered into a License, Development and Commercialization Agreement with AprilBio Co., Ltd. ("AprilBio"), upon which AprilBio granted the Company an exclusive worldwide license to develop and commercialize an IL-18BP compound ("EVO301"). The Company paid an upfront payment of $15.0 million to AprilBio, which was recognized as research and development expense during the year ended December 31, 2024. The Company is responsible for the payments of development milestones of up to $82.5 million, sales milestones of up to $377.5 million, and tiered royalty payments in the mid-to-high single digit percentage on covered product net worldwide sales. For the year ended December 31, 2025, the Company has recorded $1.5 million as research and development expense upon achievement of a development milestone under the AprilBio License, Development and Commercialization Agreement. No other milestones were achieved or recorded as research and development expenses for the years ended December 31, 2025 and 2024.

6. Commitments and Contingencies

Leases

The Company has operating leases for office space and equipment as well as finance leases of certain lab and office equipment. The Company's lab and office equipment leases each have original lease terms of three years. Generally, the Company's leases are non-cancellable and do not have any residual value guarantees or any restrictions or covenants imposed by leases.

In July 2025, the Company executed a sixty-three-month lease agreement to lease office space in Palo Alto, California. The lease is expected to commence in March 2026 and includes annual lease payments during each of the first three years of approximately $1.5 million, with an increase of approximately 3% each year thereafter for the remainder of the lease. The Palo Alto lease includes an option to terminate after thirty-nine months, subject to a one-time termination fee equal to six months of base rent. The Palo Alto lease also includes a renewal option for one additional five-year period and does not have any residual value guarantees or any restrictions or covenants. The Company is not reasonably certain to exercise either the early-termination or renewal option, and therefore neither option will be included in the measurement of the related right-of-use asset and lease liability upon commencement of the lease.

In August 2025, the Company executed a sixty-month lease agreement to lease office space in New York, New York. The lease commenced in October 2025 and includes annual lease payments of approximately $0.4 million. The New York lease is non-cancellable and does not include a renewal option, any residual value guarantees or any restrictions or covenants.

As of December 31, 2025, future minimum lease payments included in the measurement of lease liabilities were as follows (in thousands):

	Operating lease	Finance lease
2026	361	404
2027	394	183
2028	394	4
2029 and thereafter	721	—
Total undiscounted lease payments	1,870	591
Less: imputed interest	(338)	(63)
Total lease liability	1,532	528
Less: current portion	242	347
Operating and finance lease liability, net of current portion	$ 1,290	$ 181

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating leases and finance leases (in thousands):

	Year ended December 31,	
	2025	2024
Operating lease:		
Short-term lease cost	$ 1,075	$ 954
Variable lease cost	248	285
Operating lease cost	817	832
Total operating lease costs	2,140	2,071
Finance lease:		
Amortization of right-of-use assets	$ 373	$ 208
Interest on lease liabilities	75	59
Financing obligation:		
Interest expense	7	34
Total finance lease and financing obligation cost	455	301
Total lease cost	$ 2,595	$ 2,372

For the year ended December 31, 2025, cash payments were $0.8 million, $0.4 million, and $0.2 million for operating leases, finance leases and financing obligation, respectively. For the year ended December 31, 2024, cash payments were $0.8 million, $0.2 million, and $0.2 million for operating leases, finance leases and financing obligation, respectively. Interest expense is recorded within other expense in the Company's consolidated statements of operations. The weighted average discount rate and remaining terms are as follows:

	As of December 31,	
	2025	2024
Weighted-average remaining lease term (in years)		
Operating leases	4.8	0.5
Finance leases	1.6	2.4
Financing obligation	—	0.7
Weighted-average discount rate (percent)		
Operating leases	8.25%	8.00%
Finance leases	10.32%	10.61%
Financing obligation	—	12.70%

Research and Development Agreements

The Company enters into contracts in the normal course of business with clinical research organizations, contract manufacturing organizations and other third-party vendors for clinical trials, manufacturing, testing, and other research and development activities. These contracts generally provide for termination on notice, with varying termination fees, typically up to 50%, dependent on timing of notification in advance of planned activity timelines. As of December 31, 2025 and 2024, there were no amounts accrued related to termination and cancellation charges as these are not probable.

License Agreements

The Company has entered into various license agreements (Note 5), pursuant to which the Company is required to make payments contingent upon the occurrence of specified events. The Company is required to pay development and sales milestones and royalties on sales of products developed under these agreements. Except as disclosed in Note 5, no such other milestone events occurred during 2025 and 2024.

Guarantees and Indemnifications

The Company accrues a liability for any contingent liabilities when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount.

Legal proceedings

The Company was not subject to any material legal proceedings during the years ended December 31, 2025 and 2024, and, no material legal proceedings are currently pending or threatened.

7. Convertible Preferred Stock

In connection with the closing of the Company's IPO in November 2025, all outstanding shares of Preferred Stock converted into an aggregate of 19,147,559 shares of common stock and no convertible preferred stock was outstanding as of December 31, 2025. The Company's current amended and restated certificate of incorporation authorizes 500,000,000 share of common stock and 10,000,000 shares of preferred stock.

Series Seed Convertible Preferred Stock Financing

From June 2020 through May 2021, the Company sold 12,858,517 shares of Series Seed Preferred Stock, par value $0.0001 per share ("Series Seed Preferred Stock"), at $0.9692 per share for aggregate gross proceeds of $12.5 million.

Series A Convertible Preferred Stock Financing

In August 2021, the Company entered into the Series A Preferred Stock Purchase Agreement (the "Series A SPA") to issue up to an aggregate of 48,675,300 shares of Series A Preferred Stock, par value $0.0001 per share (the "Series A Preferred Stock") at a purchase price of $1.93634 per share. From August to November 2021, the Company sold 31,193,506 shares of Series A Preferred Stock. The Company also was obligated to sell, and the investors to purchase, up to 15,002,837 shares of Series A Preferred Stock at an original issuance price of $1.93634 (the "Series A Tranche Two Closing"). The Company called for Series A Tranche Two Closing in December 2022 and sold 10,664,668 shares of Series A Preferred Stock for total gross cash proceeds of $20.6 million in December 2022 and 3,434,385 shares of Series A Preferred Stock for total gross cash proceeds of $6.6 million in January 2023.

Certain investors, who had a purchase commitment to buy 903,784 shares, did not participate in the Series A Tranche Two Closing. In accordance with the Series A SPA and the Company's then in effect certificate of incorporation, all shares of Series A Preferred Stock held by such investors were converted to shares of common stock at a one-for-one ratio. The Company converted 1,678,457 shares of Series A Preferred Stock, held by the non-participating investors into shares of common stock on a one for one basis in December 2022. As the conversion occurred per the contractual terms, the Company reclassified the carrying value of shares of Series A Preferred Stock to additional paid-in-capital and common stock par value at the date of the conversion.

In February 2023, the non-participating investors that initially elected to not participate in the Series A Tranche Two Closing, purchased approximately 20 percent of the shares of Series A Preferred Stock initially forfeited in December 2022. The total number of shares purchased by these investors was 180,756. All of such shares of Series A Preferred Stock then immediately converted into shares of common stock on a one-for-one basis, in accordance with the conversion provisions of the Series A SPA.

Series A Convertible Preferred Stock Tranche Closings Forward

The Company determined that its obligation to issue and the investors' obligation to purchase additional shares of Series A Preferred Stock in the Series A Tranche Two Closing at a fixed price represented freestanding instruments and forward contracts that are accounted at fair value at the issuance date and re-measured at each reporting date until the expiration or the settlement of the obligation (the "Series A Tranche Two Forward"). Changes in the fair value of these derivatives are recorded in the consolidated statements of operations.

On December 15, 2022 (the "call date"), the Company exercised its call right under the Series A Tranche Two Forward to sell 15,002,837 additional shares of Series A Preferred Stock at the Series A Tranche Two Closing, when the total fair value of the Series A Tranche Two Forward was $4.3 million. The Company issued 10,664,668 shares of Series A Preferred Stock and settled the related forward contracts with an estimated fair value of $3.0 million in December 2022.

Series B Convertible Preferred Stock Financing

Throughout 2023, the Company sold 28,750,000 shares of Series B Preferred Stock, par value $0.0001 per share ("Series B Preferred Stock") at $2.00 per share for aggregate gross proceeds of $57.5 million.

Series C Convertible Preferred Stock Financing

In October 2024, the Company entered into the Series C SPA to issue up to an aggregate of 72,435,110 shares of Series C Preferred Stock at a purchase price of $1.59453 per share. In October 2024, the Company sold 31,493,523 shares of Series C Preferred Stock for gross proceeds of $50.2 million. The Company also was obligated to sell, and the investors to purchase, up to 40,941,587 shares of Series C Preferred Stock at an original issuance price of $1.59453 (the "Series C Tranche Two Closing") upon the decision by the Company, and approval by the board of directors, to advance the development of EVO756 following the completion of the Phase 2 trial in chronic inducible urticaria (the "Milestone Event"). The Series C Tranche Two Closing could be initiated either by the Company, upon the occurrence of the Milestone Event, or by the investors, but in no event was the Series C Tranche Two Closing to be held later than October 30, 2025.

Series C Convertible Preferred Stock Tranche Closings Forward

The Company determined that its obligation to issue and the investors' obligation to purchase additional shares of Series C Preferred Stock in the Series C Tranche Two Closing at a fixed price represent freestanding instruments and forward contracts that are accounted for at fair value at the issuance date and re-measured at each reporting date until the expiration or the settlement of the obligation (the "Series C Tranche Two Forward"). The Company had $8.9 million of forward contracts outstanding as of December 31, 2024. As the Company determined there was no change in value of the Series C Tranche Two Forward from the date of issuance in October 2024 through the year ended December 31, 2024, there was no gain or loss recorded for a change in fair value during the year ended December 31, 2024.

On May 20, 2025, the Company completed, and the board of directors approved, the achievement of the Series C Preferred Stock milestone event and as a result, on June 27, 2025, the Company issued and sold 40,941,587 shares of Series C redeemable convertible preferred stock at the original issuance price of $1.59453 when the total fair value of the Series C Tranche Two Forward was $0.0 million. The Company issued 40,941,587 shares of Series C Preferred Stock and settled the related forward contracts in June 2025, and recognized a gain of $8.9 million for the year ended December 31, 2025. The Company received aggregate gross proceeds of $65.3 million as part of the Series C Tranche Two Closing.

Pursuant to the Series C SPA, the Company issued and sold shares of Series C Preferred Stock at a purchase price of $1.59453 per share, which triggered the anti-dilution protection provision under the Company's then in effect certificate of incorporation. Due to these provisions, the conversion ratio of the Series A Preferred Stock and Series B Preferred Stock was adjusted from 8.2077 to 7.9557, and from 8.1621 to 7.8721, respectively.

The authorized, issued, and outstanding shares of the Company's convertible preferred stock and liquidation values as of December 31, 2024 were as follows (in thousands, except for share amounts):

	Authorized Shares	Outstanding Shares	Liquidation Preference	Carrying Value
Series Seed	12,858,517	12,858,517	$ 12,462	$ 14,240
Series A	43,614,102	43,614,102	87,640	79,056
Series B	28,750,000	28,750,000	60,009	57,578
Series C	72,435,110	31,493,523	50,217	40,902
Total	157,657,729	116,716,142	$ 210,328	$ 191,776

The significant rights and obligations of the Company's Series Seed Preferred Stock, Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock (collectively "Convertible Preferred Stock") were as follows prior to conversion into common stock:

Voting Rights

The holders of Convertible Preferred Stock are entitled to vote on all matters on which the common stockholders are entitled to vote. Holders of Convertible Preferred Stock and common stock vote together as a single class not as separate classes, except with respect to the election of directors. Each holder of Convertible Preferred Stock is entitled to the number of votes equal to the number of common stock shares into which the shares held by such holder could be converted as of the record date. As long as a majority of the shares of Series C Preferred Stock originally issued remain outstanding, as adjusted for any anti dilution adjustments, the holders of such shares of Series C Preferred Stock shall be entitled to elect two directors of the Company at any election of directors. As long as at least 24% of the shares of Series B Preferred Stock originally issued remain outstanding, the holders of such shares of Series B Preferred Stock shall be entitled to elect one director of the Company at any election of directors. As long as a majority of the shares of Series A Preferred Stock originally issued remain outstanding, the holders of Series A Preferred Stock shall be entitled to elect two directors of the Company at any election of directors. The holders of outstanding common stock shall be entitled to two directors of the Company at any election of directors. The holders of Convertible Preferred Stock and common stock (voting together as a single class and not as separate series, and on an as-converted basis) shall be entitled to elect any remaining directors of the Company.

Dividends

Holders of Convertible Preferred Stock are entitled to receive dividends, when, as and if declared by the board of directors, at the annual rate of 8% of the original issue price, as adjusted for any anti dilution adjustments, payable in preference and priority to any declaration or payment of any distribution on capital stock (other than dividends on shares of common stock payable in shares of common stock) of the Company. No distributions may be made with respect to the common stock unless the requisite dividends on the Convertible Preferred Stock have been declared and all declared dividends on the Convertible Preferred Stock have been paid to the holders of the Convertible Preferred Stock. Dividends are noncumulative, and the Company has never declared a dividend.

Liquidation Preference

In the event of any liquidation, dissolution, or winding up of the Company, the holders of shares of Series C Preferred Stock then outstanding shall be entitled to be paid out of the proceeds or assets of the Company available for distribution to its stockholders, before any payment shall be made to the holders of Series B Preferred Stock, Series A Preferred Stock, Series Seed Preferred Stock or common stock an amount per share equal to the liquidation preference amount, which is the original issue price per share of the Series C Preferred Stock, as adjusted for any anti-dilution adjustments, plus any dividends declared but unpaid thereon. If, upon the occurrence of such event, the proceeds are insufficient to permit the payment to holders of shares of Series C Preferred Stock of the full amounts, then the entire proceeds legally available for distribution shall be distributed ratably among the holders of shares of Series C Preferred Stock in proportion to the full preferential amount that each such holder is otherwise entitled to receive.

After the payment in full to the holders of shares of Series C Preferred Stock, the holders of shares of Series B Preferred Stock then outstanding shall be entitled to be paid out of the proceeds or assets of the Company available for distribution to its stockholders, before any payment shall be made to the holders of shares of Series A Preferred Stock, Series Seed Preferred Stock or common stock an amount per share equal to the liquidation preference amount, which is the original issue price per share of the Series B Preferred Stock, as adjusted for any anti-dilution adjustments, plus any dividends declared but unpaid thereon. If, upon the occurrence of such event, the proceeds are insufficient to permit the payment to holders of shares of Series B Preferred Stock of the full amounts, then the entire proceeds legally available for distribution shall be distributed ratably among the holders of shares of Series B Preferred Stock in proportion to the full preferential amount that each such holder is otherwise entitled to receive.

After the payment in full to the holders of shares of Series C Preferred Stock and Series B Preferred Stock, the holders of shares of Series A Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, before any payment shall be made to the holders of shares of Series Seed Preferred Stock or common stock, an amount per equal to the liquidation preference amount of respective original issue price per share, as adjusted for any anti-dilution adjustments, plus any dividends declared but unpaid. If, upon the occurrence of such event, the proceeds are insufficient to permit the payment to holders of shares of Series A Preferred Stock of the full amounts, then the entire proceeds legally available for distribution shall be distributed ratably among the holders of shares of Series A Preferred Stock in proportion to the full preferential amount that each such holder is otherwise entitled to receive.

After the payment in full to the holders of shares of Series C Preferred Stock, Series B Preferred Stock and Series A Preferred Stock, the holders of shares of Series Seed Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, before any payment shall be made to the holders of shares of common stock an amount per equal to the liquidation preference amount of respective original issue price per share, as adjusted for any anti-dilution adjustments, plus any dividends declared but unpaid. If, upon the occurrence of such event, the proceeds thus distributed among the holders of shares of Series Seed Preferred Stock shall be insufficient to permit the payment to such holders of the full preferential amounts, then the entire proceeds legally available for distribution to the Series Seed Preferred Stock shall be distributed ratably among the holders of shares of Series Seed Preferred Stock in proportion to the full preferential amount that each such holder is otherwise entitled to receive.

After the payment to the holders of Convertible Preferred Stock of the full preferential amounts specified above, the entire remaining assets of the Company legally available for distribution by the Company shall be distributed with equal priority and pro rata among the holders of the common stock in proportion to the number of shares of common stock held by them.

Conversion

Each share of Convertible Preferred Stock was convertible, at the option of the holder at any time after the date of issuance of such share into such number of shares of common stock as is determined by dividing the original issue price for such series by the applicable conversion price for such series, in effect on the date of conversion. If, after the issuance date of Convertible Preferred Stock, the Company issued or sold, or was deemed to have sold, additional shares of capital stock at a price lower than the original issuance price of the Convertible Preferred Stock, except for certain exceptions allowed, the conversion price of such Convertible Preferred Stock would be adjusted. As of December 31, 2024, the Company's Series Seed Preferred Stock and Series C Preferred Stock were convertible into the Company's shares of common stock on an 8.518-for-1 basis. The Company's Series A Preferred Stock was convertible into the Company's shares of common stock at a conversion ratio of 8.2077 to one, and the Company's Series B Preferred Stock was convertible into the Company's shares of common stock at a conversion ratio of 8.1621 to one.

Each share of Convertible Preferred Stock was automatically converted into shares of common stock at the conversion price then in effect in connection with the IPO of the Company's common stock.

8. Common Stock

As of December 31, 2025, the Company is authorized to issue 500,000,000 shares of $0.0001 par value common stock. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to prior rights of the preferred stockholders.

The Company had reserved common stock for future issuance as follows:

	December 31, 2025	December 31, 2024
Series Seed	-	1,509,545
Series A	-	5,482,142
Series B	-	3,652,131
Series C	-	3,697,272
Outstanding options	6,598,693	3,715,207
Outstanding restricted stock	328,318	437,754
Options available for grants	345,347	147,462
Total	7,272,358	18,641,513

9. Stock Option Plan

Stock Options

The Company's board of directors adopted the 2025 Equity Incentive Plan (the "2025 Plan"), which became effective in connection with the IPO and replaced the 2020 Stock Plan ("2020 Plan"). The 2025 Plan provides for the grant of incentive stock options, nonstatutory stock options, SARs, RSU awards, performance awards, and other forms of awards to employees, non-employee directors and consultants. A total of 7,312,677 shares of the Company's common stock were reserved for future issuance under the 2025 Plan, including shares underlying outstanding equity awards granted under the 2020 Stock Plan that expire, or are forfeited, cancelled, or re-acquired. In addition, the share reserve is subject to annual increases each January 1 for the first ten years following approval of the 2025 Plan of up to 5% of shares of the Company's common stock outstanding, including the number of shares of common stock issuable upon the exercise of any pre-funded warrants and preferred stock, if applicable (or a lesser number determined by the Company's board of directors). Options under the 2025 Plan may be granted for periods of up to 10 years at exercise prices no less than 100% of the fair market value of the Company's common stock on the date of grant with the exception of incentive stock options granted to a 10% holder which is no less than 110% of the fair market value of common stock on the date of grant. As of December 31, 2025, the Company had 345,347 shares available for issuance under the 2025 Plan. On January 1, 2026, the number of shares of common stock available for issuance under the 2025 Plan increased by 1,576,204 shares, which was five percent (5%) of the outstanding shares of common stock on December 31, 2025, bringing the total shares available for issuance under the 2025 Plan to 1,921,551.

In October 2025, the board of directors adopted the 2025 Employee Stock Purchase Plan (the "2025 ESPP"), which became effective in connection with the IPO. The 2025 ESPP authorizes the issuance of shares of common stock pursuant to purchase rights granted to employees. A total of 300,000 shares of the Company's common stock have been reserved for future issuance under the 2025 ESPP, in addition to any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

The following table summarizes the Company's stock option activity from January 1, 2024 to December 31, 2025:

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2024	2,293,286	$ 3.32	8.67	$ 27
Options granted	1,478,106	2.62		—
Options exercised	(6,283)	2.03		6
Options forfeited	(49,902)	2.32		—
Outstanding at December 31, 2024	3,715,207	3.08	8.52	$ 585
Options granted	2,894,709	16.69		—
Options exercised	(3,545)	1.71		5
Options cancelled or forfeited	(7,678)	2.30		35
Outstanding at December 31, 2025	6,598,693	9.05	8.55	$ 54,503
Exercisable at December 31, 2025	2,253,120	3.13	7.07	$ 31,520
Vested and expected to vest at December 31, 2025	6,604,196	$ 9.05	8.55	$ 54,580

The weighted-average grant-date fair value of options granted during the years ended December 31, 2025 and 2024 was $12.61 and $2.09 per option, respectively. The aggregate intrinsic value of options exercised for the years ended December 31, 2025 and 2024 was less than $0.1 million, respectively. Intrinsic values are calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that had exercise prices that were lower than the fair value per share of the common stock, multiplied by the related in the money options that would have been received by the option holders had they exercised their options at the end of the period.

As of December 31, 2025, the total unrecognized stock-based compensation expense for stock options was $38.6 million, which is expected to be recognized over a weighted-average period of 6.1 years. The total fair value of options vested for the years ended December 31, 2025 and 2024 was $2.3 million and $2.0 million, respectively.

The fair value of the stock options granted was estimated using the following assumptions:

	Years Ended December 31,	
	2025	2024
Expected term	5.6 - 6.6 Years	5.8 - 6.1 Years
Expected volatility	85.91% - 89.76%	104.96% - 106.94%
Risk-free interest rate	3.71% - 4.07%	4.03% - 4.63%
Fair value of common stock	$2.99 - $18.44	$1.36-$2.47
Dividend yield	0%	0%

Restricted Stock Units

In December 2024, certain employees were granted a total of 437,754 RSUs with a grant date fair value per share of $2.99, expiring on the earlier of (i) the 10-year anniversary of the date of grant or (ii) the date of termination of the employees' service for any reason. Each unit entitles the holder to one share of common stock upon vesting.

The RSUs vest as follows: (i) 25% on each anniversary of vest commencement date, (ii) 0.0911 share of common stock subject to the RSU upon issuance of each share of Series C Preferred Stock issued subsequent to October 30, 2024, and (iii) upon the first to occur of: (a) immediately prior to the consummation of a Change in Control (as defined in the award agreement) or (b) the effective date of a registration statement of the Company filed under the Securities Act for the sale of the Company's common stock, or (c) the settlement of the initial trade of shares of the Company's common stock on a nationally recognized exchange. All unvested RSUs are forfeited upon termination or resignation for any reason.

If a RSU vests, the Company will issue one share of common stock for each vested RSU.

A summary of RSU activity during the year ended December 31, 2025, is as follows:

	Number of Units Outstanding	Grant Date Fair Value per Share
Unvested balance at January 1, 2025	437,754	$ 2.99
Granted	—	—
Vested	(109,436)	—
Unvested balance at December 31, 2025	328,318	$ 2.99

As of December 31, 2025, the total unrecognized stock-based compensation expense for unvested restricted stock was $1.0 million, which is expected to be recognized over a weighted-average period of 2.9 years. Prior to the completion of the Company's IPO on November 7, 2025, the performance condition associated with the RSUs was not considered probable, and accordingly, no stock compensation expense was recognized. Upon completion of the IPO, the performance condition was met, and the Company began recognizing stock-based compensation expense for the RSUs over the remaining time-based vesting period. The Company recorded $0.3 million as stock-based compensation expenses for RSUs for the year ended December 31, 2025.

During the year ended December 31, 2025, we settled 109,436 shares underlying RSUs, of which 40,319 shares underlying RSUs were net settled by withholding 69,117 shares. The value of the RSUs withheld was $1.2 million, based on the closing price of our common stock on the settlement date. The value of RSUs withheld in each period was remitted to the appropriate taxing authorities and has been reflected as a financing activity in our condensed consolidated statements of cash flows.

Stock Appreciation Rights

In December 2024, an executive officer was granted 444,992 SARs with a base price of $2.99 per unit. The SARs expire on the earlier of (i) the 10-year anniversary of the date of grant or (ii) the date of termination of the employees' service for any reason (the "SAR Award").

The SAR Award vests as follows: (i) 25% on each anniversary of vest commencement date, (ii) 0.0061 share of common stock subject to the SAR Award upon issuance of each share of Series C Preferred Stock issued subsequent to October 30, 2024, and (iii) upon the first to occur of: (a) immediately prior to the consummation of a Change in Control (as defined in the award agreement) or (b) after an IPO, at such time as the 30-day volume-weighted average price of a share of common stock is greater than $40.75. All unvested SARs are forfeited upon termination or resignation for any reason.

If a SAR vests, the Company will issue one share of common stock, or deliver the cash equivalent, each as determined in the Company's sole discretion, for an amount equal to the fair market value of a share of common stock on the settlement date less the exercise price.

The number of SARs that vest is dependent on achieving certain performance conditions (liquidity event) and market conditions (minimum stock price). The Company determined that the SAR Award is an equity classified award since although the SARs may be settled in cash or equity, the Company has no intention or history of settling awards in cash. The Company determined that the fair value of the SAR Award was $12.27 per share for a total fair value of $5.5 million. The Company utilized a Monte Carlo simulation with the following assumptions: a 10-year term to maturity, the Company's fair value of common stock at September 30, 2024 of $2.99, estimated volatility of 108%, and risk-free rate of 4.2% to discount the ending result to present value. The valuation also includes a derived service period of 2.07 years, which is the median time to vest, as calculated by the model. This derived service period inherently contains some degree of estimation uncertainty. Prior to the completion of the Company's IPO on November 7, 2025, the performance condition associated with the RSUs was not considered probable, and accordingly, no stock compensation expense was recognized. Upon completion of the IPO, the performance condition was met, and the Company began recognizing stock-based compensation expense for the SARs over the remaining time-based vesting period. The Company recorded stock-based compensation expense of $2.1 million for SAR units for the year ended December 31, 2025.

Stock-Based Compensation Expense

Stock compensation expense recorded for the years ended December 31, 2025 and 2024, consisted of expense for stock options, RSUs and SARs. The following table is a summary of stock compensation expense by function recognized for the periods indicated (in thousands):

	Years Ended December 31, 2025	Years Ended December 31, 2024
General and administrative	$ 4,534	$ 1,017
Research and development	1,322	705
	$ 5,856	$ 1,722

The 2020 Plan provided the holders of certain stock options an election to early exercise prior to vesting. The shares are subject to the Company's lapsing repurchase right upon termination of employment, with the repurchase price being the lesser of the original exercise price or the then fair value of the Company's common stock. At December 31, 2025, less than $0.1 million of proceeds from unvested early exercised options were recognized as other current liability in the accompanying consolidated balance sheets.

The following table summarizes activity relating to early exercises of stock options for the periods indicated:

	Number of shares
Unvested balance at January 1, 2024	40,107
Vested	(21,052)
Unvested balance at December 31, 2024	19,055
Vested	(13,552)
Unvested balance at December 31, 2025	5,503

10. Income Taxes

Loss before provision for income taxes consisted of the following (in thousands):

	Year Ended December 31,	
	2025	2024
Domestic	$ (68,870)	$ (68,308)
Foreign	—	—
Loss before provision for income taxes	$ (68,870)	$ (68,308)

For the years ended December 31, 2025 and 2024 the Company was not required to pay, and did not pay, federal or state income taxes. A reconciliation of the Company's statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,			
	2025		2024	
	Amount	Percent	Amount	Percent
US federal statutory tax rate	$ (14,463)	21.00%	$ (14,345)	21.00%
State and local income taxes, net of federal income tax effect (a)	—	—	—	—
Tax credits				
Research and development tax credits	(2,289)	3.32%	(2,353)	3.44%
Nontaxable or nondeductible items				
Change in fair value of financial instruments	1,875	(2.72)%	—	—
Executive compensation limitation	837	(1.21)%	—	—
Other	276	(0.40)%	530	(0.78)%
Changes in unrecognized tax benefit	458	(0.66)%	471	(0.69)%
Change in valuation allowance	13,306	(19.33)%	15,697	(22.97)%
Total	$ —	0.00%	$ —	0.00%

(a) The majority of state taxes are in California, however due to the valuation allowance state taxes are zero.

The net deferred income tax asset balance related to the following (in thousands):

	December 31,	
	2025	2024
Deferred tax assets		
Net operating loss carryforwards	$ 11,973	$ 10,814
Tax credit	6,257	4,141
Intangibles	5,634	5,239
Capitalized research and development	26,954	16,832
Right of use liabilities	433	289
Accrued bonus	905	680
Stock compensation	525	
Deferred revenue	—	630
Other	129	477
Total deferred tax assets	52,810	39,102
Deferred tax liabilities		
Right of use assets	(420)	(286)
Total net deferred tax assets	52,390	38,816
Valuation allowance	(52,390)	(38,816)
Net deferred tax assets	$ —	$ —

The table below presents the changes in the Company's valuation allowance.

	December 31,	
	2025	2024
Valuation allowance at January 1,	$ 38,816	$ 20,931
Additional allowances	13,574	17,885
Valuation allowance at December 31,	$ 52,390	$ 38,816

As of December 31, 2025 and 2024, the Company had federal net operating loss ("NOL") carryforwards of $44.1 million and $38.5 million, respectively, which can be carried forward indefinitely. As of December 31, 2025 and 2024, the Company had state NOL carryforwards of $38.8. The state NOL carryforwards begin to expire in 2040.

As of December 31, 2025 and 2024, the Company also has federal tax credits of $6.5 million and $4.2 million, respectively, which begin to expire in 2040, and state tax credits of $1.6 million and $1.2 million, respectively, which do not expire.

Future realization of the tax benefits of existing temporary differences and net operating loss carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2025 and 2024, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current and preceding years. The Company determined that it was not possible to reasonably quantify future taxable income and determined that it is more likely than not that all of the deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance as of December 31, 2025 and 2024.

Under Internal Revenue Code Section 382, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. The Company completed a formal Section 382 study that determined an "ownership change" had occurred in August 2021 and November 2025, which limits the Company's ability to utilize its then existing tax attributes. The Company expects to be able to utilize all of its pre-change and post change federal NOL carryforwards and as such, has not recorded a deferred tax asset reduction. With regard to state NOLs and federal tax credits, the section 382 limitation should not prevent the full utilization of these attributes, provided the Company generates sufficient future taxable income to utilize these attribute before they expire. Tax losses generated since the Company's inception in 2020 may be used to offset only 80% of taxable income and carryforward indefinitely, which may require the Company to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years. Future changes in the Company's stock ownership, which may be outside of the Company's control, may trigger an "ownership change." In addition, future equity offerings or acquisitions that have equity as a component of the purchase price could result in an "ownership change." If an additional "ownership change" does occur in the future, utilization of the NOL carryforwards or other tax attributes may be limited, which could potentially result in increased future tax liability to the Company.

The calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations for both federal taxes and the many states in which the Company operates or does business in. ASC 740 states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

The Company records uncertain tax positions as liabilities in accordance with ASC 740 and adjust these liabilities when the Company's judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from the Company's current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. As of December 31, 2025 and 2024, the Company has recorded unrecognized tax benefits and if recognized would not impact the effective tax rate and has not recognized any interest or penalties related to unrecognized tax benefits.

The following table summarizes the changes to the Company's gross unrecognized tax benefits (in thousands):

	December 31,	
	2025	2024
Balance at January 1,	$ 1,064	$ 490
Additions based on tax positions related to current year	608	574
Reduction for tax positions of prior years	(75)	—
Balance at December 31,	$ 1,597	$ 1,064

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, 2020, to the present.

11. Subsequent Events

February 2026 Private Placement

On February 12, 2026, the Company entered into a Securities Purchase Agreement with certain investors pursuant to which the Company, in a private placement, sold an aggregate of 4,494,279 shares of the Company's common stock, par value $0.0001 per share at a purchase price of $27.88. The Company received gross proceeds of $125.3 million, before deducting any transaction-related expenses. In connection with the private placement, the Company entered into a registration rights agreement pursuant to which it agreed to register the resale of the shares issued in the private placement.

SIGNATURES

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

Evommune, Inc.

Date: March 5, 2026

By: /s/ Luis Peña
Luis Peña
President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Luis Peña and Kyle Carver, and each of them, as his true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such individual in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or the individual's substitute, may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ Luis Peña Luis Peña	President, Chief Executive Officer and Director (Principal Executive Officer)	March 5, 2026
/s/ Kyle Carver Kyle Carver, CPA, MBA	Chief Financial Officer (Principal Financial and Accounting Officer)	March 5, 2026
/s/ Benjamin F. McGraw Benjamin F. McGraw, III, Pharm.D.	Chairman	March 5, 2026
/s/ Eugene A. Bauer Eugene A. Bauer, M.D.	Director	March 5, 2026
/s/ David E. Cohen David E. Cohen, M.D., M.P.H.	Director	March 5, 2026
/s/ Derek DiRocco Derek DiRocco, Ph.D.	Director	March 5, 2026
/s/ Arthur Kirsch Arthur Kirsch	Director	March 5, 2026
/s/ Rob Hopfner Rob Hopfner, R.Ph., Ph.D.	Director	March 5, 2026
/s/ Felice Verduyn-van Weegen Felice Verduyn-van Weegen	Director	March 5, 2026