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 001-32157

Savara Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**84-1318182**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1717 Langhorne Newtown Road, Suite 300 Langhorne, Pennsylvania	**19047**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (512) 614-1848

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	SVRA	The Nasdaq Global Select Market

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Global Select Market on June 30, 2025, (the last business day of the registrant's most recently completed second fiscal quarter), was $544,458,670.

The number of shares of Registrant's Common Stock outstanding as of March 13, 2026 was 204,657,499.

Portions of the Registrant's Definitive Proxy Statement relating to the Annual Meeting of Shareholders, scheduled to be held on June 4, 2026, are incorporated by reference into Part III of this Report.

Table of Contents

		Page
PART I		
Item 1.	Business	4
Item 1A.	Risk Factors	27
Item 1B.	Unresolved Staff Comments	48
Item 1C.	Cybersecurity	48
Item 2.	Properties	49
Item 3.	Legal Proceedings	49
Item 4.	Mine Safety Disclosures	49
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	50
Item 6.	Reserved	50
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	51
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	57
Item 8.	Financial Statements and Supplementary Data	58
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	58
Item 9A.	Controls and Procedures	58
Item 9B.	Other Information	59
PART III		
Item 10.	Directors, Executive Officers, and Corporate Governance	60
Item 11.	Executive Compensation	60
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	60
Item 13.	Certain Relationships and Related Transactions, and Director Independence	61
Item 14.	Principal Accounting Fees and Services	61
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	62
Item 16.	Form 10-K Summary	62

Cautionary Statement Concerning Forward-Looking Statements

This Annual Report on Form 10-K, particularly in Item 1. Business, and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, and the information incorporated herein by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are based on current expectations and beliefs and involve numerous risks and uncertainties that could cause actual results to differ materially from expectations. These forward-looking statements should not be relied upon as predictions of future events as we cannot assure you that the events or circumstances reflected in these statements will be achieved or will occur. When used in this report, the words "aim," "anticipate," "believe," "continue," "could," "estimate," "expect," "indicate," "intend," "may," "plan," "predict," "seek," "should," "target," "will," "would," and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements. For example, forward-looking statements include, but are not limited to, statements about:

- *our plans, strategies, and objectives for future operations, including the execution and timing of those plans;*
- *our future financial condition or performance, including the accuracy of our estimates regarding expenses, future revenues, capital requirements, and needs for additional funding;*
- *the process, prospects, and timing for regulatory approval of our product candidate or any product candidates that we may develop;*
- *the timing, progress and results of clinical trials for our product candidate;*
- *our beliefs regarding the therapeutic benefits and efficacy of our product candidate;*
- *our beliefs regarding the treatment of conditions related to the indications targeted by our product candidate;*
- *our use of clinical research organizations and other contractors;*
- *our ability to successfully commercialize our product candidates and prospects for market success;*
- *our product candidate, including our ability to obtain and maintain intellectual property protection, third party payor coverage, and reimbursement;*
- *the size and growth of the markets for our product candidate and our ability to serve those markets;*
- *our competitive position, and developments and projections relating to both our competitors and our industry;*
- *our ability to establish and/or maintain future collaborations or strategic relationships or obtain additional funding;*
- *our ability to maintain compliance with our covenants under our long-term debt instruments and other agreements;*
- *the impact of laws and regulations and/or regulatory developments in the U.S. and other countries;*
- *the performance of our third-party suppliers and manufacturers; and*
- *our ability to attract and retain key personnel.*

If any of these risks or uncertainties materialize or any of these assumptions proves incorrect, our results could differ materially from the forward-looking statements in this report. All forward-looking statements in this report are current only as of the date of this report. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events. Unless context requires otherwise, all references in this report to "Savara," "our company," "we," "us," "our," or similar words refer to Savara Inc. together with its consolidated subsidiaries.

Summary Risk Factors

An investment in our securities involves significant risks. Below is a summary of some of the material risks associated with our business and investment in our securities. The summary does not address all risks that we face. It should be read together with the text of the full risk factors below in Item 1A. Risk Factors and the other information set forth in this annual report on Form 10-K, including our financial statements and the related notes, as well as in other documents that we file with the U.S. Securities and Exchange Commission.

- *We are substantially dependent upon the clinical, regulatory, and commercial success of our sole product candidate, molgramostim inhalation solution ("MOLBREEVI" or "molgramostim"). If we are unable to successfully complete clinical development of, obtain regulatory approval for, and successfully commercialize MOLBREEVI, our business may be harmed.*
- *Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of our product candidate. If development of our product candidate is unsuccessful or delayed, we may be unable to obtain required regulatory approvals and be unable to commercialize our product candidate on a timely basis, if at all.*
- *There is significant uncertainty regarding the regulatory approval process for any investigational new drug. Substantial further testing and validation of our product candidate and related manufacturing processes may be required, and regulatory approval may be conditioned, delayed, or denied, any of which could delay or prevent us from successfully marketing our product candidate and substantially harm our business.*
- *Our MOLBREEVI product candidate may cause undesirable side effects or adverse events or have other properties that could delay or prevent our clinical development, regulatory approval, or commercialization.*
- *Even if we receive regulatory approval for MOLBREEVI, we may face regulatory requirements that could materially and adversely affect our business, financial condition, and results of operations.*
- *If MOLBREEVI receives regulatory approval but fails to achieve significant market acceptance among the medical community, patients, or third-party payers, the revenue we generate from its sales will be limited and our business may never achieve profitability.*
- *Even if we receive regulatory approval to market our product candidate in the U.S., we may never receive approval or commercialize our product outside of the U.S., which would limit our ability to realize the full commercial potential of our product candidate.*
- *We have incurred significant losses since inception and expect that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.*
- *We may require additional financing to support our operations and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce, or terminate our product development efforts or other operations.*
- *The Hercules Loan Agreement contains covenants which may adversely impact our business and the failure to comply with such covenants could cause our outstanding debt to become immediately payable or accelerate principal payments.*
- *We do not have, and do not have plans to, establish commercial manufacturing facilities. We completely rely on third parties for the manufacture and supply of our clinical trial drug and delivery device supplies and, if approved, commercial product materials. The loss of any of these vendors or a vendor's failure to provide us with an adequate supply of clinical trial or commercial product material in a timely manner and on commercially acceptable terms, or at all, could harm our business.*
- *We rely significantly on third parties to conduct our nonclinical testing and clinical trials and other aspects of our MOLBREEVI development program, and if those third parties do not satisfactorily perform their contractual obligations or meet anticipated deadlines, the development of our MOLBREEVI product candidate could be adversely affected.*
- *Our employees, independent contractors and consultants, principal investigators, contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), other vendors, and any future commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.*

- *MOLBREEVI has received Orphan Drug Designation from the U.S. Food and Drug Administration (the "FDA") and the European Medicines Agency (the "EMA"). If a competitor obtains Orphan Drug exclusivity for a product with the same active ingredient and route of delivery as MOLBREEVI for* autoimmune pulmonary alveolar proteinosis*, we may be unable to market our product candidate until the exclusivity of the competing product expires.*
- *We expect competition in the marketplace for our MOLBREEVI product candidate should it receive regulatory approval.*
- *If we fail to attract and retain senior management and key scientific personnel and develop and maintain relationships with service providers, consultants and advisers, we may be unable to successfully develop and commercialize MOLBREEVI.*
- *We currently have limited marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidate, if approved, or generate product revenue.*
- *If we or our vendors fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity, which could negatively affect our operating results and business.*
- *If we are unable to adequately protect our intellectual property rights related to our product candidate, it could have a material adverse effect on our business.*
- *We are subject to uncertainty relating to healthcare reform measures and reimbursement policies that, if not favorable to our product, could hinder or prevent our product's commercial success, if our product candidate is approved.*
- *We face potential product liability exposure and, if successful claims are brought against us, we may incur substantial liability for a product or product candidate and may have to limit its commercialization. In the future, we anticipate that we will need to obtain additional or increased product liability insurance coverage and it is uncertain whether such increased or additional insurance coverage can be obtained on commercially reasonable terms, if at all.*
- *If MOLBREEVI is approved, we will be subject to applicable fraud and abuse, anti-kickback, physician payment transparency, and other healthcare laws and regulations, which could expose us to reputational harm, criminal prosecution, civil penalties, and other damages if it is determined we have failed to comply.*
- *Our stock price is expected to continue to be volatile.*

PART I

Item 1. Business.

Business Overview

Savara Inc. (together with its subsidiaries “Savara,” the “Company,” “we,” “our” or “us”) is a clinical stage biopharmaceutical company focused on rare respiratory diseases. Our sole program, molgramostim inhalation solution ("MOLBREEVI″ or "molgramostim"*)*, is an investigational inhaled biologic, specifically an inhaled granulocyte-macrophage colony-stimulating factor ("GM-CSF") in Phase 3 development for autoimmune pulmonary alveolar proteinosis (“autoimmune PAP”). MOLBREEVI is delivered via a proprietary eFlow® Nebulizer System (PARI Pharma GmbH, “PARI”).

Corporate Strategy

Our goal is to become a leader in rare respiratory therapeutics through the development and commercialization of novel, best-in-class medicines that address unmet medical needs in this field. Key elements of our strategy include:

- **Continued advancement of the MOLBREEVI autoimmune PAP program, the completion of the Phase 3 IMPALA-2 pivotal clinical trial of which the 96-Week open-label period of the trial is ongoing and pursuing regulatory approval**. The IMPALA-2 trial design was endorsed by regulatory authorities in the U.S. (U.S. Food and Drug Administration), Europe (European Medicines Agency), United Kingdom (Medicines and Healthcare Products Regulatory Agency), and Japan (Pharmaceuticals and Medical Devices Agency), and regulatory agencies and ethics committees in various countries and sites where the trial is being conducted. Having enrolled 164 patients (target enrollment was 160 patients), IMPALA-2 is the largest placebo-controlled trial in autoimmune PAP, and in June 2024 positive top line results from the trial were reported that demonstrated a favorable risk benefit profile for MOLBREEVI in autoimmune PAP. In March 2025, the biologics license application (“BLA”) for MOLBREEVI in autoimmune PAP was submitted to the U.S. Food and Drug Administration (“FDA”). In May 2025, we announced the receipt of a Refusal to File letter ("RTF") from the FDA. The RTF was not the result of safety concerns, the FDA did not request or recommend additional efficacy studies, and it did not impact previous designations granted by regulators for MOLBREEVI in autoimmune PAP. We resubmitted the BLA in December 2025 and requested Priority Review. In February 2026, the FDA formally filed the BLA for MOLBREEVI and granted Priority Review. MOLBREEVI in autoimmune PAP has been granted Fast Track and Breakthrough Therapy Designations by the FDA, Orphan Drug Designation by the FDA and the European Medicines Agency (EMA), as well as Innovation Passport (IP) and Promising Innovative Medicine (PIM) designations by the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA).
- **Ensuring all aspects of our manufacturing are validated and can produce product at commercial scale.** With the goal of establishing an uninterrupted supply chain and to mitigate approvability risk, we have selected high-quality CMO’s with proven track-records to support our chemistry, manufacturing, and controls ("CMC") activities. In February 2024, we entered into a Master Services Agreement with FUJIFILM Diosynth Biotechnologies (“Fujifilm”) to complete a technology transfer of the drug substance manufacturing process from GEMA Biotech S.A. (“GEMA”) and to manufacture commercial supply of MOLBREEVI. GEMA is the original drug substance manufacturer that supplied the IMPALA and IMPALA-2 clinical trials. Following the RTF from the FDA, we held a Type A meeting with the FDA. At that meeting, we gained alignment with FDA on the requirements necessary to show comparability between drug substance manufactured at GEMA and drug substance manufactured at Fujifilm and, subsequently, decided to resubmit the BLA with Fujifilm as the drug substance supplier. As part of the technology transfer process, we validated the Fujifilm drug substance manufacturing with three process performance qualification (“PPQ”) batches, and we believe the technology transfer meets the requirements outlined by the FDA. Fujifilm is manufacturing MOLBREEVI drug substance at commercial scale. We continue to work with GEMA and may decide to use them as a second source of drug substance supply following approval with Fujifilm as the drug substance manufacturer. Drug product is currently manufactured at Patheon UK Ltd. (“Patheon”), a division of ThermoFisher Scientific Inc. Following commercialization of MOLBREEVI, and pursuant to our strategy for a dual source supply chain, we plan to qualify a second source drug product manufacturer. For the supply of our exclusive, proprietary eFlow® nebulizer system that is part of the MOLBREEVI drug-device combination, we have a long-term supply agreement in place with PARI. PARI has five FDA-approved nebulizers based on the same eFlow® technology that is used in the proprietary device with MOLBREEVI. The PARI eFlow® nebulizer was used in the IMPALA and IMPALA-2 trials, and we have completed a series of lab tests and human factors studies in an effort to satisfy regulatory requirements for a drug-device combination.
- **Outsourcing capital-intensive operations.** We will continue to pursue the development and manufacturing of our product candidate by outsourcing most clinical development work and manufacturing operations. We believe our business model enables the effective and capital-efficient development of our pipeline through the use of high-quality specialist vendors and consultants.

MOLBREEVI – Autoimmune PAP

Our sole product candidate, MOLBREEVI, is an inhaled biologic. MOLBREEVI is an inhaled formulation of recombinant human GM-CSF and is being developed for the treatment of autoimmune PAP. Pulmonary alveolar proteinosis (“PAP”) is a rare lung disease characterized by the accumulation of surfactant in the alveoli (or air sacs) of the lungs. There are different types of PAP, of which autoimmune PAP is the most common.

In May 2019, the FDA granted Fast Track Designation to MOLBREEVI for the treatment of autoimmune PAP. Fast Track Designation facilitates the development and expedites the review of new drugs or biologics intended to treat serious or life-threatening conditions that demonstrate the potential to address unmet medical needs. In December 2019, the FDA granted Breakthrough Therapy Designation (“BTD”) for MOLBREEVI in autoimmune PAP based on data from the 24-Week double-blind treatment period from our IMPALA Phase 2/3 trial. Additionally, MOLBREEVI was granted Orphan Drug Designation for the treatment of autoimmune PAP in the U.S. and the European Union (“EU”), which allows for seven and ten years of exclusivity from approval, respectively. Savara has exclusive access to the investigational, proprietary PARI eFlow® Nebulizer System for this indication along with a proprietary cell bank for the active drug substance of MOLBREEVI. Additionally, in the United Kingdom ("UK"), MOLBREEVI for the treatment of autoimmune PAP was granted Innovation Passport (June 2022) and Promising Innovative Medicine (August 2022) designations by the MHRA. These designations provide the opportunity for enhanced dialogue and input from the MHRA and the Health Technology Assessment bodies in England, Scotland, and Wales.

In 2019, we announced that IMPALA, the Phase 2/3 clinical trial of MOLBREEVI for the treatment of autoimmune PAP did not meet its primary endpoint of improvement from baseline at Week 24 compared to placebo in the alveolar-arterial gradient, or (A-a)DO_2. While the trial did not meet its primary endpoint, the totality of data from the IMPALA trial gave us confidence that MOLBREEVI had the potential to address a significant unmet need in this rare lung disease. These data include:

- multiple key secondary and exploratory endpoints that either achieved p values < 0.05 or trended in favor of the active drug arms;
- results from the open-label period of the trial that demonstrated a sustained treatment effect, or continued improvement, after longer term exposure to MOLBREEVI; additionally, patients who had been on placebo during the double-blind period of the trial and switched to treatment with MOLBREEVI during the open-label period showed improvements that eventually were generally similar to those seen in patients who received MOLBREEVI during the double-blind period; and
- MOLBREEVI being generally well tolerated, and its safety profile, when compared to placebo, was generally similar except for a few events that did not lead to discontinuations.

In September 2020, results from the IMPALA trial were published in the *New England Journal of Medicine.*

In June 2021, the Phase 3 IMPALA-2 pivotal trial, which built on the key learnings from the first IMPALA trial, was initiated and enrollment completed in June 2023.

In March 2024 and October 2024, respectively, the EMA and the MHRA accepted our MOLBREEVI Pediatric Investigational Plan (“PIP”) and a pediatric autoimmune PAP trial is currently ongoing.

In June 2024, we reported top line results from the pivotal IMPALA-2 trial that demonstrated significant improvement in hemoglobin adjusted gas exchange, as measured by diffusing capacity of the lungs for carbon monoxide ("DLCO") and clinical benefit, as measured by the St. George’s Respiratory Questionnaire ("SGRQ") and Exercise Capacity (“EC”) as measured by an exercise treadmill test. MOLBREEVI was well tolerated throughout the 48-Weeks and no unexpected safety signals were seen. A summary of results are as follows:

- statistically significant improvement in mean change from baseline in DLCO versus placebo at Week 24 (primary endpoint) and Week 48 (secondary endpoint), showing durability of effect;
- statistically significant improvement in mean change from baseline in SGRQ Total Score at Week 24 (secondary endpoint);
- nominally significant improvements in mean change from baseline in SGRQ Activity Score at Week 24 and Peak metabolic equivalents ("Peak METs") (an established measure of EC) at Week 48. We considered data with a p-value <0.05 to be nominally significant;
- 97% of patients completed the double-blind treatment period through Week 48 with no trial drug related adverse events leading to discontinuation; and
- 100% of patients that completed the 48-Week double-blind period of the trial elected to participate in the 96-Week open-label period.

In February 2024 and May 2024, respectively, the EMA and FDA conditionally accepted "MOLBREEVI" as the trade name for molgramostim inhalation solution. The MOLBREEVI trade name approval will not be finalized until molgramostim inhalation solution is approved by the respective regulatory entities.

On March 26, 2025, we announced the completion of the rolling BLA submission to the FDA and our request for Priority Review.

In May 2025, we announced the receipt of an RTF from the FDA.

In August 2025, results from the IMPALA-2 trial were published in the *New England Journal of Medicine.*

In November 2025, the European Patent Office ("EPO") issued patent No. 4 496 611 titled, “Drug-Device Combination Comprising a Liquid Solution and a Nebulizer for Aerosolization of the Liquid Solution” which is jointly held by Savara and PARI and covers the combination of Savara’s investigational therapy, MOLBREEVI, and PARI’s investigational eFlow® Nebulizer System that has been optimized for the delivery of MOLBREEVI. This patent covers our drug-device combination through March 2043.

In November 2025, the EPO notified Savara that it intends to grant a patent for the liquid formulation of MOLBREEVI, which, once granted, will provide protection in Europe through March 2041.

In December 2025 we resubmitted the BLA for MOLBREEVI for treatment of patients with autoimmune PAP and requested Priority Review of the application.

In February 2026 the FDA formally filed the BLA for MOLBREEVI and Priority Review granted.

Detailed Program Description

MOLBREEVI

Background on autoimmune PAP

Autoimmune pulmonary alveolar proteinosis, known as autoimmune PAP, is a specific disease belonging to a family of distinct rare lung diseases collectively referred to as PAP. Autoimmune PAP represents about 90% of all patients with PAP and the estimated diagnosed prevalence of PAP is six to seven cases per million people in the U.S., with similar or higher prevalence reported elsewhere in the world. For example, one study estimated that the diagnosed prevalence in Japan could be three to four times the estimate of six to seven cases per million.

Autoimmune PAP is characterized by the accumulation of surfactant in the alveoli, or air sacs, of the lungs. The surfactant consists of proteins and lipids and is an important physiological substance that lines the inside of the alveoli to prevent the lungs from collapsing. The lungs continuously produce new active surfactant. In a healthy lung, the surfactant is cleared by immune cells called alveolar macrophages. However, in lungs of patients with autoimmune PAP, the macrophages fail to clear the surfactant from the alveoli, leading to gradual accumulation of surfactant in the alveoli. The root cause of autoimmune PAP is an autoimmune response (auto-antibodies) against GM-CSF, a naturally occurring protein in the body. Pulmonary macrophages need to be stimulated by GM-CSF to function properly, but in autoimmune PAP, GM-CSF is neutralized by antibodies against GM-CSF, rendering the macrophages unable to function normally, including the inability to clear surfactant from the alveoli.

Autoimmune PAP most commonly affects individuals 30-50 years of age, but people of any age can be affected. As a result of the accumulation of surfactant, gas exchange in the lungs is impaired, and patients start to experience shortness of breath, fatigue, and decreased exercise tolerance. Typically, shortness of breath is first observed upon exertion, but as the disease progresses, shortness of breath can be experienced even when a person is at rest. Patients may experience cough, sputum production, and episodes of fever, especially if secondary lung infection develops. In the long-term, the disease can lead to complications, including serious infections. Over time, autoimmune PAP can lead to pulmonary fibrosis and respiratory failure, which can be fatal and may require lung transplantation.

Current treatment options for Autoimmune PAP

In the U.S. and Europe, there are no approved medicines for the treatment of autoimmune PAP. The current therapy for autoimmune PAP is a non-standardized procedure called whole lung lavage (“WLL”), which entails washing the lungs with saline to physically remove excess surfactant from the lung. The invasive and inconvenient procedure is performed under general anesthesia and involves:

- insertion of a double-lumen endobronchial tube for lung separation;

- repeated filling of the treated lung with up to 15-50 liters of saline;
- percussion of the lung to emulsify the surfactant sediment; and
- draining the saline by gravity until the lavage fluid that is removed from the lung becomes clear.

Potential complications from WLL include rib fracture, hypoxia, pneumothorax (collapsed lung), hydrothorax (fluid in pleural cavity), superimposed infection, and acute respiratory distress syndrome ("ARDS").

WLLs are performed by highly experienced physicians at specialist sites and necessitate hospitalization. As WLL does not correct the underlying pathophysiology of the disease, nor prevent abnormal surfactant accumulation, patients who undergo the procedure may only experience temporary symptomatic relief. Once the lungs refill with surfactant, the WLL procedure may need to be repeated.

As there are no approved pharmaceutical treatments available for autoimmune PAP in the U.S. and Europe, there is an unmet need for a convenient and efficacious medicinal treatment. We believe that inhalation of MOLBREEVI activates macrophages in the alveoli, thus potentially restoring the surfactant-clearing activity of the alveolar macrophages and considerably improving oxygenation and exercise tolerance. Sargramostim (Leukine), an injectable form of GM-CSF, is approved in the U.S. for intravenous and subcutaneous administration treatment of neutropenia caused by cancer chemotherapy and other related indications. In April 2024, sargramostim was approved in Japan for the treatment of autoimmune PAP. Currently, there are no approved inhalation formulations of GM-CSF in the U.S. or Europe, nor are there any investigational drugs in clinical development for autoimmune PAP in the U.S. or Europe, other than MOLBREEVI.

The potential benefits of inhaled GM-CSF in autoimmune PAP have prompted independent clinicians and academic researchers in the U.S., Japan, and countries in Europe to study the safety and efficacy of inhaled GM-CSF in autoimmune PAP patients. In addition to our two placebo-controlled clinical trials of MOLBREEVI in this patient population—the Phase 2/3 IMPALA trial (n=138) and the Phase 3 IMPALA-2 trial, the largest placebo-controlled trial in autoimmune PAP (n=164)—several investigator-sponsored, open-label clinical trials and case studies of inhaled GM-CSF treatment have been published, with promising results on the efficacy and safety of the treatment. In total, treatment of nearly 150 autoimmune PAP patients with inhaled GM-CSF has been reported in open-label trials or retrospective cohorts, as well as several individual case reports. A case series published in *ERJ Open Research* in January 2025 retrospectively evaluated 5 autoimmune PAP patients who received molgramostim through European single-patient access supplied by Savara. Following treatment with molgramostim (mean duration of 4.2 years), the real-world outcomes data suggest molgramostim addresses the underlying pathophysiology of autoimmune PAP, resulting in improved lung function, decreased disease burden, restored patient functionality, reduced clinical symptoms, and, at the time of publication, no need for WLL. For details on the results of the IMPALA-2 trial, please see the *Clinical Development of MOLBREEVI – autoimmune PAP: Phase 3 IMPALA-2 Trial* section included in this report.

According to our review of published literature, few safety issues related to GM-CSF inhalation in patients with autoimmune PAP have been reported. However, there is still limited information available on the long-term safety of inhaled GM-CSF.

Product Description

MOLBREEVI is an inhaled formulation of a non-glycosylated recombinant human GM-CSF that we are developing for the treatment of autoimmune PAP. GM-CSF is an endogenous growth factor that stimulates the proliferation and differentiation of hematopoietic cells (blood immune cells), mainly granulocytic and monocytic cells, which defend against bacteria and viruses, and clear cellular debris and waste substances from the body. MOLBREEVI is produced in a strain of *Escherichia coli* bearing a genetically engineered plasmid containing a human GM-CSF gene.

Our product is a drug-device combination consisting of molgramostim (drug component) and a vibrating mesh nebulizer (device component). MOLBREEVI is supplied as a sterile formulation containing 300 µg of molgramostim in 1.2 mL solution. MOLBREEVI is administered once daily by inhalation via a high efficiency nebulizer, the investigational, proprietary eFlow® Nebulizer System (PARI Pharma GmbH). The eFlow®Nebulizer System is a reusable electronic inhalation system that has been optimized for administration of molgramostim. The eFlow® consists of a controller unit (AC or battery powered), a nebulizer handset, and a connection cord. The controller unit's lifespan is multiple years, and the handset is replaced monthly.

MOLBREEVI was granted Orphan Drug Designation by the FDA in October 2012 and by the EMA in July 2013 for the treatment of autoimmune PAP. It was also granted Fast Track Designation and BTD by the FDA in May 2019 and December 2019, respectively. Further, it was granted Innovation Passport (June 2022) and Promising Innovative Medicine (August 2022) designations in the UK. Since 2014, molgramostim has been available in several European countries for the treatment of autoimmune PAP for named patients following unsolicited physician requests. In September

2024, we launched the Savara Expanded Access Program ("EAP") for molgramostim in patients with autoimmune PAP. The program enables physicians to request molgramostim for eligible patients in select geographies where the product is not commercially available and in compliance with local regulatory requirements. The Savara EAP has been reviewed and allowed to proceed by the FDA and is open for requests from physicians, on behalf of autoimmune PAP patients, in select countries in North America and Europe. More information can be found on the program at www.clinicaltrials.gov, NCT06546098.

We anticipate that, if approved, MOLBREEVI will be used as a long-term treatment in patients with autoimmune PAP. There are no data yet to support the long-term benefits of inhaled GM-CSF. However, in the real-world case studies (n=5) published in ERJ Open Research, noted above, none of the five patients required WLL after >1 year on molgramostim, suggesting that molgramostim therapy may have prevented the need for WLL in these patients.

MOLBREEVI Key Advantages

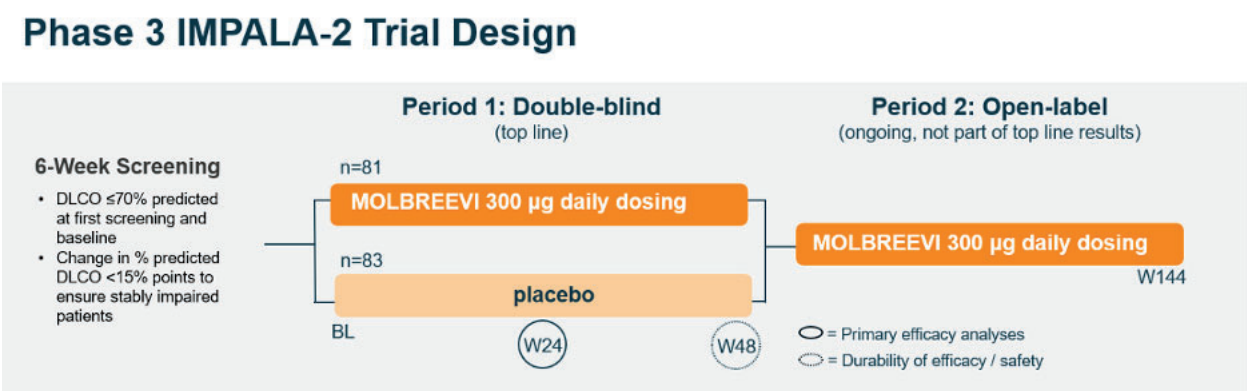
Based on data from the completed Phase 2/3 IMPALA trial and the pivotal Phase 3 IMPALA-2 trial and building upon the published investigator-sponsored treatment experience with inhaled GM-CSF, we believe MOLBREEVI has the potential to become the treatment of choice for autoimmune PAP. The following characteristics of MOLBREEVI may contribute to the clinical profile of the investigational product candidate, as well as facilitate potential regulatory approval and successful commercialization.

Specifically, MOLBREEVI offers:

- a strong product foundation that applies both a previously approved active drug substance class and drug delivery technology;
- GM-CSF delivered directly to the lungs, the primary site of macrophage dysfunction in autoimmune PAP, which could result in clinical efficacy with limited systemic adverse effects;
- a portable nebulizer system that provides a fast and convenient method of administration (nebulization time of about 3 to 5 minutes each day); this is highly desirable for long-term treatment in a chronic disease, such as autoimmune PAP;
- eligibility for strong market protection via orphan drug status, potential eligibility for biologic exclusivity that provides twelve years of total market protection in the U.S.;
- a proprietary cell bank used in the production of the drug substance; and
- an exclusive agreement for the drug delivery device that is optimized for administration of MOLBREEVI.

Clinical Development of MOLBREEVI – Autoimmune PAP

Phase 3 IMPALA-2 Pivotal Trial



IMPALA-2 is a Phase 3, 48-week, randomized, double-blind, placebo-controlled pivotal clinical trial designed to compare the efficacy and safety of MOLBREEVI 300 µg administered once daily by inhalation with matching placebo in adult patients with autoimmune PAP. The primary endpoint was the change from baseline in percent predicted DLCO, a measure of gas exchange. Secondary endpoints included changes from baseline at Week 24 and Week 48 in measures of respiratory health-related quality of life (SGRQ Total Score, SGRQ Activity Score), and exercise capacity (measured as Peak METs achieved using an exercise treadmill test). Other efficacy assessments included (A-a)DO_2 (another gas exchange measure), supplemental oxygen use, WLL frequency, patient and clinician global impression of disease severity

and disease change, chest computed tomography ("CT") scan to assess ground glass opacity score, and blood biomarkers. Enrollment in IMPALA-2 was completed at the end of June 2023 with 164 patients, exceeding the expected trial enrollment of 160 patients. Patients were randomized to receive treatment for 48 Weeks in one of two arms: MOLBREEVI 300 µg administered once daily or inhaled placebo administered once daily. The primary time point for efficacy assessment was at Week 24; however, efficacy was assessed through Week 48 to show durability of effect. Safety was assessed through Week 48. Following the 48-Week double-blind treatment period, patients had the option to transition to a 96-Week open-label period where all patients receive MOLBREEVI 300 µg administered once daily.

In June 2024, we announced positive top line results from the IMPALA-2 trial which enrolled 164 patients from 43 sites across 16 countries, making it the largest placebo-controlled trial conducted in autoimmune PAP. One hundred fifty-nine patients completed treatment during the 48-Week double-blind period—which translates to a treatment discontinuation rate of only 3%, and 100% of patients who completed the double-blind period opted to enter the 96-Week open-label MOLBREEVI treatment period.

In August 2025, results from the IMPALA-2 trial were published in the *New England Journal of Medicine*.

Top line results from the trial are as follows:

PRIMARY ENDPOINT MET:

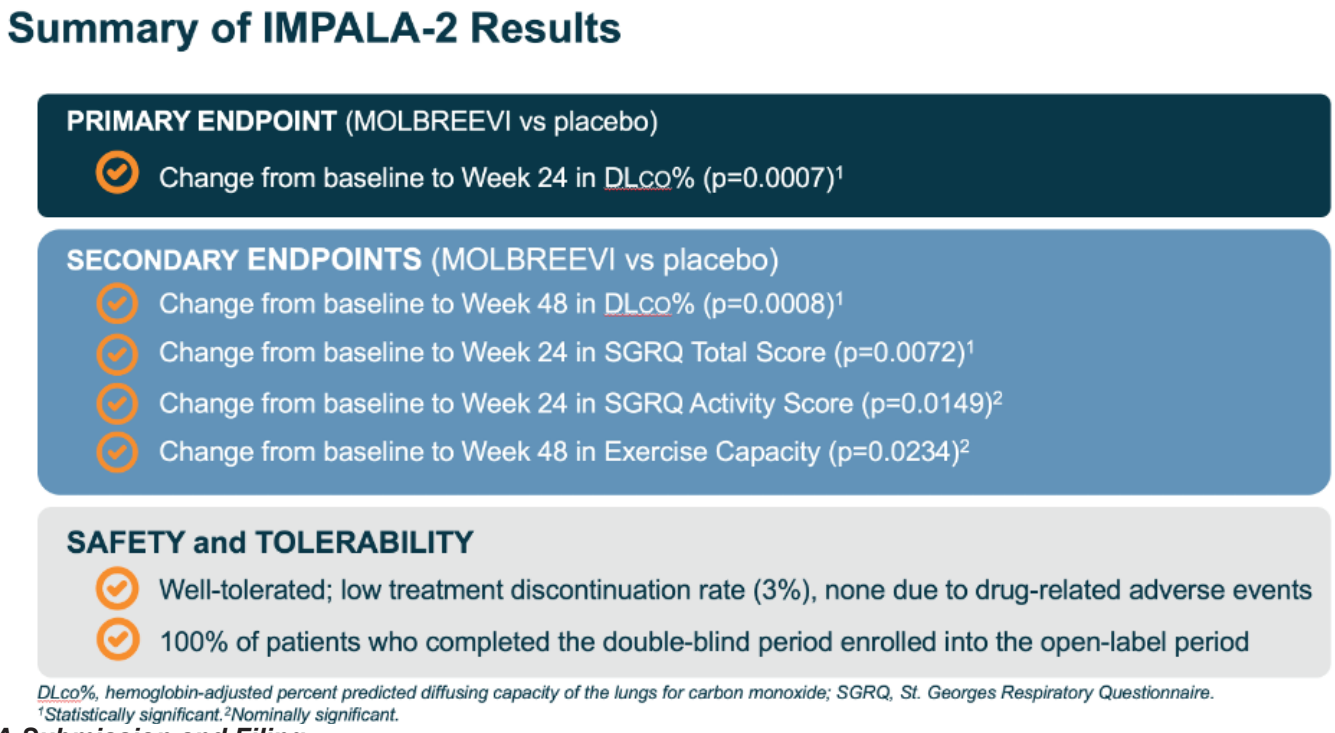
- Change from baseline at Week 24 in hemoglobin adjusted percent predicted DLCO was the primary endpoint. DLCO is a lung function measurement that assesses the ability of the lungs to transfer gas from inspired air to the bloodstream. DLCO results showed a statistically significant treatment difference in mean changes of 6.0 percentage points in favor of MOLBREEVI compared to placebo (p=0.0007).

SECONDARY ENDPOINTS:

- Gas Exchange
    - DLCO results were sustained through the double-blind period, with a treatment difference in mean changes of 6.9 percentage points at Week 48 in favor of MOLBREEVI compared to placebo (p=0.0008)—indicating durability of treatment effect.
- Clinical Benefit
    - SGRQ is a patient-reported outcome instrument that measures overall health, daily life, and a patient's perceived well-being. SGRQ Activity, a subscale of the SGRQ, assesses the patient's ability to carry out daily physical activity. A decrease from baseline in SGRQ indicates improvement (i.e. a lower number is better).
        - SGRQ Total score showed a statistically significant treatment difference in mean changes from baseline of -6.59 points at Week 24 in favor of MOLBREEVI compared to placebo (p=0.0072).
        - At Week 48, the treatment difference remained more favorable for MOLBREEVI compared to placebo at -4.87 points (p=0.1046).
        - SGRQ Activity score demonstrated a nominally significant treatment difference in mean changes from baseline of -7.81 points at Week 24 in favor of MOLBREEVI compared to placebo (p=0.0149) and remained numerically favorable with a treatment difference of -5.99 points at Week 48 (p=0.1216).
    - Exercise capacity expressed as Peak METs is a controlled assessment that required patients to exercise through standardized increases in speed and grade on a treadmill.
        - MOLBREEVI treatment resulted in an absolute mean increase in Peak METs of 1.11 compared to a mean increase of 0.7 with placebo at Week 24, with a treatment difference of 0.41 METs (p=0.0845). This improvement was maintained through Week 48, with a nominally significant treatment difference of 0.55 METs (p=0.0234).

WLL, an invasive procedure intended to clean the lungs of excess surfactant, was allowed during the trial as rescue treatment in case of worsening of autoimmune PAP. During the double-blind period, 17 patients (~10%), underwent at least one lung lavage—6 patients (7%) in the treatment arm underwent WLL, and 11 patients (13%) in the placebo arm underwent WLL.

MOLBREEVI was generally well tolerated. The frequencies of adverse events were mostly similar in both arms. Common adverse events were generally mild or moderate in severity and generally balanced across groups in frequency and severity, except for COVID-19 and diarrhea, which occurred more frequently in the MOLBREEVI group. None of the COVID-19 events was considered related to trial drug by the investigator and only one event of COVID-19 in a molgramostim-treated patient was serious and led to discontinuation.

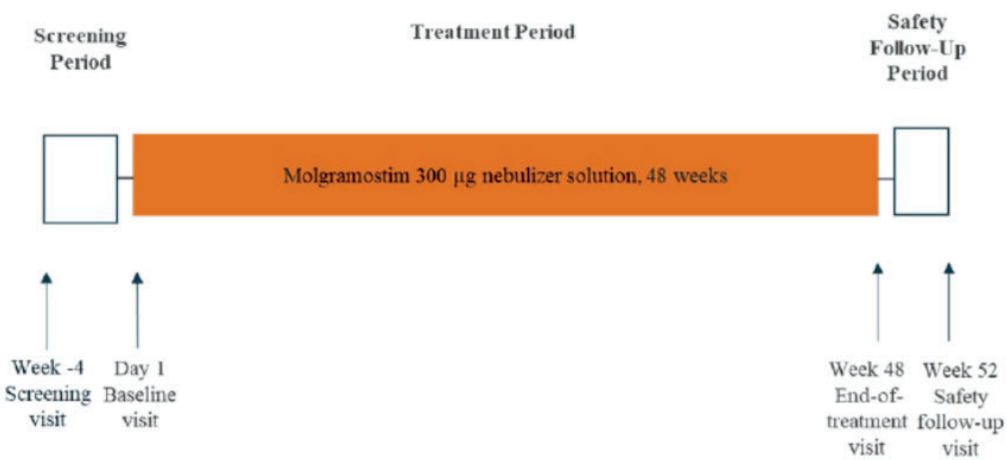


BLA Submission and Filing

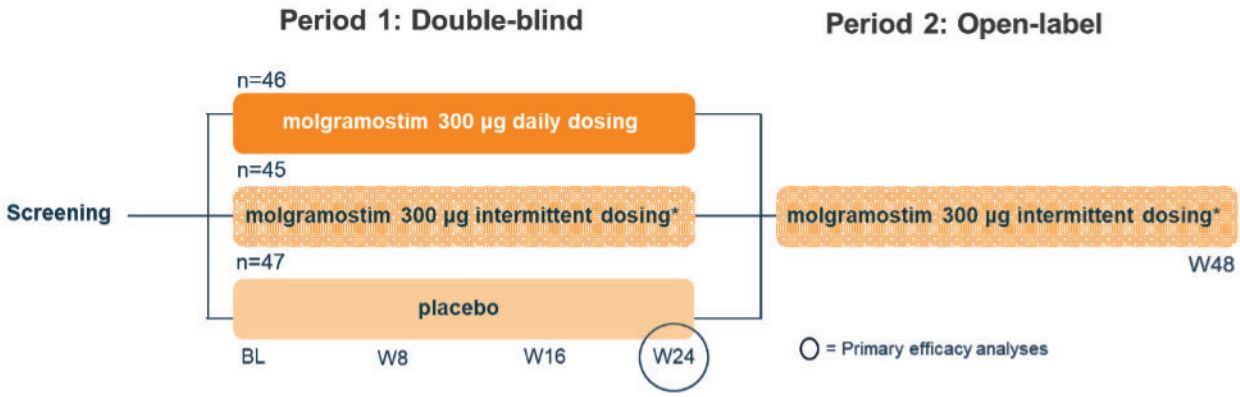
On March 26, 2025, the Company announced that it had completed the BLA submission to the FDA and would request Priority Review. In May 2025, we announced the receipt of an RTF from the FDA. We resubmitted the BLA in December 2025 and requested Priority Review of the application. In February 2026 the FDA formally filed the BLA for MOLBREEVI and granted Priority Review.

Pediatric (PIP) Trial of MOLBREEVI – IMPACT

In March 2024 and October 2024, respectively, the EU EMA and the UK MHRA accepted our MOLBREEVI Pediatric Investigational Plan. The IMPACT trial, an open-label multicenter trial evaluating the efficacy and safety of MOLBREEVI in patients 6-<18 years of age with autoimmune PAP, which is a requirement from the EMA and MHRA as a function of the agreed-upon PIP, is currently ongoing. The IMPACT clinical trial design is as follows:



Phase 2/3 IMPALA Trial



IMPALA was a Phase 2/3 randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of molgramostim in adult patients with autoimmune PAP. Patients with autoimmune PAP were randomly assigned to receive molgramostim (300 µg once daily by inhalation), either continuously or intermittently (once daily every other Week), or matching placebo. The 24-Week double-blind intervention period was followed by an open-label treatment period during which patients were treated with molgramostim intermittently. The primary end point was the change from baseline in the alveolar–arterial difference in oxygen concentration (A-aDO_2) at Week 24.

Results from the double-blind period of the IMPALA trial, published in the *New England Journal of Medicine* in September 2020, demonstrated a positive treatment effect from daily continuous administration of molgramostim. In total, 138 patients underwent randomization; 46 were assigned to receive continuous molgramostim, 45 to receive intermittent molgramostim, and 47 to receive placebo. The primary endpoint, change from baseline in A-aDO_2 was not statistically significant. This was due to 4 patients (1 in each molgramostim group and 2 in the placebo group) who received nasal oxygen therapy during arterial blood gas measurement rendering the calculation of A-aDO_2 invalid because the inspired oxygen content could not be determined. A post-hoc analysis treated these patients' data as missing and were replaced by means of imputation. For the primary endpoint—the change from baseline in A-aDO_2at week 24—mean improvement was greater among patients receiving continuous molgramostim than among those receiving placebo (−12.8 mm Hg vs. −6.6 mm Hg; estimated treatment difference, −6.2 mm Hg; p = 0.03 by comparison of least-squares means). Patients receiving continuous molgramostim also had greater mean improvement than those receiving placebo for secondary endpoints, including the change from baseline in the St. George's Respiratory Questionnaire total score at week 24 (−12.4 points vs. −5.1 points; estimated treatment difference, −7.4 points; p = 0.01 by comparison of least-squares means). For multiple other endpoints, mean improvement was greater with continuous molgramostim than with intermittent molgramostim. The percentages of patients with adverse events and serious adverse events were similar in the three groups, except for the percentage of patients with chest pain which was higher in the continuous molgramostim group; the majority of these events were assessed to be non-cardiac in origin.

In summary, in the IMPALA study, patients with autoimmune PAP treated with daily continuous administration of inhaled MOLBREEVI experienced greater mean improvements in pulmonary gas exchange and functional health status than placebo, with generally similar rates of adverse events.

Manufacturing and Supply

We do not own or operate manufacturing facilities to produce clinical or commercial quantities of MOLBREEVI. We currently have fee-for-service contracts with two drug substance manufacturers and a drug product manufacturer that cover all steps of the manufacturing process of MOLBREEVI. We expect to continue with this outsourcing model for the foreseeable future. Following approval of MOLBREEVI, and as part of our longer-term strategy for a dual-source supply chain, we plan to engage a second source manufacturer for drug product. All of our manufacturing and supply vendors are certified by National Competent Authorities to operate under current Good Manufacturing Practices ("cGMP"), a regulatory standard for the manufacture of pharmaceuticals; however, certain manufacturing and supply vendors have not yet received an FDA inspection.

MOLBREEVI drug substance is currently manufactured by two vendors. All clinical and nonclinical trials to-date have used material sourced from GEMA Biotech S.A. ("GEMA") in Buenos Aires, Argentina and validation activities are ongoing to prepare for commercial manufacturing. We have now completed the technology transfer to Fujifilm, a well-established biologics manufacturer in Billingham, UK, including production of PPQ batches and testing comparability to the material manufactured at GEMA. We have chosen to file for Regulatory approval with Fujifilm as our drug substance manufacturer.

MOLBREEVI drug product is currently manufactured by Patheon in Ferentino, Italy. Technology transfer and process validation activities with Patheon have been completed and were re-executed in 2023 as Patheon moved the manufacturing of MOLBREEVI drug product to a new state-of-art filling line in the same facility. Following approval of MOLBREEVI, we plan to engage a second source drug product manufacturer.

MOLBREEVI drug substance and drug product is currently tested in part by Selvita S.A. ("Selvita") and its affiliates, which are headquartered in Poland with additional offices in the U.S, the UK, and Croatia. Selvita is a drug discovery company engaged in provision of integrated drug discovery services, such as custom synthesis, medicinal chemistry, protein chemistry, molecular and cell biology, and analytical development, and its biology division specializes in certified testing conducted in GLP and GMP standards in areas such as pharmacodynamic testing, cytotoxicity testing, developing and validating biophysical, biochemical and cell-based assays as well as analytical methods.

MOLBREEVI is administered to the lungs using the eFlow® Nebulizer System, manufactured by PARI Pharma GmbH in Starnberg, Germany (“PARI”). The eFlow® Nebulizer System has been Conformité Européenne (“CE”) certified (CE 0123) according to the Medical Devices Directive 93/42/EEC (as amended by Directive 2007/47/EC) as a class IIa device. The device has a 510(k) clearance in the U.S. as a general device. We have an exclusive license and a long-term supply agreement with PARI, as further discussed below, covering the eFlow® Nebulizer System for the administration of MOLBREEVI.

Commercialization

Savara holds global rights to MOLBREEVI in autoimmune PAP. We continue to pursue clinical development and regulatory approvals for MOLBREEVI. We may engage with strategic partners to collaborate on implementing optimal sales and promotion activities. Our commercialization strategy will target key prescribing physicians and centers, as well as provide patients with support programs to ensure product access. We are currently seeking approval for commercialization in the U.S., EU, and the UK. We will seek additional approvals in the rest of the world where it makes regulatory and economic sense. Upon receipt of regulatory approval in any territory, we expect to commercialize MOLBREEVI and may engage with strategic partners to optimize sales and profit.

RTW Investments, LP

On October 29, 2025, we announced our entry into a purchase and sale agreement (the “Purchase Agreement”) with funds managed by RTW Investments, LP (the “Purchaser”). Under the terms of the Purchase Agreement, the Purchaser has agreed to pay us $75.0 million (the “Purchase Price”) upon approval of MOLBREEVI by the FDA on or before March 31, 2027 and subject to satisfaction of other customary closing conditions, in exchange for a true sale of assigned interests, including the right to receive royalty payments equal to a percentage of Net Sales (as defined in the Purchase Agreement) of MOLBREEVI in the U.S. The royalty rate is tiered, with the payments ranging from 7.0% to 1.0% of Net Sales in each calendar year, with the 7.0% tier increasing to 9.5% for a calendar year if the prior year’s Net Sales do not achieve a specified level. The royalty payments commence in the first calendar quarter in which there is a commercial sale of MOLBREEVI in the U.S. and end upon the receipt by the Purchaser of $187.5 million (the “Maximum Payment”). The Purchase Agreement includes a buy-back option that may allow us to pay a specified amount up to the Maximum Payment to terminate the Purchase Agreement and all obligations in the event of certain changes of control within two years of receipt of the Purchase Price. Unless otherwise agreed with the Purchaser, we are required to use a portion of the Purchase Price to repay all outstanding indebtedness. The Purchase Agreement contains customary affirmative and negative covenants, including covenants that limit or restrict the Company’s ability to, among other things, incur indebtedness (which restrictions are eliminated after the achievement by the Company of a specified amount of Net Sales), and other provisions customary for transactions of this nature, in each case subject to certain exceptions set forth in the Purchase Agreement.

Key License and Other Agreements

Parexel

We entered into a master services agreement ("Parexel MSA") with Parexel on March 5, 2021, pursuant to which Parexel provides contract research services related to our clinical trials. The Parexel MSA has an initial term of five years. We may terminate the Parexel MSA and/or any work order without cause on 60 days’ prior written notice to Parexel. Either party may terminate the Parexel MSA or any work order, and Parexel may suspend the performance of services for a material uncured breach by the other party. In addition, either party may immediately terminate the Agreement and/or any individual work order on prior written notice if (a) continuation of the services would pose an undue risk to the health and/or wellbeing of a study participant, (b) any certificate, authorization, approval or exemption from a regulatory authority required for the conduct of the services is revoked, suspended, or expires without renewal, (c) in the reasonable opinion of such party, the continuation of the services would be in violation of applicable law, or (d) the other party becomes insolvent. Concurrent with entering the Parexel MSA, we executed a work order with Parexel, under which Parexel provides services related to the IMPALA-2 pivotal trial.

Additionally, in the second quarter of 2024, the Company initiated an open-label, multicenter clinical trial, IMPACT, for pediatric subjects with autoimmune PAP under a separate work order with Parexel. In connection with the IMPACT trial, Parexel currently has the opportunity to earn various milestone payments primarily dependent upon patient enrollment, site management, project oversight, and the compliance with defined study protocols.

Please refer to *Note 10. Commitments – Manufacturing and Other* for additional detail on our financial obligations to Parexel.

PARI Pharma GmbH

We have a license and collaboration agreement related to MOLBREEVI with PARI Pharma GmbH ("PARI" and collectively the "PARI License Agreement"). Under the PARI License Agreement, we have a worldwide, exclusive license for use and commercialization of the mesh nebulizer system which was optimized for MOLBREEVI, PARI's eFlow Nebulizer System, for the pulmonary delivery of any liquid formulation containing recombinant human GM-CSF ("rhGM-CSF") as the sole active pharmaceutical ingredient for nebulization for autoimmune PAP. Following an amendment in 2018 (the "PARI Amendment"), we have the option to add other pulmonary infections to the included indications in the future.

Under the terms of the PARI License Agreement, Savara is not permitted to work with third parties to develop any inhalation device or nebulizer for the pulmonary delivery of a pharmaceutical product containing GM-CSF as the sole active ingredient. This restriction extends (i) in the European Economic Area, until marketing approval of the product in Europe or the U.S., whichever is later, or (ii) in the rest of the world, until the termination of the PARI License Agreement.

In consideration of rights granted by PARI, a one-time fee was paid upfront, and we subsequently pay an hourly rate for work performed by PARI. Additionally, we are obligated to make future milestone payments to PARI based upon the first marketing approval for the product in the U.S., EU or Japan. The PARI Amendment expanded the development milestones in the agreement to include any additional pulmonary indications for which we use the device.

If we successfully commercialize any product candidate subject to the PARI License Agreement, we are responsible for royalty payments equal to a percentage of net sales. We are obligated to make such royalty payments until the later of (i) the expiration of the last valid claim in an issued patent covering a portion of the PARI device in the applicable country or (ii) 15 years after the first commercial sale of MOLBREEVI with the PARI device in that country (the "PARI Royalty Period"). If there is no such valid patent claim covering the applicable PARI device, the royalty owed to PARI will be decreased by a specified percentage.

The license term extends on a country-by-country basis until the end of the PARI Royalty Period or until mutually agreed by the parties. The PARI License Agreement may be earlier terminated by either party (i) upon 90 days' notice (or 30 days' notice by PARI in the event of uncured non-payment by Savara) due to a material uncured breach by the other party of its obligations or warranties thereunder or (ii) due to the other party initiating bankruptcy, reorganization or liquidation, or otherwise becoming insolvent. PARI may also terminate the PARI License Agreement in certain circumstances in which Savara transfers all or substantially all of its assets to a competitor of PARI.

We also have a commercial supply agreement with PARI (the "PARI Supply Agreement") related to the supply of the PARI eFlow® Nebulizer System and related accessories for commercial use with our products after marketing approval is obtained. Pursuant to the PARI Supply Agreement, we are obligated to purchase from PARI (i) within the European Economic Area, (a) during the first five years from marketing approval, all of our requirements for the device and related accessories and (b) thereafter 80% and (ii) in the rest of the world, all of our requirements during the PARI Royalty Period. Pricing is on a per unit basis, with a reduction in price once certain purchasing volumes are met. The term of the PARI Supply Agreement extends until the end of the PARI Royalty Period and may be earlier terminated by either party (i) by mutual agreement, (ii) upon 90 days' notice (or 10 days' notice in the event of uncured non-payment by the other party) due to a material uncured breach by the other party of the PARI Supply Agreement, (iii) due to the other party initiating bankruptcy, reorganization or liquidation, or otherwise becoming insolvent, or (iv) upon termination of the PARI License Agreement.

GEMA Biotech S.A.

In April 2019, we entered into a manufacture and supply agreement with GEMA, which was amended on December 7, 2022 and December 13, 2023 (the "GEMA Agreement"), pursuant to which GEMA may supply the active pharmaceutical ingredient ("API") for MOLBREEVI exclusively to us for commercial sale and continue to supply the API to us for clinical trials and research and development activities. Additionally, GEMA transferred and assigned to us all rights, titles, and interest in and to the master cell bank and working cell bank necessary to produce the API.

Pursuant to the terms of the GEMA Agreement, GEMA agreed to undertake the actions required to comply with the requirements of the FDA and other similar regulatory authorities and obtain the approvals necessary to manufacture and supply the API to us for commercial sale.

In addition to an agreed upon price of the API, we paid GEMA a milestone payment upon the effective date of the agreement and are required to make milestone payments upon (i) completion of certain developmental activities, (ii) successful completion of a mock pre-approval inspection, and (iii) marketing approval of a product containing the API. If we successfully commercialize a product containing the API in a country, we must pay GEMA a single digit percentage royalty on annual net sales. We are obligated to make such royalty payments until the earlier of (i) 10 years after the first receipt of marketing approval for the product in that country or (ii) the date a biosimilar of such product is first sold in that country.

Additionally, the Company is subject to a purchase obligation for ten years following the date of receipt of approval by a regulatory authority of the first regulatory filing for the marketing and sale of the first MOLBREEVI product in any country. Each year, the Company will purchase from the GEMA the API required to produce a percentage of such MOLBREEVI product it sells (the “Purchase Requirement”); provided, however, that the Purchase Requirement will no longer apply if (i) the price charged by GEMA exceeds a certain price charged by an alternative supplier, (ii) there is a shortage of supply, or (iii) GEMA at any time fails to materially fulfill a purchase order.

The term of the GEMA Agreement continues until the twentieth anniversary of the date of receipt of marketing approval for a product containing the API produced by GEMA in any country and may be extended for additional twelve-month terms by the agreement of both parties. We may terminate the GEMA Agreement immediately if (i) products containing the API will not be sold or will be withdrawn from the market, (ii) the FDA or other regulatory authority withdraws marketing approval for or fails to approve products incorporating the API, (iii) three or more batches of API supplied in any six month period fail to conform to specifications, (iv) GEMA receives notice of deficiencies in its manufacturing and fails to adequately respond, or (v) GEMA fails to achieve compliance with the requirements of the FDA and other regulatory authorities necessary to manufacture and supply the API to us for commercial sale.

Fujifilm Diosynth Biotechnologies

In February 2024, we entered into a master services agreement with Fujifilm pursuant to which Fujifilm will continue to provide development and manufacturing services related to active pharmaceutical ingredient for MOLBREEVI in accordance with the terms of separate scope of work agreements to be entered into by the parties. In conjunction with execution of the master services agreement, the Company executed a scope of work between the parties, under which Fujifilm will perform a manufacturing campaign for process performance qualification of the active pharmaceutical ingredient of MOLBREEVI.

The master services agreement will continue until it is terminated by the Company or Fujifilm, which either party may do upon three months’ notice if no activities under a scope of work are in process. The Company may terminate activities under a scope of work at any time by providing written notice, subject to the payment of termination fees, as well as payment for services performed and non-cancelable costs. The master services agreement and any scope of work may also be terminated by either party due to a material uncured breach by the other party, and Fujifilm may terminate for certain unforeseen technical issues.

Patheon UK Limited

We have entered into an agreement and related work orders with Patheon under which Patheon manufactures our MOLBREEVI product candidate for clinical trials. We may terminate the agreement at any time for any business reason.

In June 2019, we entered into a master manufacturing services agreement (the “Master Manufacturing Agreement”) with Patheon and expect in the future to enter into one or more related Product Agreements (each a "Product Agreement") to govern the terms and conditions of Patheon’s manufacture of commercial supplies of MOLBREEVI.

The Master Manufacturing Agreement had an initial term ending December 31, 2024, and will automatically renew after the initial term for successive terms of two years each if there is a Product Agreement in effect, unless a party has given notice of termination. Either party may terminate the Master Manufacturing Agreement upon the other party’s uncured material breach or insolvency. Patheon may terminate the Master Manufacturing Agreement if we assign such agreement to an assignee that is unacceptable to Patheon for certain reasons, for failure to timely pay invoices, or if we forecast zero volume for six months.

Selvita S.A.

We entered into a master services agreement with Selvita on January 17, 2024 (the "Selvita MSA") under which Selvita performs batch control testing and analyses of our MOLBREEVI drug product and drug substance through certain cell-based bioassays. The Selvita MSA has a term of five years, unless either party terminates the agreement upon ninety-day notification.

Diagnostic Testing

In December 2023, we launched the aPAP ClearPath Testing Program, a no charge third-party testing program in the U.S. that was created to reduce barriers to GM-CSF autoantibody testing and educate physicians about the clinical benefits of early testing as a diagnostic tool to help confirm or rule out autoimmune PAP. Through the aPAP ClearPath Testing Program, healthcare providers can order a simple, accurate, and noninvasive blood test that can help inform their diagnostic and management decisions for the patient. The test is available in two forms—a serum-based test and a dried blood spot test. In either form, the test is a sensitive and specific quantitative immunoassay designed to detect autoimmune PAP GM-CSF autoantibodies. We partnered with TrilliumBiO, a modern health solutions provider and a Clinical Laboratory Improvement Amendments ("CLIA")-certified lab, to develop the test. As part of the aPAP ClearPath Testing Program, a supporting disease awareness campaign was launched to improve understanding of the signs and symptoms of rare respiratory diseases, including PAP, highlight the hallmark signs and symptoms of the disease, and educate physicians about the clinical benefits of early testing. In September 2024, we launched a disease state awareness campaign targeted at pulmonologists in Europe.

Expanded Access Program

In September 2024, we announced the Savara Expanded Access Program for patients with autoimmune PAP. The program enables physicians to request MOLBREEVI for eligible autoimmune PAP patients in select geographic areas where the product is not commercially available and in compliance with local regulatory requirements. The Savara Expanded Access Program has been reviewed and allowed to proceed by the FDA, and it is currently accepting requests from eligible patients in select countries in North America and Europe. The FDA’s authorization of expanded access does not represent a determination regarding the safety or effectiveness of MOLBREEVI, nor does it constitute approval of the product candidate.

Expanded Access Programs are intended to serve as a potential pathway for a patient with a serious or immediate life-threatening disease or condition to gain access to an investigational medical treatment outside of clinical trials before it is commercially available, when no comparable or satisfactory alternative therapy options are available. The program is not a substitute for the substantial evidence of effectiveness required for regulatory approval.

Government Regulation

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of drugs, such as the drug candidate we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical, and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidate. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local, and global statutes and regulations require the expenditure of substantial time and financial resources.

Government Regulation of Drugs

U.S.

The process required by the FDA before drug product candidates, like ours, may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA’s current Good Laboratory Practices regulation;
- submission to the FDA of an Investigational New Drug application ("IND"), which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board (“IRB”) or ethics committee for each clinical site before a clinical trial can begin;

- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA, after adequate completion of all required clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs and to assure that the facilities, methods, and controls are adequate to ensure the product's quality attributes, and of selected clinical investigational sites to assess compliance with current Good Clinical Practices ("GCP"); and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the U.S., which must be updated annually and when significant changes are made.

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

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

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap. Additionally, in certain instances, a fourth phase, post approval, may be necessary or required.

- *Phase 1.* The drug product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, the initial human testing is often conducted in patients.
- *Phase 2.* The drug product is evaluated in 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, optimal dosage and dosing schedule.
- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product approval.
- *Phase 4*. In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. Phase 4 trials may be required as a condition to approval of the BLA.

Phase 1, Phase 2, and Phase 3 testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the drug characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate acceptably maintains its quality attributes over its shelf life.

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies, and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including trials initiated by investigators. The submission of a BLA requires payment of a substantial user fee to the FDA, and the sponsor of an approved BLA is also subject to annual product and establishment user fees. These fees are typically increased annually. As noted previously, MOLBREEVI for the treatment of autoimmune PAP has been granted Orphan Drug Designation, and as such is exempt from the payment of user fees under current legislation.

Within 60 days following submission of the application, the FDA reviews a BLA to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been filed, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the FDA deems that the application sufficiently relates to an unmet medical need in a serious or life-threatening indication, under Priority Review, after six months the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe and effective for the indication being pursued, and the facilities in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety and effectiveness. The FDA may convene an advisory committee to provide independent expert insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort, and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our product(s). After the FDA evaluates a BLA and conducts inspections they deem necessary to evaluate compliance with applicable regulations, the FDA may issue an Approval Letter or a Complete Response Letter. An Approval Letter authorizes commercial marketing of the product in compliance with specific prescribing information. A Complete Response Letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A Complete Response Letter may request additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy ("REMS") to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more post-marketing trials and surveillance to further assess and monitor the product's safety and

effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing trials. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of its products under development.

A sponsor may seek approval of its product candidate under programs designed to accelerate the FDA's review and approval of new drugs that meet certain criteria. Specifically, new drug products are eligible for Fast-Track Designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. For a fast-track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. A fast track designated product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after the FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing trials or completion of ongoing trials after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit.

In addition, the U.S. Food and Drug Administration Safety and Innovation Act, which was enacted and signed into law in 2012, established BTD. A sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors may request the FDA to designate breakthrough therapy at the time of, or any time after, the submission of an IND, but ideally before an end-of-phase 2 meeting with the FDA. If the FDA designates breakthrough therapy for a product candidate, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller or more efficient clinical trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. BTD also allows the sponsor to submit sections of the BLA for review on a rolling basis.

Fast Track Designation, priority review and BTD do not change the standards for approval but may expedite the development or approval process.

In March 2025, the Company announced that it had completed the rolling BLA submission to the FDA and requested Priority Review. In May 2025, we received an RTF from the FDA. The RTF was not the result of safety concerns, and the FDA did not request or recommend additional efficacy studies. We resubmitted the BLA in December 2025 and requested Priority Review of the application, and in February 2026 the FDA formally filed the BLA for MOLBREEVI and granted Priority Review.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record keeping, reporting of adverse experiences, periodic reporting, distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing (as applicable) annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as potential new application fees for supplemental applications with clinical data. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and

our third-party manufacturers. Changes to the manufacturing process are strictly regulated and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may, among other things, halt our clinical trials, require us to recall a product from distribution, or withdraw approval of the BLA.

Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or potentially require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated, or judicial action that could delay or prohibit further marketing.

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

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

The FDA closely regulates the marketing, labeling, advertising, and promotion of drugs and biologics. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Government Regulation of Combination Products

Our product candidate under development will be regulated as a combination product, which means that it is comprised of two or more different components that, if marketed individually, would be subject to different regulatory paths and would require approval of independent marketing applications by the FDA. A combination product, however, is assigned to a center within the FDA that will have primary jurisdiction over its regulation on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. We believe our product candidate includes both a drug and medical device component, and will be regulated as a drug, subject to the review of the FDA's Center for Drug Evaluation and Research, which will have primary jurisdiction over premarket development and approval. The FDA's Center for Devices and Radiological Health will provide support and review of the nebulizer component of our product candidate.

European Union

MAA

To obtain approval of a drug under the EU regulatory system, an application for a marketing authorization may be submitted under a centralized, a decentralized, or a national procedure. The centralized procedure, which is compulsory for medicines produced by certain biotechnological processes or for orphan drugs, provides for the grant of a single

marketing authorization that is valid for all EU member states, which grants the same rights and obligations in each member state as a national marketing authorization. As a general rule, only one marketing authorization may be granted for drugs approved through the centralized procedure and the marketing authorization is also relevant for the European Economic Area countries.

Under the centralized procedure, the Committee for Medicinal Products for Human Use ("CHMP") is required to adopt an opinion on a valid application within 210 days, excluding clock stops when additional information is to be provided by the applicant in response to questions. On day 120 of the procedure, once the CHMP has received the preliminary assessment reports and opinions from the Rapporteur and Co-Rapporteur designated by the CHMP, it adopts a list of questions, which are sent to the applicant together with the CHMP's overall conclusions. Applicants then have three months to respond (plus an additional three-month extension, if requested). The applicant's replies are assessed, and the assessment report is revised as necessary (and may include a prepared list of outstanding issues). By day 180 of the procedures, the revised assessment report and list of outstanding issues are sent to the applicant together with the CHMP's recommendation. Applicants then have one month to respond to the CHMP (and can request a one or two-month extension). The Rapporteur and Co-Rapporteur assess the applicant's replies and then submit them for review to the CHMP and prepare a final assessment report. Following their evaluation, the CHMP gives a favorable or unfavorable opinion as to whether to grant the marketing authorization. After the adoption of the CHMP opinion, a decision must be adopted by the European Commission, after consulting the Standing Committee of the Member States. The European Commission prepares a draft decision and circulates it to the member states; if the draft decision differs from the CHMP opinion, the Commission must provide detailed explanations. The European Commission adopts a decision within 15 days of the end of the consultation procedure.

Conditional marketing authorizations may be granted for products designated as orphan medicinal products if all of the following conditions are met: (1) the risk-benefit balance of the product is positive, (2) the applicant will likely be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs, and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

Conditional marketing authorizations are valid for one year, on a renewable basis, until the holder provides a comprehensive data package. Grant of conditional marketing authorization is dependent on the applicant's ability to fulfill the conditions within an agreed upon deadline. Applicants are subject to conditions, including the requirement to complete ongoing studies or to conduct new studies with a view to confirming that the benefit-risk balance is positive or to fulfill specific obligations in relation to pharmacovigilance. Once a comprehensive data package has been supplied, the conditional marketing authorization is replaced by a regular marketing authorization.

Exclusivities

If an approved drug contains a new active substance, it is protected by data exclusivity for eight years from the notification of the Commission decision granting the marketing authorization and then by marketing protection for an additional two or three years. Overall, the drug is protected for ten or eleven years against generic competition, and no additional exclusivity protection is granted for any new development of the active substance it contains.

During the eight-year period of data exclusivity, competitors may not refer to the marketing authorization dossier of the approved drug for regulatory purposes. During the period of marketing protection, competitors may not market their generic drugs. The period of marketing protection is normally two years but may become three years if, during the eight-year data exclusivity period, a new therapeutic indication is approved that is considered as bringing a significant clinical benefit over existing therapies.

In December 2025, the EPO announced that it intends to grant a patent for the liquid formulation of MOLBREEVI, which will provide protection in Europe through March 2041.

In December 2025, the EPO issued patent No. 4 496 611 titled, "Drug-Device Combination Comprising a Liquid Solution and a Nebulizer for Aerosolization of the Liquid Solution" which is jointly held by us and PARI and covers the combination of our investigational therapy, MOLBREEVI, and PARI's investigational eFlow® Nebulizer System that has been optimized for the delivery of MOLBREEVI. This patent covers our drug-device combination through March 2043.

Orphan Drug Status

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation to drug candidates intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and 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 U.S. Orphan Drug Designation must be requested before submitting a BLA. After the FDA grants Orphan Drug Designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Although there may be some increased

communication opportunities, Orphan Drug Designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

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

Orphan drug exclusivity could block the approval of our drug candidate for seven years if a competitor obtains approval of the same product as defined by the FDA or if our drug candidate is determined to be contained within the competitor's product for the same indication or disease.

As in the U.S., designation as an orphan drug for the treatment of a specific indication in the EU must be made before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 10 years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective, or otherwise clinically superior to the orphan designated product.

The FDA and foreign regulators expect holders of exclusivity for orphan drugs to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the orphan drug.

Breakthrough Therapy Designation

In December 2019, the FDA granted the use of MOLBREEVI for the treatment of autoimmune PAP program BTD, which provides a process for expediting the development and review of drug candidates that are intended to treat a serious condition and for which preliminary evidence indicates that the drug candidate may demonstrate substantial improvement over the available therapy.

Other Healthcare Laws and Compliance Requirements

Our sales, promotion, medical education, clinical research, and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the U.S. in addition to the FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services and state and local governments. Our promotional and scientific/educational programs and interactions with healthcare professionals must comply with the federal Anti-Kickback Statute, the civil False Claims Act ("FCA"), physician payment transparency laws, privacy laws, security laws, and additional federal and state laws similar to the foregoing.

The federal Anti-Kickback Statute prohibits, among other things, the knowing and willing, direct or indirect offer, receipt, solicitation or payment of remuneration in exchange for or to induce the referral of patients, including the purchase, order, or lease of any good, facility, item or service that would be paid for in whole or part by Medicare, Medicaid, or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced-price items and services. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to increased scrutiny and review if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct illegal per se under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. The government has enforced the federal Anti-Kickback Statute to reach large settlements with healthcare companies based on sham research or consulting and other financial arrangements with physicians. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Many states have similar laws that apply to their state health care programs as well as private payers.

Federal false claims and false statement laws, including the FCA, impose liability on persons and/or entities that, among other things, knowingly present or cause to be presented claims that are false or fraudulent or not provided as claimed for payment or approval by a federal health care program. The FCA has been used to prosecute persons or entities that "cause" the submission of claims for payment that are inaccurate or fraudulent, by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, submitting claims for services not provided as claimed, or submitting claims for services that were provided but not medically necessary. Actions under the FCA may be brought by the Attorney General or as a qui tam action by a private individual, or whistleblower, in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other illegal sales and marketing practices. The government has obtained multi-million and multi-billion-dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, certain companies that were found to be in violation of the FCA have been forced to implement extensive corrective action plans, and have often become subject to consent decrees or corporate integrity agreements, restricting the manner in which they conduct their business.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers; knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services; and willfully obstructing a criminal investigation of a healthcare offense. Like the federal Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes 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.

Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payer, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that our products, once commercialized, are sold in a foreign country, we may be subject to similar foreign laws.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Physician Payments Sunshine Act, known as "Open Payments" and implemented as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposed new reporting requirements on certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, for payments or other transfers of value made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Covered manufacturers are required to collect and report detailed payment data and submit legal attestation to the accuracy of such data to the government each year.

On October 24, 2018, then President Trump signed into law the "Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act" which in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine") extends the reporting and transparency requirements under Open Payments to physician assistants, nurse practitioners, and other mid-level practitioners. Additionally, entities that do not comply with mandatory reporting requirements may be subject to a corporate integrity agreement. Certain states also mandate implementation of commercial compliance programs, impose restrictions on covered manufacturers' marketing practices and/or require the tracking and reporting of gifts, compensation, and other remuneration to physicians and other healthcare professionals.

We are also subject to data privacy and security regulation by the federal government and the states in which we conduct our business and the EU with the General Data Protection Regulation rules, which became effective in May 2018. HIPAA, as amended by the Health Information Technology and Clinical Health Act ("HITECH"), and their respective implementing regulations, imposes specified requirements on certain health care providers, plans and clearinghouses (collectively, "covered entities") and their "business associates," relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain, or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In

addition, certain states have their own laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other and/or HIPAA in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to them, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, imprisonment, contractual damages, reputational harm, and diminished profits and future earnings, any of which could adversely affect our ability to operate our business and our financial results.

In addition to the foregoing health care laws, we are also subject to the U.S. Foreign Corrupt Practices Act ("FCPA") and similar worldwide anti-bribery laws, which generally prohibit companies and their intermediaries from making improper payments to government officials or private-sector recipients for the purpose of obtaining or retaining business. We have adopted an anti-corruption policy which mandates compliance with the FCPA and similar anti-bribery laws applicable to our business throughout the world. However, we cannot assure that such a policy or procedures implemented to enforce such a policy will protect against intentional, reckless, or negligent acts committed by our employees, distributors, partners, collaborators, or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties, or prosecution and have a negative impact on our business, results of operations, and reputation.

Coverage and Reimbursement

Sales of pharmaceutical products depend significantly on the extent to which coverage and adequate reimbursement are provided by third-party payers. Third-party payers include state and federal government health care programs, managed care providers, private health insurers and other organizations. Although we currently believe that third-party payers will provide coverage and reimbursement for our product candidate, if approved, we cannot be certain of this. Third-party payers are increasingly challenging the price, examining the cost-effectiveness, and reducing reimbursement for medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. The U.S. government, state legislatures, and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement, and requirements for substitution of generic products. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results. We may need to conduct expensive clinical trials to demonstrate the comparative cost-effectiveness of our products. The product candidate that we develop may not be considered cost-effective and thus may not be covered or sufficiently reimbursed. It is time consuming and expensive for third-party payers to seek coverage and reimbursement. Thus, one payer's decision to provide coverage and adequate reimbursement for a product does not assure that another payer will provide coverage or that the reimbursement levels will be adequate. Moreover, a payer's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow third-party payers to sell our products on a competitive and profitable basis.

Healthcare Reform

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could materially affect our ability to sell our products profitably. Among policy makers and payers in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

By way of example, in March 2010, the Affordable Care Act was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. Among the provisions of the Affordable Care Act of importance to our product candidate are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs; however designated Orphan Drugs, such as MOLBREEVI, are generally exempt from these fees;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include, among others, the Budget Control Act of 2011, which mandates aggregate reductions to Medicare payments to providers of up to 2% per fiscal year effective April 1, 2013, and due to subsequent legislative amendments, will remain in effect through 2029 unless additional Congressional action is taken. In January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidate, if approved, and, accordingly, our financial operations.

There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect additional challenges and amendments in the future. It is unclear how this such effort to repeal and replace the Affordable Care Act will impact the healthcare industry or our business operations. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payers. 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.

Other Foreign Regulations

In addition to regulations mentioned above, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the U.S. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from country to country.

Intellectual Property

We strive to protect the proprietary technology that we believe is important to our business, including our product candidate and our processes. We seek patent protection in the U.S. and internationally for our products, their methods of use and any other technology to which we have rights, as appropriate, such as device exclusivity. We also rely on trade secrets that may be important to the development of our business.

Our success will, in part, depend on the ability to obtain and maintain patent and other proprietary rights in commercially important technology, inventions and know-how related to our business, the validity and enforceability of our patents, the continued confidentiality of our trade secrets as well as our ability to operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We cannot be sure patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be sure that any of our existing patents or any patents we may own or license in the future will be useful in protecting our technology and products. For this and more comprehensive risks related to our intellectual property, please see *Risk Factors – Risks Related to Our Intellectual Property*.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, significant aspects of our processes and proprietary technology portfolio are based on unpatented trade secrets

and know-how. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors, and commercial partners. These agreements are designed to protect proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. While we have confidence in our key individuals, consultants, partner organizations, and systems, agreements or security measures may be breached, and there may not be adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Competition

The pharmaceutical industry is highly competitive and subject to continuous technological change. We compete in the segment of the pharmaceutical, biotechnology, and other related markets focused on rare respiratory diseases. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies, and research institutions. We believe that key competitive factors affecting the commercial success of our product candidate will be efficacy, safety and tolerability profile, reliability, convenience of dosing, price and reimbursement. Many of our potential competitors, either alone or with their collaboration partners have substantially greater financial, technical, and human resources than us, and significantly greater experience in the discovery and development of product candidates, manufacturing, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be faster and more successful in obtaining FDA approval for therapies and achieving widespread market acceptance. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of very capable competitors. We anticipate facing intense and increasing competition as new drugs enter the market and advanced technologies become available. Our competitors' products may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our therapies obsolete or non-competitive before we can recover development and commercialization expenses.

A glycosylated GM-CSF product, sargramostim (Leukine), available in the U.S., is approved for intravenous or subcutaneous delivery in patients with neutropenia following cancer chemotherapy. Leukine has not been approved in the U.S. or Europe for the treatment of autoimmune PAP or any other acute or chronic lung disease but is sometimes used in the U.S. as an off-label, pharmacy-compounded product (injectable product compounded for inhalation delivery). The drug substance in Leukine, sargramostim, has been used in a nonclinical research project conducted by NIH/TRND in collaboration with the University of Cincinnati College of Medicine on the potential application of inhaled GM-CSF as a treatment for autoimmune PAP. No clinical trials have been conducted to date under this collaboration project. Additionally, in April 2024, sargramostim was approved by the Japanese Pharmaceuticals and Medical Device Agency ("PMDA") for the treatment of autoimmune PAP. The approval was based on a multicenter clinical trial of inhaled sargramostim in autoimmune PAP, using a standard commercially available nebulizer, which was conducted by a consortium of independent clinical investigators in Japan. Sargramostim, marketed in Japan by Nobelpharma Co. Ltd., has the potential to present a material competitive threat to the commercial success of MOLBREEVI in Japan. In addition, in November 2018 and June 2024, Partner Therapeutics, Inc., a commercial biotechnology company, was granted Orphan Drug Designation for Leukine for the treatment of PAP by the FDA and EMA, respectively. Except for the aforementioned treatments, we are not aware of any other companies developing an inhaled form of GM-CSF for autoimmune PAP in the U.S. or elsewhere.

Employees and Human Capital

We are committed to attracting and retaining the best possible talent. As of March 13, 2026, we had approximately 70 employees as well as several third-party consultants. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Attraction, Development and Retention

We believe our future success will depend in large part on our continued ability to attract and retain highly skilled employees. Our compensation program, including salary, bonus, benefits as well as short and long-term incentives, is designed to help us to attract and retain individuals whose skills are important to our current and long-term success. Our total compensation package is generally positioned within the competitive ranges of our peer market, with differences generally based on tenure, skills, and performance needed to attract and retain key talent. We have also implemented a spot bonus program that allows employees to nominate their colleagues for cash awards in recognition of notable achievements.

We believe that continued professional growth and development are essential to helping our team stay on top of current rules, laws, trends, and events which impact their duties. We seek to develop our employee talent within the organization

through access to training, continuous learning programs, and other development initiatives. We foster a culture of empowerment, transparency, and respect.

Diversity and Inclusion

We value diverse backgrounds and viewpoints and are committed to equal opportunity. We aim to recruit, hire, place, develop, compensate, and advance people based on the needs of our organization and the qualifications, performance, skills, and experience of our people. We expect to continue to enhance our workforce diversity and advance the development of diverse talent. We consistently evaluate the opportunity for diversity for both our employee workforce and our board of directors. Upon beginning employment with Savara, all employees receive training on workplace diversity and inclusion.

Health and Safety

The health and safety of our employees is a top priority, and our goal is to provide a safe and healthy work environment for all personnel. We have provided our employees the ability to work remotely in order to best manage business and personal responsibilities. We will continue to manage our business with a focus towards the safety of our employees.

Corporate Information

Our company was incorporated in Delaware in December 1995. Our website is http://www.savarapharma.com. Information found on our website is not incorporated by reference into this annual report on Form 10-K. We make our filings with the U.S. Securities and Exchange Commission (“SEC”) including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments and exhibits to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (“Exchange Act”), available free of charge on or through our website, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding our filings at http://www.sec.gov.

Trademarks

“Savara Inc.,” "autoimmune PAP ClearPath," "MOLBREEVI," and the Savara logo are trademarks of Savara or its subsidiaries in the U.S. and other jurisdictions. Other third-party logos and product/trade names are registered trademarks or trade names of their respective companies. Use or display by us of other parties’ trademarks, service marks, trade names, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark, service mark, trade name, trade dress or product owners.

Item 1A. Risk Factors.

Investment in our common stock involves a high degree of risk and uncertainty. Our business, operating results, growth prospects and financial condition are subject to various risks, many of which are not exclusively within our control, that may cause actual performance to differ materially from historical or projected future performance. We urge investors to consider carefully the risks described below, together with all of the information in this report and our other public filings, before making investment decisions regarding our securities. Each of these risk factors, as well as additional risks not presently known to us or that we currently deem immaterial, could adversely affect our business, operating results, growth prospects or financial condition, as well as the trading price of our common stock, in which case you may lose all or part of your investment.

Risks Related to Development and Commercialization of our Product Candidate

We are substantially dependent upon the clinical, regulatory, and commercial success of our sole product candidate, MOLBREEVI. If we are unable to successfully complete clinical development of, obtain regulatory approval for, and successfully commercialize MOLBREEVI, our business may be harmed.

The success of our business is dependent on our ability to advance the clinical development of our sole product candidate, MOLBREEVI, an investigational inhaled GM-CSF for the treatment of autoimmune PAP. To date, we have never obtained regulatory approvals for or commercialized a product candidate, and we may never be able to develop a marketable product. We are devoting, and expect to continue to devote, substantially all our efforts and financial resources to the development of MOLBREEVI for autoimmune PAP, including clinical trials, regulatory approval, and, if approved, commercialization. Our business depends heavily on the successful completion of clinical development and subsequent regulatory approval of MOLBREEVI for autoimmune PAP.

We are conducting IMPALA-2, a global Phase 3 pivotal trial designed to compare the efficacy and safety of MOLBREEVI 300 µg administered once daily by inhalation with matching placebo in patients with autoimmune PAP. Although we may believe the trial demonstrates promising results, regulatory authorities may analyze or weigh trial data differently, resulting in delay or failure to obtain marketing approval or a requirement to conduct confirmatory studies.

We are not permitted to commercialize MOLBREEVI in the U.S. until we receive approval of a BLA, or in any other country until we receive the requisite approvals from the appropriate regulatory authorities. Failure to obtain such approvals could impair our ability to generate revenues from the product candidate, which would have a material adverse effect on our business, operating results, growth prospects or financial condition, as well as the trading price of our common stock.

Given the developmental nature of our product candidate, we are subject to risks associated with initiating, completing, and achieving positive outcomes from our current and future clinical trials.

If we successfully complete the necessary clinical trials for our product candidate, our success will be subject to the risks associated with obtaining regulatory approvals, product launch, and commercialization, including:

- rejection of our regulatory submissions for our product candidate by the FDA or other regulatory authorities;
- delays during regulatory review and/or requirements of additional chemistry, manufacturing, and controls, nonclinical, or clinical studies, resulting in increased costs and/or delays in marketing approval and subsequent commercialization of the product candidate in the U.S. and other markets;
- inability to consistently manufacture commercial supplies of drug and delivery devices resulting in slowed market development and lower revenue;
- poor commercial sales due to:
    - the inability of our future sales organization or our potential commercialization partners to effectively sell the product candidate;
    - our lack of success in educating physicians and patients about the benefits, administration, and use of our product candidate;
    - the availability, perceived advantages, relative cost, relative safety, and relative efficacy of other products or treatments for the targeted indications of the product candidate;
    - low patient demand for the product candidate; and

- poor prescription coverage and inadequate reimbursement for our product candidate;
- our inability to enforce our intellectual property rights in our product candidate; and
- reduction in the safety profile of our product candidate following approval.

Many of these clinical, regulatory, and commercial matters are beyond our control and are subject to other risks described elsewhere in this *Item 1A, Risk Factors* section. Accordingly, we cannot assure that we will be able to advance our product candidate further through final clinical development, or obtain regulatory approval, commercialize, or generate significant revenue. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of our product candidate. If development of our product candidate is unsuccessful or delayed, we may be unable to obtain required regulatory approvals and be unable to commercialize our product candidate on a timely basis, if at all.

Pharmaceutical products are subject to stringent regulatory requirements covering quality, safety, and efficacy. Only after successfully completing extensive pharmaceutical development, nonclinical testing, and clinical trials may a product be considered for regulatory approval.

Clinical trials are expensive, difficult to design and implement, the outcome is inherently uncertain, and failure or delay may occur at any time. We may experience a number of unforeseen events that cause our clinical trials not commence or not be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including:

- inability to raise sufficient funding to initiate or continue a clinical trial;
- delays in obtaining regulatory approval to commence or extend a clinical trial;
- delays in identifying and reaching agreement on acceptable terms with prospective CROs, clinical trial sites, and investigators, which agreements can be subject to extensive negotiation and may vary significantly among trial sites;
- delays in obtaining ethics committee approval to conduct or extend a clinical trial at a prospective site;
- delays in reaching agreements on acceptable terms with prospective CMOs or other vendors for the production and supply of clinical trial material and, if necessary, drug delivery devices, which agreements can be subject to extensive negotiation;
- delays in the production or delivery of sufficient quantities of clinical trial material or drug delivery devices from our CMOs and other vendors to initiate or continue a clinical trial;
- delays in distributing clinical trial material due to import restrictions or licenses in target countries;
- delays due to product candidate recalls as the result of stability failure, excessive product complaints, or other failures of the product candidate during its use or testing;
- invalidation of clinical data caused by premature unblinding or integrity issues or by mixing up of the active drug and placebo through randomization or manufacturing errors;
- delays by CROs, CMOs, and other third-party contractors in conducting activities in accordance with applicable policies and procedures and in accordance with agreed upon timelines;
- delays in identifying and hiring or engaging, as applicable, additional employees or consultants to assist in managing clinical trial-related activities;
- delays in recruiting and enrolling individuals to participate in a clinical trial, which historically can be challenging in orphan diseases;
- delays caused by patients dropping out of a clinical trial due to side effects, concurrent disorders, difficulties in adhering to the trial protocol, unknown issues related to different patient profiles than in previous trials, or otherwise;
- delays in having patients complete participation in a clinical trial;
- delays resulting from clinical trial sites dropping out of a trial, providing inadequate staff support for the trial, problems with shipment of trial supplies to clinical sites, or focusing its staff's efforts on enrolling trials that compete for the same patient population;

- suspension of enrollment at a trial site or the imposition of a clinical hold by the FDA or other regulatory authority following an inspection of clinical trial operations at trial sites or finding of a drug-related serious adverse event;
- delays in quality control/quality assurance procedures necessary for trial database lock and analysis of unblinded data;
- delays, inconsistencies, or negative results in statistical analyses of clinical trial data;
- delays in enrollment and the treatment of patients caused by global health risks; and
- delays due to supply chain disruptions as a result of global health risks, international conflict, or other unexpected event.

Clinical trials may not begin on time or be completed in the time frames we anticipate and may be costlier than we anticipate for a variety of reasons, including one or more of those described above. The length of time necessary to successfully complete clinical trials vary significantly and is difficult to predict accurately. We may make statements regarding anticipated timing for completion of enrollment in and/or availability of results from our clinical trials, but such predictions are subject to a number of significant assumptions and actual timing may differ materially for a variety of reasons, including patient enrollment rates, length of time needed to prepare raw trial data for analysis and then to review and analyze it, and other factors described above. If we experience delays in the completion of a clinical trial, if a clinical trial is terminated, or if failure to conduct a trial in accordance with regulatory requirements or the trial's protocol leads to deficient safety and/or efficacy data, the regulatory approval and/or commercial prospects for our product candidate may be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials likely will increase our development costs. Further, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials have in the past and may in the future ultimately lead to the denial of regulatory approval of a product candidate. Even if we ultimately commercialize a product candidate, the standard of care may have changed or other therapies for the same indications may have been introduced to the market in the interim and may establish a competitive threat to us or diminish the need for our products.

Failure at any stage of clinical testing is not uncommon and we may encounter problems that would require additional, unplanned trials or cause us to abandon a clinical development program.

In addition, a clinical trial may be suspended or terminated by us, an IRB, a data safety monitoring board, the FDA, or other regulatory authorities due to a number of factors, including:

- lack of adequate funding to continue the trial;
- failure to conduct the trial in accordance with regulatory requirements or the trial's protocol;
- inspection of clinical trial operations or sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues, including adverse side effects; or
- changes in governmental regulations or administrative actions, such as lay-offs and staffing at regulatory agencies such as the FDA.

Changes in governmental regulations and guidance relating to clinical trials may occur, and we may need to amend clinical trial protocols to reflect these changes, or we may amend trial protocols for other reasons. Amendments may require us to resubmit protocols to IRBs for re-examination and approval or renegotiate terms with CROs, clinical trial sites, and investigators, all of which may adversely impact the costs or timing of or our ability to successfully complete a trial.

Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidate. There are significant risks that ongoing and future clinical trials of our product candidate will not be successful. The results of preclinical and early clinical trials may not be predictive of the results of later-stage clinical trials, and the possible lack of standardization across multiple investigative sites may induce variability in the results which can interfere with the evaluation of treatment effects. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. For example, the top line results from our IMPALA trial were released by us on June 12, 2019 and did not meet all of the statistical goals and protocol end points. On October 1, 2019, we received a written response from the FDA in connection with a Type C meeting regarding the MOLBREEVI development program for autoimmune PAP and results from IMPALA in which the FDA indicated that the data provided did not provide sufficient evidence of efficacy and safety for the treatment of autoimmune PAP.

Negative or inconclusive results could cause the FDA and other regulatory authorities to require us to repeat or conduct additional clinical trials, which could significantly increase the time and expense associated with development of that product candidate or cause us to elect to discontinue one or more clinical programs.

There is significant uncertainty regarding the regulatory approval process for any investigational new drug. Substantial further testing and validation of our product candidate and related manufacturing processes may be required, and regulatory approval may be conditioned, delayed, or denied, any of which could delay or prevent us from successfully marketing our product candidate and substantially harm our business.

Regulatory approval is required before a pharmaceutical product can be commercially marketed and sold, and various federal and foreign statutes and regulations also govern or materially influence the manufacturing, safety, labeling, storage, record keeping, and marketing of pharmaceutical products. The process of obtaining these approvals and the subsequent compliance with appropriate U.S. and foreign statutes and regulations is time-consuming and requires the expenditure of substantial resources.

Significant uncertainty exists with respect to the regulatory approval process for any investigational new drug, including MOLBREEVI. Regardless of any guidance the FDA or foreign regulatory agencies may provide a drug's sponsor during its development, the FDA or foreign regulatory agencies retain complete discretion in deciding whether to accept a BLA, or the equivalent foreign regulatory approval submission for filing or, if accepted, whether to approve a BLA. There are many components to a BLA or marketing authorization application submission in addition to clinical trial data. For example, the FDA or foreign regulatory agencies will review the sponsor's internal systems and processes, as well as those of its CROs, CMOs, and other vendors, related to development of its product candidates, including those pertaining to its clinical studies and manufacturing processes. Before accepting a regulatory approval submission for review or before approving such submission, the FDA or foreign regulatory agencies may request that we provide additional information that may require significant resources and time to generate. For example, in May 2025 we received the RTF requesting the Company provide additional data related to Chemistry, Manufacturing, and Controls. The FDA or foreign regulatory agencies may choose not to approve a BLA or its equivalent for a variety of reasons, including a decision related to the safety or efficacy data, manufacturing controls or systems, or for any other issues that the agency may identify related to the development of its product candidates. Even if one or more Phase 3 clinical trials are successful in providing statistically significant evidence of the efficacy and safety of the investigational drug, the FDA or foreign regulatory agencies may not consider efficacy and safety data from the submitted trials adequate scientific support for a conclusion of effectiveness and/or safety and may require one or more additional Phase 3 or other trials prior to granting marketing approval. If this were to occur, the overall development cost for the product candidate would be substantially greater and competitors may bring products to market before us, which could impair our ability to generate revenues from the product candidate, or even seek approval, if blocked by a competitor's Orphan Drug exclusivity, which would have a material adverse effect on our business, financial condition, and results of operations.

Further, development of our product candidate and/or regulatory approval may be delayed for reasons beyond our control. Regulations or policies may be changed prior to submission of a marketing application that result in delays or require higher hurdles than currently anticipated. These may occur as a result of drug scandals, recalls, or a political environment unrelated to our products. For example, the FDA has granted MOLBREEVI for autoimmune PAP Fast Track and BTD, which are each designed to expedite the development and review of certain drugs. If there were a change in FDA policies and we were to lose those designations, it could cause delays in the regulatory review process. Additionally, changes in FDA priorities due to a new administration, layoffs, or U.S. federal government shut-downs or budget sequestrations, such as the shut-down that occurred from October 1, 2025 until November 12, 2025, may result in significant reductions to the FDA's budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidate or obtain regulatory approval for our product candidate.

Even if the FDA or foreign regulatory agencies grant approvals for a product candidate, the conditions or scope of the approval(s) may limit successful commercialization of the product candidate and impair our ability to generate substantial sales revenue. For example, MOLBREEVI could be approved with restrictions for use only by patients unresponsive to the current standard of care, or the FDA may approve label claims with age restrictions and/or treatment duration limitations. The FDA may limit the label of MOLBREEVI to a subset of patients based on a review of which patient groups had the greatest efficacious response in clinical trials. Such label restriction may be undesirable and may limit successful commercialization. The FDA or foreign regulatory agencies may also only grant marketing approval contingent on the performance of costly post-approval nonclinical or clinical studies, or subject to warnings or contraindications that limit commercialization. Additionally, even after granting approval, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, and continued compliance with cGMP, GCP, international conference on

harmonization regulations, and good laboratories practice ("GLP"), which are regulations and guidelines that are enforced by the FDA or foreign regulatory agencies for all clinical development and for any clinical studies that we conduct post-approval. The FDA or foreign regulatory agencies may decide to withdraw approval, add warnings, or narrow the approved indications in the product label, or establish risk management programs that could restrict distribution of our products. These actions could result from, among other things, safety concerns, including unexpected side effects or drug interaction problems, or concerns over misuse of a product. If any of these actions were to occur following approval, we may have to discontinue commercialization of the product, limit our sales and marketing efforts, implement risk minimization procedures, and/or conduct post-approval studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues.

Our MOLBREEVI product candidate may cause undesirable side effects or adverse events or have other properties that could delay or prevent our clinical development, regulatory approval, or commercialization.

Undesirable side effects or adverse events caused by our MOLBREEVI product candidate could interrupt, delay, or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all indications, and in turn prevent us from commercializing our product candidate. A significant challenge in clinical development is that the patient population in early trials, where small numbers of patients are required, is different from the patient population observed in later stage trials, where larger groups of patients are required. As such, efficacy or safety results may differ significantly between trials. If we fail to demonstrate the efficacy of our drug candidate or undesirable side effects occur, they could possibly prevent approval, which would have a material and adverse effect on our business.

Additionally, the patient population in our clinical trials is a defined subset of patients who have agreed to enter the trials. It is possible undesirable side effects could be seen in the larger addressable patient population that were not observed in the clinical trials. If our product candidate receives marketing approval and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as a boxed warning or a contraindication;
- we may be required to change the way the product is administered, conduct additional clinical trials, or change the labeling of the product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenue from its sale.

Even if we receive regulatory approval for MOLBREEVI, we may face regulatory requirements that could materially and adversely affect our business, financial condition, and results of operations.

Even if initial regulatory approval is obtained, as a condition to the initial approval, the FDA or a foreign regulatory agency may impose significant restrictions on a product’s indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or marketing surveillance programs, any of which would limit the commercial potential of the product. Our MOLBREEVI product candidate also will be subject to ongoing FDA requirements related to the manufacturing processes, labeling, packaging, storage, distribution, advertising, promotion, record-keeping, and submission of safety and other post-market information regarding the product. For instance, the FDA may require changes to approved drug labels, require post-approval clinical studies, and impose distribution and use restrictions on certain drug products. In addition, approved products, manufacturers, and manufacturers’ facilities are subject to continuing regulatory review and periodic inspections. If previously unknown problems with a product are discovered, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, the FDA may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we or a CMO of ours fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or enforcement letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend or terminate any ongoing clinical trials;

- refuse to approve pending applications or supplements to approved applications;
- exclude our product from reimbursement under government healthcare programs, including Medicaid or Medicare in the U.S.;
- impose restrictions or affirmative obligations on our or our CMO's operations, including costly new manufacturing requirements;
- close the facilities of a CMO; or
- seize or detain products that are deemed to be adulterated.

If MOLBREEVI receives regulatory approval but fails to achieve significant market acceptance among the medical community, patients, or third-party payers, the revenue we generate from its sales will be limited and our business may never achieve profitability.

Our success will depend in substantial part on the extent to which our product candidate, if approved, is accepted by the medical community and patients and reimbursed by third-party payers, including government payers. The degree of market acceptance with respect to our approved product, if any, will depend upon a number of factors, including:

- the safety and efficacy of our product as demonstrated in clinical trials;
- acceptance in the medical and patient communities of our product as a safe and effective treatment;
- the product's taste, ease of use, or features associated with the delivery device;
- the perceived advantages of our product over alternative treatments, including with respect to the incidence and severity of any adverse side effects and the cost of treatment;
- the indications for which our product is approved;
- claims or other information (including limitations or warnings) in the product's approved labeling;
- reimbursement and coverage policies of government and other third-party payers;
- availability of alternative treatments;
- pricing and cost-effectiveness of our product relative to alternative treatments;
- smaller-than-expected market size due to lack of disease awareness of a rare disease, or the patient population with a specific rare disease being smaller than anticipated;
- inappropriate diagnostic efforts due to limited knowledge and/or resources among clinicians;
- difficulties identifying patients;
- the prevalence of off-label substitution of chemically equivalent products or alternative treatments; and
- the resources we devote to marketing our product and restrictions on promotional claims we can make with respect to the product.

We cannot predict with reasonable accuracy whether physicians, patients, healthcare insurers, health maintenance organizations, or the medical community in general, will accept or utilize our product, if approved. If our product candidate is approved but does not achieve an adequate level of acceptance by these parties, we may not generate sufficient revenue to become or remain profitable. In addition, our efforts to educate the medical community and third-party payers regarding benefits of our product may require significant resources and may never be successful.

If we determine that our product candidate may not achieve adequate market acceptance or that the potential market size does not justify additional expenditures on the program, we may reduce our expenditures on the development and/or the process of seeking regulatory approval of the product candidate while we evaluate whether and on what timeline to move the program forward.

Even if we receive regulatory approval to market our product candidate in the U.S., we may never receive approval or commercialize our product outside of the U.S., which would limit our ability to realize the full commercial potential of our product candidate.

In order to market products outside of the U.S., we must establish and comply with the numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. The time required to obtain approval

in other countries generally differs from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S., as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the U.S. As described above, such effects include the risks that our product candidate may not be approved for all indications requested, which could limit the uses of our product candidate and have an adverse effect on product sales, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up trials.

Risks Related to Our Capital Requirements and Financial Condition

We have incurred significant losses since inception and expect that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.

We are a clinical development-stage biopharmaceutical company, and we have not been profitable since we commenced operations and may not ever achieve profitability. In addition, we have limited history as an organization and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Drug development is a highly speculative undertaking and involves a substantial degree of risk. We have not obtained any regulatory approvals for a product candidate, commercialized a product candidate, or generated any product revenue. We have devoted significant resources to research and development and other expenses related to our ongoing clinical trials and operations, in addition to acquiring product candidates.

For the year ended December 31, 2025, we incurred a net loss of $118.8 million, and net cash used in operating activities was $101.0 million. At December 31, 2025, our cash, cash equivalents and short-term investment securities were approximately $235.7 million, and working capital was approximately $221.2 million. At December 31, 2025, we had an accumulated deficit of $608.1 million. We expect to continue to incur substantial operating losses for the next several years as we seek to advance our MOLBREEVI product candidate through clinical development, global regulatory approvals, and commercialization. No revenue from operations will likely be available until, and unless, our current product candidate, MOLBREEVI, is approved by the FDA or another regulatory agency and successfully marketed, or we enter into an arrangement that provides for licensing revenue or other partnering-related funding, outcomes which we may not achieve.

We may require additional financing to support our operations and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce, or terminate our product development efforts or other operations.

Since our Aravas subsidiary was formed in 2007, most of our resources have been dedicated to the development and acquisition of our product candidates, primarily MOLBREEVI. Our priority remains the continued development of MOLBREEVI for the treatment of autoimmune PAP. We cannot estimate with reasonable certainty the actual amounts necessary to successfully complete the development and commercialization of our product candidate, and there is no certainty that we will be able to raise the necessary capital on reasonable terms or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce, or terminate our establishment of sales and marketing, manufacturing or distribution capabilities, development activities, other activities that may be necessary to commercialize our product candidate, or conduct preclinical or clinical trials.

Our capital requirements for the foreseeable future will depend in large part on, and could increase significantly as a result of, our expenditures on our development programs. Future expenditures on our development programs are subject to many uncertainties, and will depend on, and could increase significantly as a result of, many factors, including:

- the number, size, complexity, results, and timing of our drug development programs;
- the timing and terms of any collaborative or other strategic arrangement that we may establish;
- the number of clinical and nonclinical studies necessary to demonstrate acceptable evidence of the safety and efficacy of our product candidate;
- changes in standards of care which could increase the size and complexity of our clinical trials;
- the number of patients who participate, the rate of enrollment, and the ratio of randomized to evaluable patients in each clinical trial;

- the ability to locate patients to participate in a trial given the limited number of patients available for orphan or ultra-orphan indications;
- the number and location of sites and the rate of site initiation in each trial;
- the duration of patient treatment and follow-up;
- the potential for additional safety monitoring or other post-marketing trials that may be requested by regulatory agencies;
- the time and cost to manufacture clinical trial material and commercial product, including process development and scale-up activities, and to conduct stability studies, which can last several years;
- the degree of difficulty and cost involved in securing alternate manufacturers or suppliers of drug product, components, or delivery devices, as necessary to meet FDA requirements and/or commercial demand;
- the costs, requirements, timing of, and the ability to, secure regulatory approvals;
- the extent to which we increase our workforce and the costs involved in recruiting, training, and incentivizing new employees;
- the costs related to developing, acquiring, and/or contracting for sales, marketing, and distribution capabilities, supply chain management capabilities, and regulatory compliance capabilities, if we obtain regulatory approval for our product candidate and commercialize it without a partner;
- the costs involved in evaluating competing technologies and market developments or the loss in sales in case of such competition;
- the costs involved in establishing, enforcing, or defending patent claims and other proprietary rights; and
- the continuing negative impacts of global health risks.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidate, technologies, future revenue streams, or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our stockholders will be diluted, and the terms of any new equity securities may have preferential rights over our common stock. In particular, due to the price per share of our common stock, any sale of our equity securities to raise significant capital would result in substantial ownership dilution to our stockholders. If we raise additional capital through debt financing, it may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures, or subject to specified financial ratios, any of which could restrict our ability to develop and commercialize our product candidate or operate as a business.

The Hercules Loan Agreement contains covenants which may adversely impact our business and the failure to comply with such covenants could cause our outstanding debt to become immediately payable or accelerate principal payments.

We are a party to a Loan and Security Agreement, dated March 26, 2025, with the lenders party thereto (the "Lenders") and Hercules Capital, Inc., as administrative agent and collateral agent, which was amended by the First Amendment dated January 26, 2026 (the "First Amendment") (the loan agreement as amended, the "Hercules Loan Agreement"), pursuant to which we have borrowed $30 million of term loans and may borrow up to an additional $75 million of term loans if we are able to satisfy the conditions precedent described under *Note 7. Debt Facility* of the consolidated financial statements in this annual report on Form 10-K. As security for our borrowings under the Hercules Loan Agreement, we pledged substantially all of our assets. The Hercules Loan Agreement includes a number of restrictive covenants, including restrictions on incurring additional debt, making investments, granting liens, disposing of assets, paying dividends, and redeeming or repurchasing capital stock, and a number of affirmative covenants, including the Cash Requirement and the Conditional Minimum Revenue Covenant (as such terms are defined in *Note 7. Debt Facility* and *Note 16. Subsequent Events* of the consolidated financial statements in this annual report on Form 10-K). Collectively, these covenants could constrain our ability to grow our business through acquisitions or engage in other transactions. The Hercules Loan Agreement includes customary events of default, such as our failure to pay amounts due, our failure to comply with covenants, or the occurrence of an event that would reasonably be expected to have a material adverse event on our business. Upon the occurrence and during the continuation of an event of default, the Lenders could declare all outstanding loans under the Hercules Loan Agreement immediately due and payable and exercise remedies against us and the collateral. Such an event would have a material adverse effect on our liquidity, financial condition, operating results, business, and prospects and cause the price of our common stock to decline.

Refer to *Note 7. Debt Facility* and *Note 16. Subsequent Events* of the consolidated financial statements in this annual report on Form 10-K for additional discussion.

Any future acquisitions that we make could disrupt our business and harm our financial condition.

We may, from time to time, evaluate potential strategic acquisitions of complementary businesses, products, or technologies. In addition, we may evaluate joint ventures, licensing opportunities, and other collaborative projects. We may not be able to identify appropriate acquisition candidates or strategic partners, or successfully negotiate, finance, or integrate acquisitions of any businesses, products, or technologies. Furthermore, the integration of any acquisition and management of any collaborative project may divert our management's time and resources from our core business and disrupt our operations. Any cash acquisition we pursue would diminish the funds otherwise available to us for other uses. Any acquisition using our stock would dilute our stockholders' ownership interests.

If we engage in acquisitions of companies, products, or technologies in order to execute our business strategy, we may need to raise additional capital. We may raise additional capital in the future through one or more financing vehicles that may be available to us including (i) new collaborative agreements; (ii) expansions or revisions to existing collaborative relationships; (iii) private financings; (iv) other equity or debt financings; (v) monetizing assets; and/or (vi) the public offering of securities.

If we are required to raise additional capital in the future, it may not be available on favorable financing terms within the time required, or at all. If additional capital is not available on favorable terms when needed, we will be required to raise capital on adverse terms or significantly reduce operating expenses through the restructuring of our operations or deferral of strategic business initiatives. If we raise additional capital through a public offering of securities, a substantial number of additional shares may be issued, which may negatively affect our stock price and these additional shares will dilute the ownership interest of our current investors.

We have IPR&D and future impairment of IPR&D may have an adverse impact on our future financial condition and results of operations.

As of December 31, 2025, we had IPR&D of approximately $11.6 million. Our intangible assets have been previously impaired and remain subject to additional impairment analyses whenever an event or change in circumstances indicates the carrying amount of such an asset may not be recoverable and is tested annually on September 30th. Events giving rise to impairment are difficult to predict and are an inherent risk in the pharmaceutical industry. Some of the potential risks that could result in impairment of our IPR&D include negative clinical trial results, adverse regulatory developments, delay or failure to obtain regulatory approval, additional development costs, changes in the manner of our use or development of our product candidate, competition, earlier than expected loss of exclusivity, pricing pressures, higher operating costs, geopolitical conflicts, changes in tax laws, prices that third parties are willing to pay for our IPR&D or similar assets in an arm's-length transaction being less than the carrying value of our IPR&D, and other adverse market and economic environment changes or trends. Events or changes in circumstances may lead to significant impairment charges on our IPR&D in the future, which could materially adversely affect our financial condition and results of operations.

Adverse developments affecting financial institutions, companies in the financial services industry, or the financial services industry generally, such as actual events or concerns involving liquidity, defaults, or non-performance, could adversely affect our operations and liquidity.

Actual events involving limited liquidity, defaults, non-performance, or other adverse developments that affect financial institutions or other companies in the financial services industry, or the financial services industry generally, or concerns or rumors about any such events, have in the past and may in the future lead to market-wide liquidity problems. For instance, in 2023 the Federal Deposit Insurance Corporation ("FDIC") took control of Silicon Valley Bank, where the Company maintains depository accounts and has a debt facility.

Although the failure of Silicon Valley Bank did not cause us to experience any material impacts on our financial condition or results of operations, our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired if the financial institutions with which we have arrangements face liquidity constraints or failures. In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations, or result in violations of federal or state wage and hour laws, any of which could have material adverse impacts on our operations and liquidity.

Risks Related to Our Dependence on Third Parties

We do not have, and do not have plans to, establish commercial manufacturing facilities. We completely rely on third parties for the manufacture and supply of our clinical trial drug and delivery device supplies and, if approved, commercial product materials. The loss of any of these vendors or a vendor's failure to provide us with an adequate supply of clinical trial or commercial product material in a timely manner and on commercially acceptable terms, or at all, could harm our business.

We outsource the manufacture of our MOLBREEVI product candidate and do not plan to establish our own manufacturing facilities. To manufacture our product candidate, we have made numerous custom modifications at CMOs, making us highly dependent on these CMOs. For clinical and commercial supplies, if approved, we have supply agreements with third party CMOs for drug substance, finished drug product, drug delivery devices and other necessary components of our MOLBREEVI product candidate. While we have secured long-term commercial supply agreements with many of the third party CMOs, we would need to negotiate agreements for commercial supply with several important CMOs, and we may not be able to reach agreement on acceptable terms. In addition, we rely on these third parties to conduct or assist us in key manufacturing development activities, including qualification of equipment, developing and validating methods, defining critical process parameters, releasing component materials, demonstrating comparability of drug substance and drug product, and conducting stability testing, among other things. If these third parties are unable to perform their tasks successfully in a timely manner, whether for technical, financial, or other reasons, we may be unable to secure clinical trial material, or commercial supply material if approved, which likely would delay the initiation, conduct, or completion of our clinical trials or prevent us from having enough commercial supply material for sale, which would have a material and adverse effect on our business. There have been and could be additional delays in the manufacturing supply chain for our product candidate, including delays in procurement of materials for certain of our clinical trials, potentially resulting in delays in clinical trials and recruitment. Further, we have experienced an increase in costs associated with the supply chain disruption. The extent to which circumstances such as global health threats, global conflicts, and social unrest impact our ability to procure sufficient supplies for the development and commercialization of our product candidate going forward will depend on the severity and duration of such circumstances. For example, one of our CMOs for drug substance operates in Argentina, which is experiencing high inflation, a weakening currency, labor strikes and social and political unrest. Those conditions could result in supply chain disruptions or increased costs.

All manufacturers of our clinical trial material and, if approved, commercial product, including drug substance manufacturers, must comply with cGMP requirements enforced by the FDA through its facilities inspection program and applicable requirements of foreign regulatory authorities. These requirements include manufacturing, quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our clinical trial material may be unable to comply with these cGMP requirements and with other FDA, state, and foreign regulatory requirements. While we and our representatives generally monitor and audit our manufacturers' systems, we do not have full control over their ongoing compliance with these regulations. Although the responsibility to maintain cGMP compliance is a requirement of third-party manufacturers, we bear ultimate responsibility for our supply chain and compliance with regulatory standards. Failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay or failure to obtain product approval, product seizure or recall, or withdrawal of product approval.

Identification of and discussions with alternative vendors, if necessary, may be protracted and/or unsuccessful, or these new vendors may be unsuccessful in producing the same results as the current primary vendors producing the material. Therefore, if our primary and back-up vendors become unable or unwilling to perform their required activities, we could experience protracted delays or interruptions in the supply of clinical trial material and, ultimately, product for commercial sale, which would materially and adversely affect our development programs, commercial activities, operating results, and financial condition.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling-up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, and shortages of qualified personnel. Our product candidate has not been manufactured at the scale we believe will be necessary to maximize its commercial value and, accordingly, after initial licensure and commercialization, we may encounter difficulties in attempting to scale-up production and may not succeed in that effort on a timely basis or at all. In addition, the FDA or other regulatory authorities may impose additional requirements as we scale up initial production capabilities, which may delay our scale-up activities and/or add expense.

If our manufacturers encounter any of the aforementioned difficulties or otherwise fail to comply with their contractual obligations or there are delays entering commercial supply agreements due to capital constraints, we may have insufficient quantities of material to support ongoing and/or planned clinical trials or to meet commercial demand, if

approved. In addition, any delay or interruption in the supply of materials necessary or useful to manufacture our product candidate could delay the completion of our clinical trials, increase the costs associated with our development programs, and depending upon the period of delay, require us to commence new clinical trials at significant additional expense or terminate the trials completely. Delays or interruptions in the supply of commercial product could result in increased cost of goods sold and lost sales. We cannot provide assurance that manufacturing or quality control problems will not arise in connection with the manufacture of our clinical trial material or commercial product, if approved, or that third-party manufacturers will be able to maintain the necessary governmental licenses and approvals to continue manufacturing such clinical trial material or commercial product, as applicable. In addition, MOLBREEVI is currently manufactured entirely outside the U.S. and, as a result, we may experience interruptions in supply due to shipping or customs difficulties or regional instability. Furthermore, changes in currency fluctuations, shipping costs, or import tariffs could adversely affect cost of goods sold. Any of the above factors could cause us to delay or suspend anticipated or ongoing trials, regulatory submissions, or commercialization of our product candidate, entail higher costs, or result in being unable to effectively commercialize our product. Our dependence upon third parties for the manufacture of our clinical trial material may adversely affect our future costs and our ability to develop and commercialize our product candidate on a timely and competitive basis.

We rely significantly on third parties to conduct our nonclinical testing and clinical trials and other aspects of our MOLBREEVI development program, and if those third parties do not satisfactorily perform their contractual obligations or meet anticipated deadlines, the development of our MOLBREEVI product candidate could be adversely affected.

We do not employ personnel or possess the facilities necessary to conduct many of the activities associated with our programs. We engage consultants, advisors, CROs, and others to assist in the design and conduct of nonclinical and clinical trials of our product candidate, with interpretation of the results of those trials, and with regulatory activities, and we expect to continue to outsource all or a significant amount of such activities. For example, we have engaged a CRO, Parexel, to support our IMPALA-2 pivotal clinical trial development activities, and we are substantially dependent upon Parexel for the conduct of the IMPALA-2 pivotal trial. Many important aspects of our development programs are and will continue to be outside our direct control, and our third-party service providers may not perform their activities as required or expected, including the maintenance of GCP, GLP, and cGMP compliance, which are ultimately our responsibility to ensure. Further, such third parties may not be as committed to the success of our programs as our own employees and, therefore, may not devote the same time, thoughtfulness, or creativity to completing projects or problem-solving as our own employees would. To the extent we are unable to successfully manage the performance of third-party service providers, our business may be adversely affected.

The CROs that we engage to execute our clinical trials play a significant role in the conduct of the trials, including patient enrollment and the collection and analysis of trial data. We likely will depend on CROs and clinical investigators to conduct future clinical trials and to assist in analyzing data from completed trials and developing regulatory strategies for our product candidate. Individuals working at the CROs with which we contract, as well as investigators at the sites at which our trials are conducted, are not our employees, and we have limited control over the amount or timing of resources that they devote to their programs. In addition, our CROs may be affected by business or workforce interruptions for many reasons over which they and we have limited control. If our CROs, trial investigators, and/or third-party sponsors fail to devote sufficient time and resources to trials of our product candidate, if we and/or our CROs do not comply with all GLP and GCP regulatory and contractual requirements, or if their performance is substandard, we may delay commencement and/or completion of these trials, submission of applications for regulatory approval, regulatory approval, and commercialization of our product candidate. Failure of CROs to meet their obligations to us could adversely affect development of our product candidate.

In addition, CROs we engage may have relationships with other commercial entities, some of which may compete with us. Through intentional or unintentional means, our competitors may benefit from lessons learned on our projects that could ultimately harm our competitive position. Moreover, if a CRO fails to properly, or at all, perform our activities during a clinical trial, we may not be able to enter into arrangements with alternative CROs on acceptable terms or in a timely manner, or at all. Switching CROs may increase costs and divert management time and attention. In addition, there likely would be a transition period before a new CRO commences work. These challenges could result in delays in the commencement or completion of our clinical trials, which could materially impact our ability to meet our desired and/or announced development timelines and have a material adverse impact on our business and financial condition.

Our employees, independent contractors and consultants, principal investigators, CROs, CMOs, other vendors, and any future commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors and consultants, principal investigators, CROs, CMOs, other vendors, and any future commercial partners may engage in fraudulent conduct or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with manufacturing standards required by cGMP or our standards, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, and to report financial information or data accurately or disclose unauthorized activities to them. The misconduct of our employees and other service providers could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Although we have adopted a code of business conduct and ethics, it is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us or our service providers, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. For example, if one of our manufacturing partners were placed under a consent decree, we may be hampered in our ability to manufacture clinical or commercial supplies.

The company intends to establish a redundant supply chain with second sources of drug substance and drug product manufacture. If the product manufactured at the second sources of manufacture is not demonstrated to be comparable with materials used in the clinical program, we may not be able to commercialize from these second sources.

We have engaged third-parties for our drug product and drug substance manufacturing to serve as second source manufacturers and suppliers of MOLBREEVI to attain uninterrupted supply and mitigate approvability risk. If the second sources do not demonstrate the ability to provide comparable product to our primary sources, the supply chain and scalability to commercialize MOLBREEVI could be adversely impacted.

Any new manufacturer or supplier would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing of such product or ingredients required by us. The FDA or foreign regulatory agency may require us to conduct additional clinical trials, collect stability data, and provide additional information concerning any new supplier, or change in a validated manufacturing process, including scaling-up production, before we could distribute products from that manufacturer or supplier or revised process. For example, if we were to engage a third party other than our current CMOs to supply the drug substance or drug product for future clinical trials or commercial sale, the FDA or regulatory authorities outside of the U.S. may require us to conduct additional clinical and nonclinical studies to ensure comparability of the drug substance or drug product manufactured by our current CMOs to that manufactured by the new supplier. Changing of suppliers is particularly challenging for companies like us, with inhalation products, because any change could alter the performance of the drug product.

Risks Related to Competition, Retaining Key Employees and Managing Growth

MOLBREEVI has received Orphan Drug Designation from the FDA and the EMA. If a competitor obtains Orphan Drug exclusivity for a product with the same active ingredient and route of delivery as molgramostim for autoimmune PAP, we may be unable to market our product candidate until the exclusivity of the competing product expires.

MOLBREEVI has received Orphan Drug Designation in the U.S. by the FDA and in Europe by the EMA for the treatment of autoimmune PAP. If approval is received to market MOLBREEVI, the FDA will not approve a similar product, with the same active ingredient as MOLBREEVI, for seven years and the EMA will not approve a similar product to MOLBREEVI for ten years, unless we are unable to produce enough supply to meet demand in the marketplace or another similar product with the same active ingredient is deemed clinically superior. Similar product candidates with the same active ingredient and route of delivery may be granted Orphan Drug Designation during the development, but the Orphan Drug exclusivity is granted only to the first of such products approved, which means there is risk that a competitor product candidate may receive approval and Orphan Drug exclusivity before us, thus preventing us from marketing our product candidate until the exclusivity of the competing product expires. Also, the Orphan Drug status will not prevent a competitor with a different active ingredient from competing with our product candidate. If we are prevented from marketing MOLBREEVI for autoimmune PAP due to a competitor's Orphan Drug exclusivity, it would have a material adverse effect on our business.

We expect competition in the marketplace for our MOLBREEVI product candidate should it receive regulatory approval.

The development and commercialization of new drug products is highly competitive and subject to rapid and significant change. Developments by others may render potential application of our MOLBREEVI product candidate in autoimmune PAP obsolete or noncompetitive, even prior to completion of its development and approval. If successfully developed and approved, we expect our product candidate will face competition. We may not be able to compete successfully against organizations with competitive products, particularly large pharmaceutical companies. Many of our potential competitors have significantly greater financial, technical, and human resources than us, and may be better equipped to develop, manufacture, market, and distribute products. Many of these companies operate large, well-funded research, development, and commercialization programs, have extensive experience in nonclinical and clinical trials, obtaining FDA and other regulatory approvals, and manufacturing and marketing products, and have multiple products that have been approved or are in late-stage development. These advantages may enable them to receive approval from the FDA or any foreign regulatory agency before us and prevent us from competing due to their orphan drug protections. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Furthermore, heightened awareness on the part of academic institutions, government agencies, and other public and private research organizations of the potential commercial value of their inventions have led them to actively seek to commercialize the technologies they develop, which increases competition for investment in our programs. Competitive products may be more effective, easier to dose, or more effectively marketed and sold than ours, which would have a material adverse effect on our ability to generate revenue.

Although we are not aware of any companies developing an inhaled form of GM-CSF for the treatment of autoimmune PAP, sargramostim (Leukine), a yeast-derived recombinant human granulocyte-macrophage colony stimulating factor, rhu-GM-CSF, which is a product of Partner Therapeutics, Inc., is being pharmacy-compounded and utilized by some patients in the U.S. for the off-label treatment of autoimmune PAP. We cannot assess the effectiveness of its off-label administration to patients with autoimmune PAP or the number of autoimmune PAP patients in the U.S. using Leukine as a pharmacy-compounded off-label treatment. Additionally, in April 2024, Partner Therapeutics' partner, Nobelpharma Co. Ltd., received regulatory approval from the PMDA to market sargramostim for the treatment of autoimmune PAP in Japan. Sargramostim has the potential to present a material competitive threat to the commercial success of MOLBREEVI in Japan which could have a material adverse effect on our business.

If we fail to attract and retain senior management and key scientific personnel and develop and maintain relationships with service providers, consultants and advisers, we may be unable to successfully develop and commercialize our product candidate.

We have historically operated with a limited number of employees that manage third parties for most development activities. Institutional knowledge is concentrated within a small number of employees. Our success depends on our continued ability to attract, retain, and motivate highly qualified management, clinical, and scientific personnel. Our future success is highly dependent upon the contributions of our senior management, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals, who all have at-will employment arrangements with us, could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, or the commercialization of our product candidate.

Replacing key employees may be a difficult, costly, and protracted process, and we may not have other personnel with the capacity to assume all the responsibilities of a key employee upon his/her departure. Transition periods can be difficult to manage and may cause disruption to our business.

In addition, there may be intense competition from other companies and organizations for qualified personnel. Other companies and organizations with which we compete for personnel may have greater financial and other resources and different risk profiles than us, and a history of successful development and commercialization. If we cannot attract and retain skilled personnel, as needed, we may not achieve our development and other goals.

The success of our business will depend on our ability to develop and maintain relationships with respected service providers and industry-leading consultants and advisers. If we cannot develop and maintain such relationships as needed, the rate and success at which we can develop and commercialize our product candidate may be limited. In addition, our outsourcing strategy, which has included engaging consultants that spend considerable time to manage key functional areas, may subject us to scrutiny under labor laws and regulations, which may divert management time and attention and have an adverse effect on our business and financial condition.

We currently have limited marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidate, if approved, or generate product revenue.

To commercialize our MOLBREEVI product candidate, if approved, in the U.S. and other jurisdictions we seek to enter, we must build our marketing, sales, managerial, and other non-technical capabilities, or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product receives regulatory approval, we expect to market such product in the U.S. through a focused, specialized sales force, which will be costly and time consuming. Institutionally, we have no prior experience in the marketing and sale 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. Outside of the U.S., we may consider collaboration arrangements. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product in certain markets. Any failure or delay in the development of our internal sales, marketing, and distribution capabilities would adversely impact the commercialization of our product. If we are not successful in commercializing our MOLBREEVI product, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we would incur significant additional losses.

To establish a sales and marketing infrastructure and expand our manufacturing capabilities, we will need to increase the size of our organization, and we may experience difficulties in managing this growth.

As we advance our MOLBREEVI product candidate through the development process and to commercialization, we will need to continue to expand our development, regulatory, quality, managerial, sales and marketing, operational, finance, and other resources to manage our operations and clinical trials, continue our development activities, and commercialize our product candidate, if approved. As our operations expand, we expect that we will need to manage additional relationships with various manufacturers and collaborative partners, suppliers, and other organizations.

Due to our limited financial resources and our limited experience in managing a company with such anticipated growth, we may not be able to effectively maintain or manage the expansion of our operations or recruit and train additional qualified personnel. In addition, the physical expansion of our operations may lead to significant costs and may divert our management attention and resources. Any inability to manage growth could delay the execution of our development and strategic objectives, or disrupt our operations, which could materially impact our business, revenue, and operating results.

Risks Related to Our Business Operations

Our operations might be interrupted and financial results could be adversely impacted by the occurrence of a natural disaster, acts of war or terrorism, tariffs, IT system malfunction, telecommunication and electrical failures or other catastrophic event, or public health crises, such as a pandemic.

Our corporate headquarters is located in a commercial facility in Langhorne, Pennsylvania. Important documents and records, including copies of our regulatory documents and other records for our product candidate, are located both at a secure offsite document storage facility as well as at our own facilities, and we depend on our facilities for the continued operation of our business. Natural disasters and other catastrophic events, such as wildfires and other fires, earthquakes and extended power interruptions, public health crises, severe weather conditions, social unrest or acts of war or terrorism could significantly disrupt our operations and result in additional, unplanned expense. Any natural disaster or catastrophic event could disrupt our business operations and result in setbacks to our development programs. Even though we believe we carry commercially reasonable insurance, we might suffer losses that are not covered by or exceed the coverage available under these insurance policies.

In addition, our operations may be adversely impacted by international conflict, such as the ongoing conflicts in Ukraine and Russia or social unrest, such as that currently in Argentina. The political and physical conditions in those regions, as well as neighboring countries, may disrupt our supply chain and increase our costs, which may adversely affect our ability to conduct ongoing clinical trials and impact patients' ability to partake in our clinical trials. While we do not believe these conflicts will have a material impact on our current operations, given the rapidly evolving situation, the full impact remains uncertain.

Tariffs (including tariffs that have been or may in the future be imposed by the U.S. or other countries), trade protection measures, import or export licensing requirements, trade embargoes, sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), other trade barriers (including further legislation or actions taken by the United States or other countries that restrict trade), and protectionist or retaliatory measures taken by the United States or other countries could have a negative impact on our operations and supply chain.

Our business and operations would suffer in the event of third-party computer system failures, cyber-attacks on third-party systems, or deficiency in our cybersecurity.

We rely on IT systems, including third-party "cloud based" service providers, to keep financial records, maintain laboratory data, clinical data and corporate records, communicate with staff and external parties, and operate other critical functions. This includes critical systems such as email, other communication tools, electronic document repositories, and archives. If any of these third-party IT providers are compromised due to computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war, telecommunication failures, electrical failures, cyber-attacks, or cyber-intrusions over the internet, then sensitive emails or documents could be exposed or deleted. Similarly, we could incur business disruption if our access to the internet is compromised, and we are unable to connect with third-party IT providers. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion by computer hackers, foreign governments, or cyber-terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. In addition, we rely on those third parties to safeguard important confidential personal data regarding our employees and patients enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in a third-party IT provider's operations, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing, or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in loss or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and development of our product candidate could be delayed or could fail.

We have experienced and may continue to experience attempts to breach our security and attempts to introduce malicious software into our IT systems; however, to date and to our knowledge, such attacks have not resulted in any material damage to us. Because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for the Company to be adversely impacted. Moreover, because the techniques used to gain access to or sabotage systems often are not recognized until launched against a target, we may be unable to anticipate the methods necessary to defend against these types of attacks, and we cannot predict the extent, frequency or impact these attacks may have on us. To the extent our business is interrupted, this impact could result in reputational, competitive, operational, or other business harm as well as financial costs and regulatory action, and the theft or unauthorized use or publication of our trade secrets and other confidential business information as a result of such an incident could adversely affect our competitive position.

We are continually working to maintain reliable systems to improve our operations. Our efforts include, but are not limited to, the following: firewalls, antivirus protection, patches, log monitors, routine backups with offsite retention of storage media, system audits, data partitioning, and routine password modifications. Our internal IT systems environment continues to evolve, and our business policies and internal security controls may not keep pace as new threats emerge. No assurance can be given that our efforts to continue to enhance our systems will be successful.

The Company's remote working arrangements could significantly increase the Company's digital and cybersecurity risks.

A majority of our employees work remotely from their homes. With the shift to remote working and the use of virtual board and executive management meetings, cybersecurity risks are exponentially greater. Additionally, the Company's adoption of remote work arrangements may introduce additional threats to our information technology networks and infrastructure. Technology in employees' homes may not be as robust and could cause the networks, information systems, applications, and other tools available to employees to be more limited or less reliable than in our offices. These cyber risks include greater phishing, malware, and other cybersecurity attacks, vulnerability to disruptions of our information technology infrastructure and telecommunication systems for remote operations, increased risk of unauthorized dissemination of confidential information, limited ability to restore the systems in the event of a systems failure or interruption, greater risk of a security breach resulting in destruction or misuse of valuable information, and potential impairment of our ability to perform critical functions, including wiring funds, all of which could expose us to risks of data or financial loss, litigation and liability and could seriously disrupt our operations.

If we or our vendors fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity, which could negatively affect our operating results and business.

In the ordinary course of business, we collect, receive, use, retain, transfer, and otherwise process, personal data and other sensitive and confidential information. As a result of our data processing activities, we are subject to a number of state, national, and foreign laws and regulations related to the collection, use, retention, protection, disclosure, transfer, and other processing of personal data, including the General Data Protection Regulation ("GDPR") in the EU, the UK GDPR and Data Protection Act 2018 in the UK, and numerous federal and state laws in the U.S. The scope of these laws

can be broad, and the statutory penalties can be high. For example, the GDPR imposes stringent requirements for the processing of personal data of individuals within the EU and provides for substantial penalties for non-compliance that can be up to the greater of €20 million or 4% of global annual revenues.

The legal landscape in this area is rapidly evolving as different jurisdictions adopt new laws governing data privacy, which can differ in scope and applicability, subject to different interpretations, and be inconsistent among jurisdictions. In the U.S., California enacted the California Consumer Privacy Act in 2018, which requires covered companies to provide new disclosures to California consumers and affords those consumers new rights related to their personal data. Since then, additional states have adopted their own comprehensive data privacy laws. Outside the U.S., in addition to the GDPR and UK statutes referenced above, many jurisdictions either have data protection laws in place or continue to advance proposals for similar legislation and regulation. The increasing number, complexity, and potential inconsistency of current and future laws and regulations relating to privacy, data protection, and data security in the U.S. and other countries make our compliance obligations more difficult and costly. Because many of these laws are new, there is little clarity as to their interpretation, as well as a lack of precedent for the scope of enforcement. As the laws to which we are subject increase and the requirements change, we may be required to implement additional mechanisms to comply, which may be difficult and require us to incur additional costs. If we or our vendors fail to comply with applicable data privacy laws or experience a breach of security that results in unauthorized disclosure of personal information, we could be subject to government investigations and enforcement actions, significant penalties, civil litigation, and reputational harm, and our business could be adversely impacted.

We must comply with the U.S. Foreign Corrupt Practices Act and similar foreign anti-corruption laws.

We are subject to anti-corruption laws, including the FCPA, the UK Bribery Act 2010, and other anti-corruption laws that apply in countries where we conduct business. Under those laws, it is generally illegal to pay, offer to pay, or authorize the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

We face the risk that an employee or agent could be accused of violating one or more of these laws, particularly in geographies where significant overlap exists between local government and healthcare industries. In many countries, hospitals are operated by the government and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Such an accusation, even if unwarranted, could prove disruptive to our developmental and commercialization efforts. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions, and the SEC may suspend or bar issuers from trading securities on U.S. exchanges for violations of those provisions.

Our operations also subject us to similar laws in other countries. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the EU, and the provision of benefits or advantages to physicians is also governed by the national anti-bribery laws. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual country. These requirements are provided in the national laws, industry codes, or professional codes of conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

Risks Related to Our Intellectual Property

If we are unable to adequately protect our intellectual property rights related to our product candidate, it could have a material adverse effect on our business.

Our commercial success depends on our ability to adequately protect our intellectual property rights related to MOLBREEVI for the treatment of autoimmune PAP. We intend to rely on regulatory exclusivity, such as through Orphan Drug exclusivity, as our primary barrier to competition. Additionally, we have an exclusive supply agreement for the proprietary delivery device used for MOLBREEVI and a proprietary cell bank used in the production of the drug substance. Our success will depend on our ability to:

- obtain and maintain exclusivity rights with respect to our products and their uses;
- prevent third parties from infringing upon our proprietary rights;
- maintain proprietary know-how and trade secrets;

- operate without infringing upon the patents and proprietary rights of others; and
- obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur, or if necessary, to secure exclusive rights to them, both in the U.S. and in foreign countries.

We intend to rely on regulatory exclusivity for protection of our MOLBREEVI product candidate, if approved for commercial sale. Implementation and enforcement of regulatory exclusivity, which may consist of regulatory data protection and market protection, varies widely from country to country. Failure to qualify for regulatory exclusivity, or failure to obtain or maintain the extent or duration of such protections that we expect for our product candidate, if approved, could affect our decision on whether to market the products in a particular country or countries or could otherwise have an adverse impact on our revenue or results of operations. For MOLBREEVI, which is administered via nebulization, we may rely on regulatory exclusivity for the combination of MOLBREEVI and its delivery system. However, there is no assurance that our MOLBREEVI product and its delivery system, if approved, will benefit from this type of market protection.

In addition to regulatory exclusivity, we have sought to protect our intellectual property rights by filing patent applications related to our MOLBREEVI product candidate; however, there is no guarantee that patents will issue from any pending or future applications or that claims allowed will be sufficient to protect the technology we develop or that is used by us, our CMOs, or our other service providers. The patent prosecution process is expensive and time-consuming; we may not be able to file or prosecute patents on certain aspects of our product candidate at a reasonable cost, in a timely fashion, or at all, and we may fail to identify patentable aspects of inventions made during development activities before it is too late to obtain patent protection. Further, defects of form in the preparation or filing of our patent applications may exist, or may arise in the future, which may cause them to be invalid or unenforceable.

Any patents that are issued to us may be limited in scope or challenged, invalidated, infringed, or circumvented, including by our competitors. Even if a patent issues and is held valid and enforceable, rights we have under the patent may not provide a competitive advantage to us. Competitors may be able to design around our patents, such as by using pre-existing or newly developed technology. Additionally, given the amount of time required for the development, testing, and regulatory review of new drug candidates, patents protecting such candidates might expire shortly after such candidates are commercialized. If competitors can develop and commercialize technology and products similar to ours, our ability to successfully commercialize our technology and products may be impaired.

We also rely on unpatented know-how and trade secrets and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with employees, consultants, collaborators, and others. We also have invention or patent assignment agreements with our employees and certain consultants. The steps we have taken to protect our proprietary rights, however, may not be adequate to preclude misappropriation of or otherwise protect our proprietary information or prevent infringement of our intellectual property rights, and we may not have adequate remedies for any such misappropriation or infringement. In addition, it is possible that inventions relevant to our business could be developed by a person not bound by an invention assignment agreement with us or independently discovered by a competitor.

We may rely on trademarks, trade names, and brand names to distinguish our MOLBREEVI product, if approved for commercial sale, from the products of our competitors. However, our trademark applications may not be approved. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks, in which case we may expend substantial resources to defend our proposed or approved trademarks and may enter into agreements with third parties that may limit our use of our trademarks. If our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote significant resources to advertising and marketing these new brands. For example, we filed a trademark for the name “Savara” and were challenged. We decided to terminate the application, but we may revisit such filings at a future date. Further, our competitors may infringe on our trademarks, or we may not have adequate resources to enforce our trademarks.

We may not be able to enforce our intellectual property rights outside of the U.S.

Enforcement of intellectual property rights in certain countries outside the U.S. has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries will likely be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions, which could permit others to use our discoveries or to develop and commercialize our technology and products without any compensation to us.

Third parties may claim that our product, if approved, infringes on their proprietary rights and may challenge the approved use or uses of a product or its patent rights through litigation or administrative proceedings, and defending such actions may be costly and time consuming, divert management attention away from our business, and result in an unfavorable outcome that could have an adverse effect on our business.

Our commercial success depends on our ability and the ability of our CMOs and component suppliers to develop, manufacture, market, and sell our product candidate and use our proprietary technology without infringing the proprietary rights of third parties. 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 or may be developing products. Because patent applications can take years to publish and issue, there currently may be pending applications, unknown to us, that may later result in issued patents that our product candidate or technology infringe, or that the process of manufacturing our product or any of our respective component materials, or the component materials themselves, infringe, or that the use of our product candidate or technology infringe.

We or our CMOs or component material suppliers may be exposed to, or threatened with, litigation by a third party alleging that our product candidate and/or technology infringe its patents or other intellectual property rights, or that one or more of the processes for manufacturing our product or any of our respective component materials, or the component materials themselves, or the use of our product candidate or technology, infringe its patents or other intellectual property rights. If a third-party patent or other intellectual property right is found to cover our product candidate, technology, or our uses, or any of the underlying manufacturing processes or components, we could be required to pay damages and could be unable to commercialize our product or use our technology or method unless we are able to obtain a license to the patent or intellectual property right. A license may not be available to us in a timely manner or on acceptable terms, or at all. In addition, during litigation, the third-party alleging infringement could obtain a preliminary injunction or other equitable remedy that could prohibit us from making, using, selling, or importing our product, technology, or method.

There generally is a substantial amount of litigation involving patent and other intellectual property rights in the industries in which we operate, and the cost of such litigation may be considerable. We can provide no assurance that our product candidate or technology will not infringe patents or rights owned by others, licenses to which might not be available to us in a timely manner or on acceptable terms, or at all. If a third-party claims that we or our CMOs or component material suppliers infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, with or without merit, may be expensive and time consuming to litigate and may divert management's time and attention from our business;
- substantial damages for infringement, including the potential for treble damages and attorneys' fees, which we may have to pay if it is determined that the product and/or its use at issue infringes or violates the third party's rights;
- a court prohibiting us from selling or licensing the product unless the third party licenses its intellectual property rights to us, which it may not be required to do;
- if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross-licenses to the third party; and
- redesigning our product or process so they do not infringe, which may not be possible or may require substantial expense and time.

There may be issued or filed claims covering our product, product candidate, or technology or those of our CMOs or component material suppliers or the use of our product, product candidate, or technology. Additionally, such patents may be issued or filed in the future. Because of the large number of patents issued and patent applications filed in the industries in which we operate, there is a risk that third parties may allege they have patent rights encompassing our product, product candidate, or technology, or those of our CMOs or component material suppliers, or uses of our product, product candidate, or technology.

In the future, it may be necessary for us to enforce our proprietary rights, or to determine the scope, validity, and unenforceability of other parties' proprietary rights, through litigation or other dispute proceedings, which may be costly, and to the extent we are unsuccessful, adversely affect our rights. In these proceedings, a court or administrative body could determine that our claims, including those related to enforcing patent rights, are not valid or that an alleged infringer has not infringed our rights. The uncertainty resulting from the mere institution and continuation of any patent or other proprietary rights-related litigation or interference proceeding could have a material and adverse effect on our business prospects, operating results, and financial condition.

Risks Related to Our Industry

We are subject to uncertainty relating to healthcare reform measures and reimbursement policies that, if not favorable to our product, could hinder or prevent our product's commercial success, if our product candidate is approved.

The unavailability or inadequacy of third-party payer coverage and reimbursement could negatively affect the market acceptance of our product candidate and the future revenues we may expect to receive. The commercial success of our product candidate, if approved, will depend on the extent to which the costs of such product will be covered by third-party payers, such as government health programs, commercial insurance, and other organizations. Third-party payers are increasingly challenging the prices and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. These challenges to prices may be problematic to us since our products are targeted for a small number of patients (those suffering from an orphan disease), thus requiring us to charge very high prices to recover development costs and achieve a profit on our revenue. If these third-party payers do not consider our product to be cost-effective compared to other therapies, we may not obtain coverage for our product after approval as a benefit under the third-party payers' plans or, even if we do, the level of coverage or payment may not be sufficient to allow us to sell our product on a profitable basis.

Significant uncertainty exists as to the reimbursement status for newly approved drug products, including coding, coverage, and payment. There is no uniform policy requirement for coverage and reimbursement for drug products among third-party payers in the U.S., therefore coverage and reimbursement for drug products can differ significantly from payer to payer. The coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product to each payer separately, with no assurance that coverage and adequate payment will be applied consistently or obtained. The process for determining whether a payer will cover and how much it will reimburse a product may be separate from the process of seeking approval of the product or for setting the price of the product. Even if reimbursement is provided, market acceptance of our product may be adversely affected if the amount of payment for our product proves to be unprofitable for healthcare providers or less profitable than alternative treatments or if administrative burdens make our product less desirable to use. Third-party payer reimbursement to providers of our product, if approved, may be subject to a bundled payment that also includes the procedure of administering our product or third-party payers may require providers to perform additional patient testing to justify the use of our product. To the extent there is no separate payment for our product, there may be further uncertainty as to the adequacy of reimbursement amounts.

The continuing efforts of governments, private insurance companies, and other organizations to contain or reduce costs of healthcare may adversely affect:

- our ability to set an appropriate price for our product;
- the rate and scope of adoption of our products by healthcare providers;
- our ability to generate revenue or achieve or maintain profitability;
- the future revenue and profitability of our potential customers, suppliers, and collaborators; and
- our access to additional capital.

Our ability to successfully commercialize our product will depend on the extent to which governmental authorities, private health insurers, and other organizations establish what we believe are appropriate coverage and reimbursement for our product. The containment of healthcare costs has become a priority of governments worldwide, and the prices of drug products have been a focus in this effort. For example, President Trump has signed multiple executive orders addressing prescription drug pricing and access, including one in May 2025 aiming to establish a "most favored nation" ("MFN") drug pricing policy, which would tie U.S. drug prices to the lowest prices paid for drugs in other countries. Certain manufacturers have entered into voluntary agreements with the Trump Administration on MFN pricing, and the Centers for Medicare & Medicaid Services has announced initiatives that would take steps to implement MFN pricing for Medicaid and Medicare Parts B and D programs. Adoption or expansion of MFN pricing policies could result in downward pressure on U.S. pricing and may impact our decision about when or whether to launch MOLBREEVI in markets outside of the U.S., if approved. We expect that federal, state, and local governments in the U.S., as well as in other countries, will continue to consider legislation directed at lowering the total cost of healthcare. In addition, in certain foreign markets, the pricing of drug products is subject to government control, and reimbursement may in some cases be unavailable or insufficient. It is uncertain whether and how future legislation, whether domestic or abroad, could affect prospects for our product candidate or what actions federal, state, or private payers for healthcare treatment and services may take in response to any such healthcare reform proposals or legislation.

Furthermore, healthcare reform measures that may be adopted in the future are unpredictable, and the potential impact on our operations and financial position is uncertain, but may result in more rigorous coverage criteria, lower reimbursement, and additional downward pressure on the price we may receive for approved products. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products, if approved.

We face potential product liability exposure and, if successful claims are brought against us, we may incur substantial liability for a product or product candidate and may have to limit its commercialization. In the future, we anticipate that we will need to obtain additional or increased product liability insurance coverage and it is uncertain whether such increased or additional insurance coverage can be obtained on commercially reasonable terms, if at all.

Our business (in particular, the use of our product candidate in clinical trials and the sale of any products for which we obtain marketing approval) will expose us to product liability risks. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies, or others selling or involved in the use of our products. If we cannot successfully defend ourselves against any such claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products and loss of revenue;
- impairment of our business reputation;
- delays in enrolling patients to participate in our clinical trials;
- withdrawal of clinical trial participants;
- a "clinical hold," suspension or termination of a clinical trial or amendments to a trial design;
- significant costs of related litigation;
- substantial monetary awards to patients or other claimants; and
- the inability to commercialize our product candidate.

We maintain limited product liability insurance for our clinical studies, but our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

We expect that we will expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidate, but we may be unable to obtain product liability insurance on commercially acceptable terms or may not be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect us against potential losses. Large judgments have been awarded in class action lawsuits based on drug products that had unanticipated side effects. A successful product liability claim or series of claims brought against us, if judgments exceed our insurance coverage, could consume a significant portion of our cash and adversely affect our business.

If MOLBREEVI is approved, we will be subject to applicable fraud and abuse, anti-kickback, physician payment transparency, and other healthcare laws and regulations, which could expose us to reputational harm, criminal prosecution, civil penalties, and other damages if it is determined we have failed to comply.

Although we do not currently have any drug products on the market, if MOLBREEVI is approved and we begin commercialization, we will be subject to healthcare statutory and regulatory requirements designed to prevent fraud and abuse and increase transparency. Healthcare providers, physicians, and third-party payers will play a primary role in the recommendation and prescription of MOLBREEVI, and our current and future arrangements with those parties may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute MOLBREEVI. The applicable laws and regulations are described under the heading, "*Other Healthcare Laws and Compliance Requirements"* in Part I, Item 1 – Business of this annual report on Form 10-K, and include, but are not limited to, the False Claims Act, Anti-Kickback Statute, and Physician Payments Sunshine Act.

Efforts to ensure that our future business arrangements with third parties comply with these laws and regulations could involve substantial costs and may require us to undertake or implement additional policies or measures. Although we strive to structure our business arrangements to comply with the applicable requirements, we may face claims by private parties, and claims, investigations and other proceedings by governmental authorities, relating to allegations that our business practices violate applicable law. Any such action against us, even if we successfully defend ourselves against it, could cause reputational harm, result in significant legal expenses, and divert our management's attention from the

operation of our business. If courts or governmental authorities conclude that we have violated the law, or we find it necessary or appropriate to settle any such claims, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

Risks Related to our Common Stock

Our stock price is expected to continue to be volatile.

The market price of our common stock and our stock price will continue to be subject to significant volatility and fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- failed or inconclusive data results from our clinical trials;
- our ability to obtain regulatory approvals for our product candidate, and delays or failures to obtain such approvals;
- failure to meet or exceed any financial and development projections that we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- failure of our product candidate, if approved, to achieve commercial success;
- failure to maintain our existing third-party license and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our product candidate;
- any inability to obtain adequate supply of our product candidate or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services, or technologies by our competitors;
- 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;
- failure to obtain sufficient capital to fund our business objectives;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- 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;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships, or capital commitments;
- adverse publicity relating to the autoimmune PAP market generally, including with respect to other products and potential products in such market;
- the introduction of technological innovations or new therapies that compete with or influence the demand for our product;

- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. Additionally, financial markets and the global economy may be adversely affected by the current or anticipated impact of the ongoing military conflicts in the Middle East and Ukraine or other related geopolitical events. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, such as the decline in our stock price, stockholders have often instituted class action securities litigation against those companies. For example, in September 2025, a putative class action complaint was filed against the Company and certain of our executive officers asserting violations of federal securities laws, as further described in *Note 10. Commitments* in the notes to our consolidated financial statements in this annual report on Form 10-K. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

If we fail to satisfy all applicable Nasdaq continued listing requirements, including the $1.00 minimum closing bid price requirement, our common stock may be delisted from Nasdaq, which could have an adverse impact on the liquidity and market price of our common stock.

Our common stock is currently listed on the Nasdaq Global Select Market, which has qualitative and quantitative continued listing requirements, including corporate governance requirements, public float requirements, and a $1.00 minimum closing bid price requirement. If we are unable to satisfy any of the continued listing requirements, Nasdaq may take steps to delist our common stock. Such a delisting would likely have an adverse effect on the market liquidity of our common stock, decrease the market price of our common stock, result in the potential loss of confidence by investors, suppliers, customers, and employees, fewer business development opportunities, and adversely affect our ability to obtain financing for the continuation of our operations.

We do not expect to pay any cash dividends in the foreseeable future.

We expect to retain any future earnings to fund the development and growth of our business and do not expect to pay any cash dividends. As a result, capital appreciation, if any, of our common stock will be stockholders' sole source of gain, if any, for the foreseeable future.

We may be unable to use certain of our net operating losses and other tax assets.

We have substantial tax loss carry forwards for U.S. federal income tax and state income tax purposes. In general, our net operating losses and tax credits have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. In particular, our ability to fully use certain U.S. tax loss carry forwards and general business tax credit carry forwards generated up to and including December 2023 to offset future income or tax liability is limited under section 382 of the Internal Revenue Code of 1986, as amended. Changes in the ownership of our stock, including those resulting from the issuance of shares of our common stock offerings or upon exercise of outstanding options, may limit or eliminate our ability to use certain net operating losses and tax credit carry forwards in the future.

Item 1B. Unresolved Staff Comments.

We do not have any unresolved comments issued by the SEC staff.

Item 1C. Cybersecurity.

Cyber Risk Management and Strategy

As part of our enterprise risk management program, we have implemented and maintain policies and processes to identify and mitigate risks posed by cybersecurity threats. Our policies and processes are based upon the National Institute of Standards and Technology ("NIST") Cybersecurity Framework, and we utilize technologies to help identify and manage potential cyber threats. We have also secured cyber-specific insurance coverage as part of our overall insurance portfolio.

We have engaged an independent, third-party services provider to assist in monitoring our information technology systems, as well as identifying, assessing, and mitigating the associated cyber risk. With that provider, we conduct periodic assessments of our information security program to evaluate the effectiveness of applicable security controls, which include penetration testing, vulnerability scanning, and red teaming. Our Chief Financial and Administrative Officer ("CF&AO") reviews the results of those assessments with our third-party provider to reasonably address any identified potential gaps. We also utilize a range of tools and services to help ensure material threats are prevented or the risks of

such threats are mitigated, which include, network and endpoint monitoring, system patching, user and server backups, annual awareness training, and periodic vulnerability evaluation. Management reviews monthly monitoring reports and meets with our third-party provider on a regular basis to review activities and debrief on any key IT-related issues.

We have an employee education program that includes annual training designed to raise awareness of cybersecurity threats, and we require employees to review and acknowledge our IT Security Policy on an annual basis. Additionally, we have adopted an IT Incident Response Plan that outlines the procedures to be followed in response to a data breach, whether internal or through a third-party, that are designed to help contain, assess, and respond to the incident and mitigate potential harm.

Our systems periodically experience directed attacks intended to lead to interruptions and delays in our operations as well as loss, misuse, or theft of information and other data, confidential information, or intellectual property. However, to date, these incidents have not had a material impact on our operations. Any significant disruption to our service or access to our systems could adversely affect our business and results of operation. Further, a penetration of our systems or a third-party's systems or other misappropriation or misuse of information could subject us to business, regulatory, litigation, and reputation risk, which could have a negative effect on our business, financial condition and results of operations. See Risk Factors – Risks Related to Information Technology and Data Privacy.

Governance Related to Cybersecurity Risks

The Audit Committee of our Board of Directors is responsible for the general oversight of risks related to data privacy and cybersecurity. The Audit Committee periodically reviews the Company's cybersecurity program with management, including (i) the adequacy of controls and security for the Company's information technology systems and (ii) the Company's response plan in the event of a security breach impacting those systems. Our CF&AO has primary responsibility for overseeing the day-to-day management of cybersecurity risks and has served in that role for three years. Our CF&AO oversees the policies and processes described above and provides the periodic management briefings to the Audit Committee, including any cybersecurity incidents and related responses. Further, at least annually, the Board of Directors receives updates of potential cybersecurity incidents, as well as the data privacy and compliance programs, and its members actively participate in discussions with management regarding cybersecurity risks.

Item 2. Properties.

As of December 31, 2025, our corporate headquarters is located in Langhorne, Pennsylvania where we lease approximately 6,435 square feet of office space. Refer to *Note 2. Summary of Significant Accounting Policies* in the notes to our consolidated financial statements in this annual report on Form 10-K for additional discussion.

We believe that our existing facilities are adequate for the near-term. When our existing leases expire, we may look for alternate space for our operations. We believe that suitable alternative space would be available on commercially reasonable terms if required in the future.

Item 3. Legal Proceedings.

From time to time, we may become involved in various claims and legal proceedings. Regardless of outcome, litigation and other legal and administrative proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. We are not currently a party to any material pending litigation or other material legal proceeding.

On September 8, 2025, a putative securities class action complaint, *Ho, et al. v. Savara Inc., et al.*, was filed against the Company and certain of our executive officers in the United States District Court for the Eastern District of Pennsylvania. On each of December 4, 2025 and January 16, 2026, a stockholder derivative complaint was filed in the United States District Court for the Eastern District of Pennsylvania against our directors, certain of our officers, and the Company as a nominal defendant, *Norman v. Pauls, et al.* and *Lasky v. Pauls, et al.*, respectively. Those stockholder derivative complaints were consolidated on February 3, 2026. The securities class action complaint was voluntarily dismissed by the co-lead plaintiffs on February 6, 2026, and the stockholder derivative complaint was voluntarily dismissed by the plaintiffs on February 12, 2026. For more information, see the description under the heading "Litigation" in *Note 10. Commitments* in the notes to our consolidated financial statements in this Annual Report on Form 10-K.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock trades on the Nasdaq Global Select Market under the ticker symbol "SVRA."

As of March 13, 2026, we had approximately 86 record holders of our common stock. The number of beneficial owners is substantially greater than the number of record holders because a large portion of our common stock is held of record through brokerage firms in "street name."

Unregistered Sales of Equity Securities

None that have not been previously reported.

Item 6. Reserved

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and related notes appearing elsewhere in this report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those identified under Item 1A. Risk Factors in this report.

Overview

Savara Inc. (together with its subsidiaries "Savara," the "Company," "we," "our" or "us") is a clinical-stage biopharmaceutical company focused on rare respiratory diseases. Our sole program, MOLBREEVI, an inhaled biologic, is a granulocyte-macrophage colony-stimulating factor ("GM-CSF") in development for autoimmune pulmonary alveolar proteinosis ("autoimmune PAP"). Savara previously announced positive topline results from IMPALA-2, the Phase 3 clinical trial of MOLBREEVI in autoimmune PAP and the submission of the Biologics License Application ("BLA") to the FDA for MOLBREEVI in autoimmune PAP. In May 2025, Savara announced the Company had received a Refusal to File letter ("RTF") from the FDA. The Company resubmitted the BLA in December 2025 and requested Priority Review, and the FDA formally filed the BLA for MOLBREEVI in February 2026 and granted Priority Review. MOLBREEVI in autoimmune PAP has been granted Fast Track and Breakthrough Therapy Designations by the FDA, Orphan Drug Designation by the FDA and the European Medicines Agency ("EMA"), as well as Innovation Passport ("IP") and Promising Innovative Medicine ("PIM") designations by the UK's Medicines and Healthcare Products Regulatory Agency ("MHRA"). Savara, together with its wholly-owned subsidiaries, which include Aravas Inc. and Savara ApS, operate in one segment with its principal office in Langhorne, Pennsylvania, though a majority of our employees work remotely.

Since inception, we have devoted substantially all of our efforts and resources to identifying and developing our product candidates, recruiting personnel, and raising capital. We have incurred operating losses and negative cash flow from operations and have no product revenue from inception to date. From inception to December 31, 2025, we have raised net cash proceeds of approximately $738.1 million, primarily from underwritten offerings of our common stock, private placements of common stock, and debt financings.

We have never been profitable and have incurred operating losses in each year since inception. Our net losses were $118.8 million and $95.9 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $608.1 million. Our operating losses primarily resulted from expenses attributed to our research and development programs and from general and administrative costs associated with our operations.

We have chosen to operate by outsourcing our manufacturing and most of our clinical operations. We expect to incur significant additional expenses and continue to incur operating losses for at least the next several years as we initiate and continue the clinical development of, and seek regulatory approval for, our product candidate. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve regulatory approval.

As of December 31, 2025, we had cash and cash equivalents of $33.2 million and short-term investments of $202.5 million. Although we have sufficient capital to fund many of our planned activities, we may need to continue to raise additional capital to further fund the development of, and seek regulatory approvals for, our product candidate and begin to commercialize any approved product. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidate.

Recent Events

BLA Submission Complete

On December 22, 2025, Savara announced that it had resubmitted the MOLBREEVI BLA to the FDA for the potential treatment of autoimmune PAP, a chronic and debilitating rare lung disease characterized by the abnormal build-up of surfactant in the alveoli. The Company requested Priority Review of the application. In February 2026, the FDA formally filed the BLA for MOLBREEVI and granted Priority Review.

October 2025 Underwritten Public Offering of Common Stock

On October 31, 2025, the Company sold pursuant to an underwritten public offering (i) an aggregate of 28,452,381 shares of the Company's common stock for $4.20 per share, including 4,642,857 shares of common stock sold pursuant to the exercise in full by the underwriters of their option to purchase additional shares, and (ii) pre-funded warrants to purchase an aggregate of 7,142,857 shares of common stock at an exercise price of $0.001 per share (the "2025 Pre-Funded

Warrants") for $4.199 per pre-funded warrant (collectively, the "October 2025 Offering"). The October 2025 Offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-279274), which was previously filed with the Securities Exchange Commission on May 9, 2024 and declared effective on May 21, 2024, and a prospectus supplement filed with the SEC on October 30, 2025. The October 2025 Offering resulted in net proceeds to the Company of approximately $140.2 million, after deducting final underwriting discounts, commissions, and other estimated offering expenses. The Company intends to use the net proceeds for working capital and general corporate purposes, which include, but are not limited to, the funding of clinical development of and pursuing regulatory approval for MOLBREEVI, investing in our commercialization infrastructure and supply, commercial launch preparation activities in the United States and European Union and general and administrative expenses.

Royalty Purchase and Sale Agreement

On October 29, 2025, we entered into the Purchase Agreement, pursuant to which the Purchaser agreed to pay us $75.0 million upon approval of MOLBREEVI by the FDA on or before March 31, 2027 and subject to satisfaction of other customary closing conditions, in exchange for a true sale of assigned interests, including the right to receive royalty payments equal to a percentage of Net Sales (as defined in the Purchase Agreement) of MOLBREEVI in the United States.

Debt Financing

On January 26, 2026, we entered into the First Amendment to the Hercules Loan Agreement. As amended, the Hercules Loan Agreement provides for the Company to borrow up to an aggregate of $105 million of term loans.

The First Amendment reset the timing and conditions to the Company's ability to draw up to $75 million of additional term loans under the Loan Agreement, subject in each case to FDA approval of the Company's MOLBREEVI product candidate for the treatment of autoimmune PAP (the "Approval Milestone").

Pursuant to the First Amendment, upon achievement of the Approval Milestone, the Company may borrow up to $75 million of additional term loans under the Loan Agreement, as follows:

- Up to $45 million through the earlier of (i) 120 days following the Approval Milestone or (ii) June 30, 2027 (the "First Post-Approval Tranche").
- Beginning upon the earlier of the full draw or expiration of the First Post-Approval Tranche, up to $30 million through the earlier of (i) 120 days following the Approval Milestone or (ii) June 30, 2027.

Refer to *Note 7. Debt Facility* and *Note 16. Subsequent Events* in the notes to our consolidated financial statements in this annual report on Form 10-K for additional discussion.

Litigation Dismissal

On February 6, 2026, the co-lead plaintiffs of the securities class action claim filed against the Company on September 8, 2025, as described in *Note 10. Commitments* to our consolidated financial statements in this Annual Report on Form 10-K, voluntarily dismissed the action without prejudice as to all defendants. On February 12, 2026, the plaintiffs in the stockholder derivative action described in *Note 10. Commitments* to our consolidated financial statements in this Annual Report on Form 10-K voluntarily dismissed the action without prejudice as to all defendants.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates. Refer to *Note 2. Summary of Significant Accounting Policies* in the notes to our consolidated financial statements in this annual report on Form 10-K for additional discussion.

Accrued Research and Development Expenses

We record the costs associated with research, nonclinical and clinical trials, and manufacturing development as incurred. These costs are a significant component of our research and development expenses, with a substantial portion of our on-going research and development activities conducted by third party service providers, including contract research, regulatory support, and manufacturing organizations.

We accrue for expenses resulting from obligations under agreements with CROs, CMOs, and other outside service providers for which payment flows do not match the periods over which materials or services are provided to us. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with CROs, CMOs, and other outside service providers. These estimates are typically based on contracted amounts applied to the activities performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services. We make significant judgments and estimates in determining the accrual balance in each reporting period. In the event advance payments are made to a CRO, CMO, or outside service provider, the payments will be recorded as a prepaid asset which will be amortized or expensed as the contracted services are performed. As actual costs become known, we adjust our prepaids and accruals and related expense. Inputs, such as the services performed, the number of patients enrolled, or the trial duration, may vary from our estimates, resulting in adjustments to research and development expense in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our results of operations. To date, we have not experienced any material deviations between accrued and actual research and development expenses.

Acquired IPR&D

In accordance with ASC Topic 350, *Intangibles – Goodwill and Other*, our IPR&D is determined to have an indefinite life and, therefore, is not amortized. Instead, it is tested for impairment annually and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying value may be impaired.

With respect to the impairment testing of acquired IPR&D, ASU 2011-08, *Intangibles – Goodwill and Other (Topic 350): Testing Goodwill for Impairment*, and ASU 2012-02, *Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment*, provide us a two-step impairment process with the option to first assess qualitative factors to determine whether the existence of events or circumstances leads us to determine that it is more-likely-than not (that is, a likelihood of more than 50%) that our acquired IPR&D is impaired. If we choose to first assess qualitative factors and we determine that it is more-likely-than not acquired IPR&D is not impaired, we are not required to take further action to test for impairment.

When we perform a quantitative assessment of acquired IPR&D, we compare its carrying value to its estimated fair value to determine whether an impairment exists. In previous years, due to a lack of Level 1 or Level 2 inputs, the Multi-Period Excess Earnings Method (“MPEEM”), which is a form of the income approach, was used to estimate the fair value of acquired IPR&D when performing a quantitative assessment. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset’s projected incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life. We evaluate potential impairment of our acquired IPR&D annually on September 30th, utilizing a qualitative approach and determining if it was more-likely-than not that the fair value was impaired.

Our determinations as to whether, and if so, the extent to which acquired IPR&D become impaired are highly judgmental and, in the case of applying the MPEEM approach to estimate fair value, are based on significant assumptions regarding our projected future financial condition and operating results, changes in the manner of our use of the acquired assets, development of our acquired assets or our overall business strategy, and regulatory, market, and economic environment and trends.

If the associated research and development effort is abandoned, the related asset will be written-off, and we will record a non-cash impairment loss on our consolidated statements of operations and comprehensive loss. For those products that reach regulatory approval or commercialization, the IPR&D asset will be amortized over its estimated useful life.

Financial Operations Overview

Research and Development Expenses

We recognize research and development expenses as they are incurred. These expenses consist primarily of the following:

- expenses incurred under agreements with CROs, consultants, and clinical trial sites that conduct research and development activities on our behalf;
- laboratory and vendor expenses related to the execution of our clinical trials;

- contract manufacturing expenses, primarily for the production of clinical supplies; and
- internal costs that are associated with activities performed by our research and development organization, which primarily consist of:
    - personnel costs, which include salaries, benefits, and stock-based compensation expense;
    - facilities and other expenses, which include expenses for maintenance of facilities and depreciation expense; and
    - regulatory expenses and technology license fees related to development activities.

We expect research and development expenses will remain significant in the future as we advance our MOLBREEVI product candidate through clinical trials and pursue regulatory approvals, which will require a significant increased investment in regulatory support and contract manufacturing activities, including investing in the development of second source manufacturers and clinical supplies.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in timely developing and achieving regulatory approval for our product candidate. The probability of success of our product candidate may be affected by numerous factors, including clinical data, competition, intellectual property rights, manufacturing capability, and commercial viability. As a result, we are unable to accurately determine the duration and completion costs of our development projects or when and to what extent we will generate revenue from the commercialization and sale of MOLBREEVI.

General and Administrative Expenses

General and administrative ("G&A") expenses consist primarily of salaries, benefits, and related costs for personnel in executive, finance and accounting, legal, and investor relations; as well as professional and consulting fees for accounting, legal, investor relations, business development, human resources, and information technology services. Other G&A expenses include facility lease and insurance costs.

Other Income, Net

Other income (expense) includes amortization expense related to capitalized debt issuance costs and debt discount under our Amended Loan Agreement with Silicon Valley Bank. Interest expense is typically reported net of interest income, which includes interest earned on our cash, cash equivalent, and short-term investment balances. Other income (expense) also includes net unrealized and realized gains and losses from foreign currency transactions, foreign exchange derivatives not designated as hedging, refundable tax credits generated by some of our foreign subsidiaries, and securities subject to fair value accounting as well as any other non-operating gains and losses.

Results of Operations – Comparison of Years Ended December 31, 2025 and 2024

	Year ended December 31, 2025	2024	Dollar Change
(in thousands)			
Operating expenses:			
Research and development	$ 81,404	$ 78,029	$ 3,375
General and administrative	42,056	25,037	17,019
Depreciation and amortization	87	130	(43)
Total operating expenses	123,547	103,196	20,351
Loss from operations	(123,547)	(103,196)	(20,351)
Other income, net	4,710	7,315	(2,605)
Net loss	$ (118,837)	$ (95,881)	$ (22,956)

Research and Development

Research and development expenses increased $3.4 million, or 4.3%, to $81.4 million for the year ended December 31, 2025 from $78.0 million for the year ended December 31, 2024. This increase is primarily due to the performance of tasks related to our MOLBREEVI program, which includes $5.7 million of costs related to regulatory affairs and quality assurance, primarily driven by the BLA submission; $0.5 million of costs related to our chemistry, manufacturing, and controls activities; $1.0 million other departmental overhead; partially offset by a decrease of $3.8 million in clinical costs.

General and Administrative

General and administrative expenses increased $17.0 million, or 68.0%, to $42.1 million for the year ended December 31, 2025 from $25.0 million for the year ended December 31, 2024. The increase is due to higher personnel and related costs, in terms of compensation and an increase in valuation and stock awards, driven by strategic workforce expansion to support and scale operations of $11.2 million; certain commercial activities of $3.1 million; and other overhead of $2.7 million primarily driven by expanded patient advocacy and medical affairs activities.

Other Income, Net

Other income, net decreased $2.6 million to $4.7 million for the year ended December 31, 2025 from $7.3 million for the year ended December 31, 2024. The decrease is primarily related to lower interest income as a result of reduced balances and less favorable rates and returns on our short-term investments, in addition to a loss on extinguishment of debt.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2025, we had $33.2 million in cash and cash equivalents, $202.5 million in short-term investments, and an accumulated deficit of $608.1 million. Since inception through December 31, 2025, our operations have been financed primarily by net cash proceeds of approximately $738.1 million, primarily from underwritten offerings of our common stock, private placements of common stock, and debt financings.

We have used and intend to use the net proceeds from these offerings for working capital and general corporate purposes, which include, but are not limited to, the funding of clinical development of and pursuing regulatory approval for our product candidate and general and administrative expenses. As we continue to progress on the IMPALA-2 trial, pursue regulatory approval, and invest in pre-commercial activities, we will continue to monitor our liquidity and capital requirements.

Debt Facility

As discussed in *Note 7. Debt Facility* and *Note 16. Subsequent Events* in the notes to the consolidated financial statements in this annual report on Form 10-K, on March 26, 2025, we entered into the Hercules Loan Agreement which was amended by the First Amendment on January 26, 2026. As amended, the Hercules Loan Agreement provides for the Company to borrow up to an aggregate of $105 million of term loans. Proceeds from the initial $30 million tranche drawn under the Hercules Loan Agreement were used to repay all outstanding obligations under the Amended Loan Agreement with Silicon Valley Bank, a division of First Citizens BancShares, with a carrying value of $29.9 million, to pay certain expenses incurred in connection with the financing, and for general corporate purposes. The First Amendment reset the timing and conditions to the Company's ability to draw up to $75 million of additional term loans under the Hercules Loan Agreement, subject in each case to the Approval Milestone.

Pursuant to the First Amendment, upon achievement of the Approval Milestone, the Company may borrow up to $75 million of additional term loans under the Loan Agreement, as follows:

- Up to $45 million through the earlier of (i) 120 days following the Approval Milestone or (ii) June 30, 2027.
- Beginning upon the earlier of the full draw or expiration of the First Post-Approval Tranche, up to $30 million through the earlier of (i) 120 days following the Approval Milestone or (ii) June 30, 2027.

Common Stock Sales Agreement

Effective April 2, 2025, the Company terminated the Sales Agreement, dated July 6, 2021, with Evercore Group, LLC (the "ATM Agreement"), pursuant to which the Company had been authorized to conduct "at the market offerings" (as defined as defined in Rule 415 under the Securities Act of 1933, as amended) of its common stock. During the year ended December 31, 2024, the Company sold 6,038,650 shares of the Company's common stock pursuant to the ATM Agreement resulting in net proceeds of $24.4 million. The Company did not sell any shares of common stock under the ATM Agreement during the year ended December 31, 2025.

Recent Underwritten Offerings of Common Stock

October 2025

We completed the October 2025 Offering, which resulted in net proceeds to the Company of approximately $140.2 million, after deducting final underwriting discounts, commissions, and other estimated offering expenses and including the

underwriter's option to purchase additional shares of our common stock at the public offering price as discussed in *Note 9. Stockholders' Equity* in the notes to the consolidated financial statements included in this annual report on Form 10-K.

July 2024

On July 1, 2024, we sold an aggregate of 26,246,720 shares of our common stock, par value $0.001 per share, pursuant to an underwritten offering of our common stock (the "July 2024 Offering") at an offering price of $3.81 per share. The July 2024 Offering resulted in net proceeds of $93.8 million as discussed in *Note 9. Stockholders' Equity* in the notes to the consolidated financial statements included in this annual report on Form 10-K.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Year ended December 31,	
	2025	2024
	(in thousands)	
Cash used in operating activities	$ (101,037)	$ (89,088)
Cash used in investing activities	(18,440)	(39,941)
Cash provided by financing activities	137,806	117,577
Effect of exchange rate changes on cash and cash equivalents	(277)	(5)
Net change in cash	$ 18,052	$ (11,457)

Cash flows from operating activities

Cash used in operating activities for the year ended December 31, 2025 was $101.0 million, consisting of a net loss of $118.8 million offset by a net increase in operating assets and liabilities of $5.0 million and $12.8 million of net noncash charges. The change in our net operating assets and liabilities was primarily due to an increase in accrued liabilities, specifically, compensation, research and development costs for MOLBREEVI, and the royalty agreement derivative. Net noncash charges are comprised of depreciation and amortization including right-of-use assets, amortization of debt issuance costs, loss on extinguishment of debt, accretion on discount to short-term investments, and stock-based compensation.

Cash used in operating activities for the year ended December 31, 2024 was $89.1 million, consisting of a net loss of $95.9 million offset by a net increase in operating assets and liabilities of $1.8 million and $5.0 million of net noncash charges. The change in our net operating assets and liabilities was primarily due to an increase in accrued liabilities, specifically, compensation and research and development costs for MOLBREEVI. Net noncash charges are mainly comprised of amortization of debt issuance costs, accretion on discount to short-term investments, and stock-based compensation.

Cash flows from investing activities

Cash used in or provided by investing activities for the years ended December 31, 2025 and 2024 was primarily the result of net sale and maturities of short-term investments.

Cash flows from financing activities

Cash provided by financing activities of $137.8 million for the year ended December 31, 2025 was primarily the result of net proceeds from the October 2025 Offering, net proceeds from the Hercules Loan Agreement partially offset by repayment of the SVB Loan, and repurchase of shares for minimum tax withholdings. Refer to *Note 9. Stockholders' Equity* of the consolidated financial statements in this annual report on Form 10-K for additional discussion of the October 2025 Offering.

Cash provided by financing activities of $117.6 million for the year ended December 31, 2024 was primarily the result of net proceeds from the July 2024 Offering and at the market offerings. Refer to *Note 9. Stockholders' Equity* of the consolidated financial statements in this annual report on Form 10-K for additional discussion of the July 2024 Offering.

Future Funding Requirements

We have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval for and commercialize our product candidate. At the same time, we expect our expenses to increase in connection with our ongoing development and manufacturing activities, particularly as we continue the research, development, manufacture, and clinical trials of, and seeking regulatory approval for, our product candidate. In addition, subject to obtaining regulatory approval of our product candidate, we anticipate we may need additional funding in connection with our continuing operations.

As of December 31, 2025, we had cash, cash equivalents, and short-term investments of $235.7 million. Although we have sufficient capital to fund our planned activities, including those discussed in *Note 10. Commitments – Manufacturing and Other* of the consolidated financial statements in this annual report on Form 10-K, we may need to raise additional capital to further fund the development of and seek regulatory approvals for our product candidate and to begin commercialization of any approved product. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidate.

Although we believe we are well capitalized based on our current operations, until we can generate a sufficient amount of product revenue to finance our cash requirements, we may finance our future cash needs primarily through the issuance of additional equity securities and potentially through borrowings, grants, and strategic alliances with partner companies. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or commercialization efforts or grant rights to develop and market product candidate to third parties that we would otherwise prefer to develop and market ourselves.

Manufacturing and Other Commitments and Contingencies

We are subject to various manufacturing royalties and payments and other commitments related to MOLBREEVI.

For a summary of the contingent milestone payments and commitments, refer to *Note 10. Commitments – Manufacturing and Other*, of the consolidated financial statements in this annual report on Form 10-K.

Other Contracts

We enter into contracts in the normal course of business with various third parties for research studies, clinical trials, testing, and other services. These contracts generally provide for termination upon notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Recent Accounting Pronouncements

Refer to *Note 2. Summary of Significant Accounting Policies – Recent Accounting Pronouncements*, of the consolidated financial statements in this annual report on Form 10-K for a discussion of recent accounting pronouncements and their effect, if any, on us.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Market Risk

We have market risk exposure related to our cash, cash equivalents, and short-term investment securities. Such interest earning instruments carry a degree of interest rate risk; however, we have not been exposed, nor do we anticipate being exposed, to material risks due to changes in interest rates. A hypothetical 1% change in interest rates during any of the periods presented would not have a material impact on our condensed consolidated financial statements. Additionally, our investment securities are fixed income instruments denominated and payable in U.S. dollars and have short-term maturities, typically less than twelve months, and typically carry credit ratings of “A” at a minimum by two of three Nationally Recognized Statistical Rating Organizations, specifically Moody’s, Standard & Poor’s, or Fitch. As such, we do not believe that our cash, cash equivalents, and short-term investment securities have significant risk of default or illiquidity.

Interest Rate Risk

We also have interest rate exposure related to our long-term debt. Refer to *Note 7. Debt Facility* and *Note 16. Subsequent Events* in the notes to the consolidated financial statements in this annual report on Form 10-K. The Hercules Loan Agreement bears interest equal to the greater of (i) the prime rate reported in The Wall Street Journal, plus 1.45%, which was 8.2% on December 31, 2025. Changes in the prime rate would have impacted our interest expense associated

with our secured term loan. If a 10% change in interest rates from the interest rates on December 31, 2025, were to have occurred, this change would not have had a material effect on our interest expense with respect to outstanding borrowed amounts.

Foreign Currency Exchange Risk

We use the U.S. Dollar ("USD") as our functional and reporting currency, and therefore, are subject to the risk of fluctuations in foreign currency exchange rates. The financial statements of the Company's wholly-owned subsidiaries are recorded in their functional currency and translated into USD. Our foreign currency exchange rate risk is primarily related to translation of our assets and liabilities from our foreign subsidiaries' functional currencies to USD. The cumulative effect of changes in exchange rates between the foreign entity's functional currency and the reporting currency is reported in *Accumulated other comprehensive gain (loss)* in the condensed consolidated balance sheet.

Additionally, we have vendors in Denmark, the United Kingdom, and elsewhere in Europe, and pay those vendors in local currency, Danish Krone, British Pound Sterling or Euros, respectively. Accordingly, our results of operations and cash flows are subject to fluctuations due to changes in foreign currency exchange rates, particularly changes in the Euro, British Pound Sterling and Danish Krone. Our expenses are generally denominated in the currencies of the jurisdictions in which we conduct our operations, which are primarily in the United States as well as the European Union and the United Kingdom. Our results of operations and cash flows may be adversely affected due to an expansion of non-U.S. dollar denominated contracts, growth of our international entities and operations and changes in foreign exchange rates or a weakening or strengthening of the USD against the Euro, British Pound Sterling and Danish Krone.

During the years ended December 31, 2025 and 2024, we recognized a gain on foreign currency translation of $0.7 million and a loss on foreign currency translation $0.5 million, respectively, recorded as a component of *Other comprehensive income (loss)* in our condensed statements of operations. In general, the effect of a hypothetical 10% change in foreign currency exchange rates applicable to our business on December 31, 2025 would not have a material impact on our on our results of operations or financial condition. We are currently not engaged in any hedging strategies. As our international operations grow, we will continue to reassess our approach to manage the risk relating to fluctuations in currency rates.

Inflation Risk

Additionally, inflation generally affects us by increasing our cost of labor, supplies and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented.

Item 8. Financial Statements and Supplementary Data.

The consolidated financial statements and supplementary financial information required by this item are filed with this report as described under Item 15 *Exhibits, Financial Statement Schedules*.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management has evaluated, under the supervision and with the participation of our Chief Executive Officer and Chief Financial & Administrative Officer, the effectiveness of our disclosure controls and procedures as of December 31, 2025, pursuant to and as required by Rule 13a-15(b) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial & Administrative Officer have concluded that, as of December 31, 2025, our disclosure controls and procedures, as defined by Rule 13a-15(e) under the Exchange Act, were effective and designed to ensure that (i) information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (ii) information is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial & Administrative Officer, as appropriate, to allow timely decisions regarding required disclosures.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial & Administrative Officer, we assessed the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). As a result of that assessment,

management concluded that our internal control over financial reporting was effective as of December 31, 2025 based on criteria in *Internal Control - Integrated Framework* (2013) issued by the COSO.

As a smaller reporting company, we were not required to obtain an audit on the effectiveness of our internal control over financial reporting as of December 31, 2025.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information:

Rule 10b5-1 Trading Plans

Our policy governing transactions in our securities by our directors, officers and employees permits our directors, officers and employees to enter into trading plans complying with Rule 10b5-1 under the Exchange Act. The following table describes the written plans for the sale of our securities adopted, modified or terminated by our executive officers and directors the quarter ended December 31, 2025, each of which was entered into during an open trading window and is intended to satisfy the affirmative defense conditions of of Exchange Act Rule 10b5-1(c) or any non-Rule 10b5-1 trading arrangement as defined in 17 CFR § 229.408(c) (each, a Trading Plan).

Name and Title	Date of Adoption of Trading Plan	Scheduled Start Date of Trading Plan	Scheduled Expiration Date of Trading Plan	Maximum Shares Subject to Trading Plan	Date Plan Terminated (1)
David Ramsay Member of the Board of Directors	12/18/2025	12/18/2025	12/31/2026	400,000	N/A

(1) A Trading Plan may expire on an earlier date if all contemplated transactions are completed before such Trading Plan's expiration date, upon termination by broker or the holder of the Trading Plan, or as otherwise provided in the Trading Plan.

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

Not applicable

PART III

Certain information required by Part III of this report is omitted from this report pursuant to General Instruction G(3) of Form 10-K because we will file a definitive proxy statement pursuant to Regulation 14A for our 2026 annual meeting of stockholders (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this report, and the information included in the Proxy Statement that is required by Part III of this report is incorporated herein by reference.

Item 10. Directors, Executive Officers, and Corporate Governance.

Code of Ethics

We have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer, or persons performing similar functions, as well as all of our other officers, directors, and employees. This code of ethics is a part of our code of business conduct and ethics, and is available on our corporate website at http://www.savarapharma.com. We intend to disclose future amendments to, or waivers of, certain provisions of our code of ethics that apply to our principal executive officer, principal financial officer, principal accounting officer, or persons performing similar functions on our corporate website within four business days following such amendment or waiver.

The other information required by this item will be set forth in the Proxy Statement and is incorporated into this report by reference.

Item 11. Executive Compensation.

The information required by this item will be set forth in the Proxy Statement and is incorporated into this report by reference.

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

The other information required by this item will be set forth in the Proxy Statement and is incorporated into this report by reference.

Equity Compensation Plan Information

The table below provides information about our common stock that, as of December 31, 2025, may be issued upon the exercise of options and the vesting of RSUs under the following equity compensation plans (which are all our equity compensation plans; provided, however, that new equity awards may only be issued under the 2024 Omnibus Incentive Plan and the 2021 Inducement Plan):

- Amended and Restated 2015 Omnibus Incentive Plan (the "2015 Plan")
- 2024 Omnibus Incentive Plan (the "2024 Plan")
- Savara Inc. Stock Option Plan (the "2008 Plan")
- 2021 Inducement Equity Incentive Plan (the "2021 Inducement Plan")

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights [1] (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders			
2008 Plan [2]	127,612	$ 1.60	—
2015 Plan [3]	6,616,163	$ 2.60	—
2024 Plan [4]	10,120,937	$ 3.39	3,134,152
Equity compensation plans not approved by security holders			
2021 Inducement Plan [5]	3,283,750	$ 2.59	1,098,321
Total	**20,148,462**		**4,232,473**

(1) The weighted average exercise price does not take into account the shares issuable upon vesting of outstanding RSUs, which have no exercise price.

(2) Represents shares issuable upon the exercise of outstanding options granted under the 2008 Plan.

(3) Represents shares issuable upon the exercise of outstanding options granted under the 2015 Plan.

(4) Includes 3,868,937 shares issuable upon the exercise of outstanding options granted under the 2024 Plan and 6,252,000 shares issuable upon the vesting of RSUs granted under the 2024 Plan.

(5) Includes 2,630,750 shares issuable upon the exercise of outstanding options granted under the 2021 Inducement Plan and 653,000 shares issuable upon the vesting of RSUs granted under the 2021 Inducement Plan.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated into this report by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth in the Proxy Statement and is incorporated into this report by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents Filed. The following documents are filed as part of this report:

(1) Financial Statements. The following report of RSM US LLP and financial statements:

- Report of Independent Registered Public Accounting Firm
- Consolidated Balance Sheets as of December 31, 2025 and 2024
- Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2025 and 2024
- Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2025 and 2024
- Consolidated Statements of Cash Flows for the years ended December 31, 2025 and 2024
- Notes to Consolidated Financial Statements

(1) Financial Statement Schedules. See subsection (c) below.

(2) Exhibits. See subsection (b) below.

(b) Exhibits. The exhibits filed or furnished with this report are set forth on the Exhibit Index immediately following the signature page of this report, which Exhibit Index is incorporated herein by reference.

(c) Financial Statement Schedules. All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

Item 16. Form 10-K Summary.

Not applicable.

Exhibit Index

Exhibit Number	Description
3.1	Savara Inc. Amended and Restated Certificate of Incorporation, as amended (Incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 12, 2024).
3.2	Amended and Restated Bylaws of Savara, Inc., dated March 28, 2023 (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on March 30, 2023).
4.1	Form of common stock certificate of the Registrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Annual Report on Form 10-K filed on March 14, 2018.)
4.2	Warrant to Purchase Shares of Common Stock of the Registrant issued to Life Science Loans II, LLC on April 28, 2017 (Incorporated by reference to Exhibit 4.3 to the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2017.)
4.3	Warrant to Purchase Shares of Common Stock of the Registrant issued to Silicon Valley Bank on April 28, 2017 (Incorporated by reference to Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2017.)
4.4	Amendment to Warrant to Purchase Shares of Common Stock of the Registrant issued to Life Science Loans II, LLC on June 26, 2017. (Incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2017.)
4.5	Amendment to Warrant to Purchase Shares of Common Stock of the Registrant issued to SVB Financial Group on June 26, 2017. (Incorporated by reference to Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2017.)
4.6	Warrant to Purchase Shares of Common Stock of the Registrant issued to Life Science Loans II, LLC on June 26, 2017. (Incorporated by reference to Exhibit 4.3 to the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2017.)
4.7	Warrant to Purchase Shares of Common Stock of the Registrant issued to Silicon Valley Bank on June 26, 2017. (Incorporated by reference to Exhibit 4.4 to the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2017.)
4.8	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on October 25, 2017.)
4.9	Warrant to Purchase Shares of Common Stock of the Registrant issued to Life Science Loans II, LLC on December 4, 2018. (Incorporated by reference to Exhibit 4.19 to the Registrant's Annual Report on Form 10-K filed on March 13, 2019.)
4.10	Warrant to Purchase Shares of Common Stock of the Registrant issued to Silicon Valley Bank on December 4, 2018. (Incorporated by reference to Exhibit 4.20 to the Registrant's Annual Report on Form 10-K filed on March 13, 2019.)
4.11	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on December 20, 2019.)
4.12	Form of Pre-Funded Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on December 20, 2019.)
4.13	Second Amendment to Warrant to Purchase Common Stock dated January 31, 2020, to Warrant to Purchase Common Stock of the Registrant issued to Life Science Loans II, LLC on April 28, 2017 (as amended by that certain Amendment to Warrant to Purchase Common Stock dated as of June 26, 2017) (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on February 3, 2020.)
4.14	Second Amendment to Warrant to Purchase Common Stock dated January 31, 2020, to Warrant to Purchase Common Stock of the Registrant issued to Silicon Valley Bank on April 28, 2017 (as amended by that certain Amendment to Warrant to Purchase Common Stock dated as of June 26, 2017) (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on February 3, 2020.)
4.15	Amendment to Warrant to Purchase Common Stock of the Registrant dated January 31, 2020, to Warrant to Purchase Common Stock of the Registrant issued to Life Science Loans II, LLC on June 26, 2017 (Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed on February 3, 2020.)
4.16	Amendment to Warrant to Purchase Common Stock of the Registrant dated January 31, 2020, to Warrant to Purchase Common Stock of the Registrant issued to Silicon Valley Bank on June 26, 2017 (Incorporated by reference to Exhibit 4.4 to the Registrant's Current Report on Form 8-K filed on February 3, 2020.)

4.17		Amendment to Warrant to Purchase Common Stock of the Registrant dated January 31, 2020, to Warrant to Purchase Common Stock of the Registrant issued to Life Science Loans II, LLC on December 4, 2018 (Incorporated by reference to Exhibit 4.5 to the Registrant's Current Report on Form 8-K filed on February 3, 2020.)
4.18		Amendment to Warrant to Purchase Common Stock of the Registrant dated January 31, 2020, to Warrant to Purchase Common Stock of the Registrant issued to Silicon Valley Bank on December 4, 2018 (Incorporated by reference to Exhibit 4.6 to the Registrant's Current Report on Form 8-K filed on February 3, 2020.)
4.19	*	Description of Registered Securities.
4.20		Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on March 11, 2021.)
4.21		Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on July 13, 2023).
4.22	*	Form of Pre-Funded Warrant to Purchase Common Stock in October 31, 2025 public offering.
10.1	#	Savara Inc. Amended and Restated 2015 Omnibus Incentive Plan, as amended (Incorporated by reference to Appendix A of the Registrant's Proxy Statement filed on April 19, 2022.)
10.2	#	Form of Non-Statutory Stock Option Grant Agreement – Director (for grants to non-employee directors) under the 2015 Omnibus Incentive Plan (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on June 16, 2015.)
10.3	#	Form of Incentive Stock Option Grant Agreement – Exempt Employees under the 2015 Omnibus Incentive Plan (Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on June 16, 2015.)
10.4	#	Form of Incentive Stock Option Grant Agreement – Non-Exempt Employees under the 2015 Omnibus Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on June 16, 2015.)
10.5	#	Form of Non-Statutory Stock Option Grant Agreement – General under the 2015 Omnibus Incentive Plan (Incorporated by reference to Exhibit 10.8 to the Registrant's Annual Report on Form 10-K filed on March 14, 2018.)
10.6	#	Form of Grant of Restricted Stock Units under the 2015 Omnibus Incentive Plan. (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed on November 8, 2017.)
10.7	#	Aravas Inc. (formerly Savara Inc.) Stock Option Plan (Incorporated by reference to Exhibit 10.53 to the Registrant's Registration Statement on Form S-4 filed on February 10, 2017.)
10.8	#	Aravas Inc. (formerly Savara Inc.) Form of Incentive Stock Option Agreement (Incorporated by reference to Exhibit 10.54 to the Registrant's Registration Statement on Form S-4 filed on February 10, 2017.)
10.9		Savara Inc. 2021 Inducement Equity Incentive Plan (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on January 20 2023.)
10.10		Form of Non-Statutory Stock Option Agreement – Under the 2021 Inducement Equity Incentive Plan (Incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K filed on March 30, 2022.)
10.11		Form of Restricted Stock Unit Agreement (Inducement Award) – Under the 2021 Inducement Equity Incentive Plan (Incorporated by reference to Exhibit 10.17 to the Registrant's Annual Report on Form 10-K filed on March 30, 2022.)
10.12	#	Form of Director and Officer Indemnification Agreement (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on October 23, 2006.)
10.13	+	Commercial Supply Agreement dated April 24, 2015 between PARI Pharma GmbH and Serendex Pharmaceuticals A/S (Incorporated by reference to Exhibit 10.62 to the Registrant's Registration Statement on Form S-4 filed on February 10, 2017.)
10.14	+	Research Collaboration and License Agreement dated November 7, 2014 between PARI Pharma GmbH and Serendex Pharmaceuticals A/S (Incorporated by reference to Exhibit 10.63 to the Registrant's Registration Statement on Form S-4 filed on February 10, 2017.)
10.15	+	Amendment No. 1, effective May 23, 2018, to the Research Collaboration and License Agreement between Savara Inc. (as successor in interest to Serendex Pharmaceuticals A/S) and PARI Pharma GmbH dated November 7, 2014 (Incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2018.)
10.16		Securities Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 20, 2019.)
10.17		Registration Rights Agreement (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on December 20, 2019.)

10.18	+	Manufacture and Supply Agreement, dated as of April 26, 2019, between Savara ApS and GEMABIOTECH SAU (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2019.)
10.19	+	Master Services Agreement by and between Savara Inc. and Parexel International (IRL) Limited, effective January 6, 2021 (Incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q filed on May 13, 2021.)
10.20	+	Work Order under Master Services Agreement by and between Savara Inc. and Parexel International (IRL) Limited, effective January 6, 2021 (Incorporated by reference to Exhibit 10.5 of the Registrant's Quarterly Report on Form 10-Q filed on May 13, 2021.)
10.21		Amended and Restated Executive Employment Agreement, dated December 13, 2022, between Savara Inc. and Matthew Pauls (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 15, 2022.)
10.22		Amended and Restated Executive Employment Agreement, dated December 13, 2022, between Savara Inc. and David Lowrance (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on December 15, 2022.)
10.23	+	Amendment No. 1 to the Manufacture and Supply Agreement, dated December 7, 2022 entered into by and between Savara ApS and GEMABIOTECH SAU (Incorporated by reference to Exhibit 10.33 to the Registrant's Annual Report on Form 10-K filed on March 30, 2023.)
10.24		Executive Employment Agreement, dated February 13, 2023, between Savara Inc. and Rob Lutz (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on February 13, 2023.)
10.25		Lease Agreement, dated July 7, 2021, between Savara Inc. and 1717 OSSRE, LLC. (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on May 15, 2023.)
10.26		First Amendment to Lease Agreement, dated February 28, 2023, between Savara Inc. and 1717 OSSRE, LLC. (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on May 15, 2023.)
10.27	+	Amendment No. 2 to the Manufacture and Supply Agreement, dated December 13, 2023 entered into by and between Savara ApS GEMABIOTECH SAU (Incorporated by reference to Exhibit 10.36 to the Registrant's Annual Report on Form 10-K filed on March 7, 2024.)
10.28	+	Master Services Agreement, dated February 13, 2024, by and between Fujifilm Diosynth Biotechnologies UK Limited, Fujifilm Diosynth Biotechnologies Texas, LLC, and Fujifilm Diosynth Biotechnologies U.S.A., Inc. and Savara Inc. (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2024.)
10.29		Savara Inc. 2021 Inducement Equity Incentive Plan, as amended (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on March 7, 2024).
10.30		Savara Inc. 2024 Omnibus Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K/A (Amendment No. 1) filed on June 10, 2024).
10.31	#	Form of Incentive Stock Option Award Agreement under the 2024 Omnibus Incentive Plan. (Incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed on November 12, 2024.)
10.32	#	Form of Nonqualified Stock Option Award Agreement under the 2024 Omnibus Incentive Plan. (Incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q filed on November 12, 2024.)
10.33	#	Form of Restricted Stock Unit Award Agreement under the 2024 Omnibus Incentive Plan. (Incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q filed on November 12, 2024.)
10.34		Executive Employment Agreement, dated October 15, 2024, between Savara Inc. and Braden Parker. (Incorporated by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K filed on March 27, 2025.)
10.35		Executive Employment Agreement, dated August 24, 2023, between Savara Inc. and Anne Erickson. (Incorporated by reference to Exhibit 10.39 to the Registrant's Annual Report on Form 10-K filed on March 27, 2025.)
10.36		Amended and Restated Executive Employment Agreement, dated March 13, 2025, between Savara Inc. and Kathleen McCabe. (Incorporated by reference to Exhibit 10.40 to the Registrant's Annual Report on Form 10-K filed on March 27, 2025.)
10.37	+	Master Services Agreement by and between Savara ApS and Selvita S.A., effective January 17, 2024 (Incorporated by reference to Exhibit 10.41 to the Registrant's Annual Report on Form 10-K filed on March 27, 2025.)
10.38		Loan and Security Agreement, dated March 26, 2025, between the Company and the lenders party thereto and Hercules Capital, Inc., as administrative agent and collateral agent. (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on May 13, 2025.)

10.39	*,#	Purchase and Sales Agreement By and Between Savara Inc. and 4010 Royalty Investments ICAV, an Umbrella Irish Collective Asset-Management Vehicle with Segregated Liability Between Sub-Funds, for and behalf of its Sub-Fund, 4010 Royalty Investments Fund 1, dated October 29, 2025.
10.40	*	Executive Employment Agreement, dated December 9, 2025, between Savara Inc. and Yasmine Wasfi.
10.41	*,#	First Amendment, dated January 26, 2025, to the Loan and Security Agreement March 26, 2025, between the Company and the lenders party thereto and Hercules Capital, Inc., as administrative agent and collateral agent.
10.42		Underwriting Agreement, dated October 29, 2025, by and among Savara Inc., Jefferies LLC and Piper Sandler & Co., as representatives of the several underwriters named therein (incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed on October 30, 2025).
19.1		Insider Trading and Disclosure Policy. (Incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K/A filed on April 25, 2025.)
21.1		List of Subsidiaries (Incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K filed on March 30, 2023.)
23.1	*	Consent of RSM US LLP, Independent Registered Public Accounting Firm
24.1		Power of Attorney included on page 67 of this Form 10-K
31.1	*	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a)
31.2	*	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a)
32.1	**	Certification of principal executive officer and principal financial officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97		Clawback Policy
101.INS		Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH		Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104		Cover Page Interactive Data File (embedded within the Inline XBRL document)

\# Indicates management contract or compensatory plan

\+ Certain portions of this exhibit have been redacted pursuant to Item 601(b)(10) of Regulation S-K.

* Filed herewith.

** These certifications are being furnished solely to accompany this report pursuant to 18 U.S.C. 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation by reference language in such filing.

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.

Savara Inc.

Date: March 13, 2026

By: /s/ Matthew Pauls
Matthew Pauls
Chief Executive Officer and Chair of the Board of Directors

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Matthew Pauls and Dave Lowrance, and each of them acting individually, as his or her attorney-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorney to any and all amendments to said Report.

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/ Matthew Pauls Matthew Pauls	Chief Executive Officer and Chair of the Board of Directors (Principal Executive Officer)	March 13, 2026
/s/ Dave Lowrance Dave Lowrance	Chief Financial and Administrative Officer (Principal Financial and Accounting Officer)	March 13, 2026
/s/ David Ramsay David Ramsay	Director	March 13, 2026
/s/ Joseph McCracken Joseph McCracken	Director	March 13, 2026
/s/ Nevan Elam Nevan Elam	Director	March 13, 2026
/s/ Rick Hawkins Rick Hawkins	Director	March 13, 2026
/s/ An Van Es-Johansson An Van Es-Johansson	Director	March 13, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm (PCAOB ID: 49)	F-2
Consolidated Balance Sheets as of December 31, 2025 and 2024	F-4
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2025 and 2024	F-5
Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2025 and 2024	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2025 and 2024	F-7
Notes to Consolidated Financial Statements	F-8

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Savara Inc.

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

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

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

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

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

Research and Development Costs
As described in Note 2 to the financial statements, the Company records expenses of research and development activities, including nonclinical studies, third-party contract services for clinical trials, and manufacturing development. Clinical trials and contract manufacturing activities performed by third parties are expensed based upon estimates of work completed with respective contract research organizations ("CROs") or contract manufacturing organizations ("CMOs") and other third-party vendors. Though expenses are based on signed agreements, the complexity involved in determining expenses arises from agreements containing multiple milestones that require management's analysis to determine expenses based on the progress made against benchmarks including but not limited to patients enrolled, services performed, and equipment purchased.

During 2025, the Company incurred $81.4 million of research and development expenses. The Company recorded an accrued liability of $6.4 million for expenses incurred but not yet invoiced, and a prepaid expense of $3.2 million for payments made to vendors in excess of costs incurred.

Given the significant judgments and estimates in accounting for research and development expenses, we have determined this area to be a critical audit matter.

Our audit procedures related to research and development costs included the following procedures, among others:

- For a sample of significant clinical trials and contract manufacturing services, we
  - Inspected the related contracts, purchase orders, statements of work and other contractual documentation.
  - Tested the completeness and accuracy of the underlying data used to develop the estimates.
  - Performed corroborating inquiries with the Company's research and development and finance personnel.
  - Inspected information from third-party service providers to understand the nature and progress of the studies and confirmed study related data directly with certain third-party service providers.
  - Inspected third-party service provider invoices and evidenced corresponding payments.

/s/ RSM US LLP

We have served as the Company's auditor since 2019.

Boston, Massachusetts
March 13, 2026

Savara Inc. and Subsidiaries
Consolidated Balance Sheets
(in thousands, except for share and per share amounts)

	As of December 31, 2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 33,180	$ 15,128
Short-term investments	202,522	181,199
Prepaid expenses and other current assets	5,914	5,808
Total current assets	241,616	202,135
Property and equipment, net	100	165
In-process R&D	11,636	10,337
Other non-current assets	84	242
Total assets	$ 253,436	$ 212,879
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,757	$ 4,545
Accrued expenses and other current liabilities	14,639	10,179
Total current liabilities	20,396	14,724
Long-term liabilities:		
Long-term debt	29,907	26,619
Other long-term liabilities	—	87
Total liabilities	50,303	41,430
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $0.001 par value, 300,000,000 shares authorized as of December 31, 2025 and 2024; 204,567,283 and 172,423,223 shares issued and outstanding as of December 31, 2025 and 2024, respectively	204	173
Additional paid-in capital	811,103	661,276
Accumulated other comprehensive loss	(87)	(750)
Accumulated deficit	(608,087)	(489,250)
Total stockholders' equity	203,133	171,449
Total liabilities and stockholders' equity	$ 253,436	$ 212,879

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

Savara Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except for share and per share amounts)

	Years ended December 31, 2025	2024
Operating expenses:		
Research and development	$ 81,404	$ 78,029
General and administrative	42,056	25,037
Depreciation and amortization	87	130
Total operating expenses	123,547	103,196
Loss from operations	(123,547)	(103,196)
Other income, net:		
Interest income, net	4,162	6,467
Foreign currency exchange gain	310	51
Tax credit income	784	797
Loss on extinguishment of debt	(546)	—
Total other income, net	4,710	7,315
Net loss	$ (118,837)	$ (95,881)
Net loss per share:		
Basic and diluted	$ (0.53)	$ (0.48)
Weighted-average common shares outstanding:		
Basic and diluted	222,387,531	198,191,936
Other comprehensive income (loss):		
Gain (loss) on foreign currency translation	665	(523)
Unrealized gain (loss) on short-term investments	(2)	44
Total comprehensive loss	$ (118,174)	$ (96,360)

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

Savara Inc. and Subsidiaries
Consolidated Statements of Changes in Stockholders' Equity
Years Ended December 31, 2025 and 2024
(in thousands, except share amounts)

	Stockholders' Equity					
	Common Stock					
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance on December 31, 2023	**138,143,545**	**$ 140**	**$ 533,872**	**$ (393,369)**	**$ (271)**	**$ 140,372**
Issuance of common stock in underwritten public offering, net of offering cost	26,246,720	26	93,772	—	—	93,798
Issuance of common stock upon at the market offerings, net	6,038,650	6	24,368	—	—	24,374
Issuance of common stock upon exercise of stock options	388,185	—	347	—	—	347
Issuance of common stock for settlement of RSUs	1,117,750	1	(1)	—	—	—
Repurchase of shares for minimum tax withholdings	(286,627)	—	(995)			(995)
Issuance of common stock upon exercise of prefunded warrants	775,000	—	7	—	—	7
Reimbursement of commissions from prior issuance of common stock upon at the market sales, net	—	—	46	—	—	46
Stock-based compensation	—	—	9,860	—	—	9,860
Foreign exchange translation adjustment	—	—	—	—	(523)	(523)
Unrealized gain on short-term investments	—	—	—	—	44	44
Net loss	—	—	—	(95,881)	—	(95,881)
Balance on December 31, 2024	**172,423,223**	**$ 173**	**$ 661,276**	**$ (489,250)**	**$ (750)**	**$ 171,449**
Issuance of common stock and pre-funded warrants in underwritten public offering, net of offering cost	28,452,381	28	140,200	—	—	140,228
Issuance of common stock upon exercise of pre-funded warrants	2,165,021	2	—	—	—	2
Issuance of common stock upon exercise of stock options	190,686	—	347	—	—	347
Issuance of common stock for settlement of RSUs	2,148,000	1	(1)	—	—	—
Repurchase of shares for minimum tax withholdings	(812,028)	—	(5,140)	—	—	(5,140)
Stock-based compensation	—	—	14,421	—	—	14,421
Foreign exchange translation adjustment	—	—	—	—	665	665
Unrealized gain on short-term investments	—	—	—	—	(2)	(2)
Net loss	—	—	—	(118,837)	—	(118,837)
Balance on December 31, 2025	**204,567,283**	**$ 204**	**$ 811,103**	**$ (608,087)**	**$ (87)**	**$ 203,133**

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

Savara Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(in thousands)

	Years ended December 31, 2025	2024
Cash flows from operating activities:		
Net loss	$ (118,837)	$ (95,881)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	87	130
Reduction in the carrying value of right-of-use assets	158	145
Amortization of debt issuance costs	453	271
Loss on extinguishment of debt	546	
Accretion on discount to short-term investments	(2,866)	(5,442)
Stock-based compensation	14,421	9,860
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	97	(2,383)
Non-current assets	98	11
Accounts payable and accrued expenses and other current liabilities	4,806	4,201
Net cash used in operating activities	(101,037)	(89,088)
Cash flows from investing activities:		
Purchase of property and equipment	(22)	(25)
Purchase of available-for-sale securities, net	(204,899)	(204,916)
Maturity of available-for-sale securities	182,200	165,000
Sale of available-for-sale securities, net	4,281	—
Net cash used in investing activities	(18,440)	(39,941)
Cash flows from financing activities:		
Repayment of long-term debt	(27,229)	—
Proceeds from long-term debt, net	29,598	—
Issuance of common stock issued in underwritten offering, net of offering costs	140,228	93,798
Issuance of common stock upon exercise of prefunded warrants	2	7
Issuance of common stock upon at the market offerings, net	—	24,374
Proceeds from exercise of stock options	347	347
Reimbursement of commissions from the prior issuance of common stock upon at the market sales, net	—	46
Repurchase of shares for minimum tax withholdings	(5,140)	(995)
Net cash provided by financing activities	137,806	117,577
Effect of exchange rate changes on cash and cash equivalents	(277)	(5)
Increase (decrease) in cash and cash equivalents	18,052	(11,457)
Cash and cash equivalents beginning of period	15,128	26,585
Cash and cash equivalents end of period	$ 33,180	$ 15,128
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,201	$ 2,124

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

1. Description of Business and Basis of Presentation

Description of Business

Savara Inc. (together with its subsidiaries “Savara,” the “Company,” “we” or “us”) is a clinical-stage biopharmaceutical company focused on rare respiratory diseases. The Company’s sole program, molgramostim inhalation solution (*"*MOLBREEVI" or "molgramostim"), is an investigational inhaled biologic, specifically an inhaled granulocyte-macrophage colony-stimulating factor ("GM-CSF") in Phase 3 development for autoimmune pulmonary alveolar proteinosis (“autoimmune PAP”). The Company and its wholly-owned domestic and foreign subsidiaries operate in one segment with its principal office in Langhorne, Pennsylvania, though a significant portion of employees work remotely.

Since inception, Savara has devoted its efforts and resources to identifying and developing its product candidates, recruiting personnel, and raising capital. Savara has incurred operating losses and negative cash flow from operations and has no product revenue from inception to date. The Company has not yet commenced commercial operations.

Basis of Presentation

The consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (“U.S. GAAP”) as defined by the Financial Accounting Standards Board (the “FASB”).

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements of the Company are stated in U.S. dollars. These financial statements include the accounts of the Company and its wholly-owned subsidiaries. The financial statements of the Company’s wholly-owned subsidiaries are recorded in their functional currency and translated into the reporting currency. The cumulative effect of changes in exchange rates between the foreign entity’s functional currency and the reporting currency is reported in Accumulated other comprehensive loss. All intercompany transactions and accounts have been eliminated in consolidation.

Liquidity

As of December 31, 2025, the Company had an accumulated deficit of approximately $608.1 million. The Company used cash from operations of approximately $101.0 million for the year ended December 31, 2025. The cost to further develop and obtain regulatory approval for any drug is substantial and, as noted below, the Company may have to take certain steps to maintain a positive cash position. Although the Company has sufficient capital to fund many of its planned activities, it may need to continue to raise additional capital to further fund the development of, and seek regulatory approvals for, its product candidate and begin to commercialize any approved product.

The Company is currently focused on the development of MOLBREEVI for the treatment of autoimmune PAP and believes such activities will result in the continued incurrence of significant research and development and other expenses related to this program. If the Company’s product candidate does not gain regulatory approval or, if approved, fails to achieve market acceptance, the Company may never become profitable. Even if the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. The Company intends to cover its future operating expenses through cash and cash equivalents on hand, short-term investments, and through a combination of equity offerings, debt financings, government or other third-party funding, and other collaborations and strategic alliances with partner companies. The Company cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to the Company or its stockholders.

The Company had cash and cash equivalents of $33.2 million and short-term investments of $202.5 million as of December 31, 2025, which is sufficient to fund the Company's operations for at least the next twelve months subsequent to the issuance date of its consolidated financial statements for the year ended December 31, 2025. The Company may continue to raise additional capital as needed through the issuance of additional equity securities and through borrowings and strategic alliances with partner companies. However, if such additional financing is not available timely and at adequate levels, the Company may need to reevaluate its long-term operating plans. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company currently maintains depository accounts with Silicon Valley Bank, an FDIC insured entity. In order to mitigate risks associated with our banking deposits, the Company maintains a significant portion of its liquidity in U.S. Treasury money market funds and other short-term investments with custodial services provided by U.S. Bank, N.A. and FNZ, refer to *Note 5. Short-term Investments* and *Note 8. Fair Value Measurements*.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires the Company to make certain estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Management's estimates include those related to the accrual of research and development and general and administrative costs, certain financial instruments recorded at fair value, stock-based compensation, and the valuation allowance for deferred tax assets. The Company bases its estimates on historical experience and on various other market-specific and relevant assumptions that it believes to be reasonable under the circumstances. Accordingly, actual results could be materially different from those estimates.

Risks and Uncertainties

The product candidate being developed by the Company requires approval from the U.S. Food and Drug Administration (the "FDA") or foreign regulatory agencies prior to commercial sales. There can be no assurance that the Company's product candidate will receive the necessary approvals. If the Company is denied regulatory approval of its product candidate, or if approval is delayed, it will have a material adverse impact on the Company's business, results of operations, and financial position.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the successful discovery and development of drug candidates, raising additional capital, development of competing drugs and therapies, protection of proprietary technology, and market acceptance of the Company's products. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company's future success.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and institutional bank money market accounts with original maturities of three months or less when acquired and are stated at cost, which approximates fair value.

Short-term Investments

The Company has classified its investments in debt securities with readily determinable fair value as available-for-sale securities. These securities are carried at estimated fair value with the aggregate unrealized gains and losses related to these investments reflected as a part of Accumulated other comprehensive loss within stockholders' equity.

The fair value of the investments is based on the specific quoted market price of the securities or comparable securities at the balance sheet dates. We review investments for impairment whenever the fair value of an available-for-sale security is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable. Unrealized losses are evaluated for impairment under Accounting Standards Update ("ASC") 326, Financial Instruments - Credit Losses, to determine if the impairment is credit-related or noncredit-related. Credit-related impairment is recognized as an allowance on the balance sheet with a corresponding adjustment to net loss, and noncredit-related impairment is recognized in other comprehensive (loss) income, net of taxes. The fair value of the investments is based on the specific quoted market price of the securities or comparable securities at the balance sheet dates. Refer to *Note 5. Short-term Investments* for additional discussion.

Concentration of Credit Risk

We are subject to credit risk from our portfolio of cash equivalents and marketable securities. These investments were made in accordance with our investment policy which specifies the categories, allocations, and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. We maintain our cash and cash equivalents and marketable securities with a limited number of financial institutions. Deposits held with the financial institutions exceed the amount of insurance provided on such deposits. We are exposed to credit risk in the event of a default by the financial institutions holding our cash and cash equivalents and marketable securities to the extent recorded on the consolidated balance sheets.

Research and Development Costs

The Company records the costs associated with research, nonclinical and clinical trials, and manufacturing development as incurred. These costs are a significant component of the Company's research and development expenses, with a substantial portion of the Company's on-going research and development activities conducted by third party service providers, including contract research and manufacturing organizations.

The Company accrues for expenses resulting from obligations under agreements with contract research organizations (“CROs”), contract manufacturing organizations (“CMOs”), and other outside service providers for which payment flows do not match the periods over which materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with CROs, CMOs, and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services. The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. In the event advance payments are made to a CRO, CMO, or outside service provider, the payments will be recorded as a prepaid asset which will be amortized or expensed as the contracted services are performed. As actual costs become known, the Company adjusts its prepaids and accruals. Inputs, such as the services performed, the number of patients enrolled, or the trial duration, may vary from the Company’s estimates, resulting in adjustments to research and development expense in future periods. Changes in these estimates that result in material changes to the Company’s accruals could materially affect the Company’s results of operations. To date, the Company has not experienced any material deviations between accrued and actual research and development expenses. Refer to *Note 4. Accrued Expenses and Other Current Liabilities* for additional discussion.

License and Collaboration Agreements

From time to time the Company enters, and may continue to enter, into license and collaboration agreements with third parties whereby the Company purchases the rights to develop, market, sell and/or distribute the underlying pharmaceutical products or drug candidates. Pursuant to these agreements, the Company may be required to make up-front payments, milestone payments contingent upon the achievement of certain pre-determined criteria, royalty payments based on specified sales levels of the underlying products, and/or certain other payments. Up-front payments are either expensed immediately as research and development or capitalized. The determination to capitalize amounts related to licenses is based on management’s judgments with respect to stage of development, the nature of the rights acquired, alternative future uses, developmental and regulatory issues and challenges, the net realizable value of such amounts based on projected sales of the underlying products, the commercial status of the underlying products, and/or various other competitive factors. Milestone payments made prior to regulatory approval are generally expensed as incurred and milestone payments made subsequent to regulatory approval are generally capitalized as an intangible asset. Royalty payments are expensed as incurred. Other payments made pursuant to license and collaboration agreements, which are generally related to research and development activities, are expensed as incurred.

Acquired In-Process Research and Development

In accordance with Accounting Standards Codification ("ASC") Topic 350, *Intangibles – Goodwill and Other*, the Company's acquired IPR&D is determined to have an indefinite life and, therefore, is not amortized. Instead, it is tested for impairment annually and between annual tests if the Company becomes aware of an event or a change in circumstances that would indicate the carrying value may be impaired.

With respect to the impairment testing of acquired IPR&D, Accounting Standards Update ("ASU") 2011-08, *Intangibles – Goodwill and Other (Topic 350): Testing Goodwill for Impairment*, and ASU 2012-02, *Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment*, provides for a two-step impairment process with the option to first assess qualitative factors to determine whether the existence of events or circumstances leads to the determination that it is more-likely-than not (that is, a likelihood of more than 50%) that acquired IPR&D is impaired. If the Company chooses to first assess qualitative factors and it determines that it is more-likely-than not acquired IPR&D is not impaired, the Company is not required to take further action to test for impairment.

When the Company performs a quantitative assessment of acquired IPR&D, it compares its carrying value to its estimated fair value to determine whether an impairment exists. Due to a lack of Level 1 or Level 2 inputs, the Multi-Period Excess Earnings Method (“MPEEM”), which is a form of the income approach, was used to estimate the fair value of acquired IPR&D when performing a quantitative assessment. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset’s projected incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life. The Company evaluates potential impairment of its acquired IPR&D annually on September 30th, utilizing a qualitative approach and determining if it was more-likely-than not that the fair value was impaired.

Our determinations as to whether, and if so, the extent to which acquired IPR&D become impaired are highly judgmental and, in the case of applying the MPEEM approach to estimate fair value, are based on significant assumptions regarding our projected future financial condition and operating results, changes in the manner of our use of the acquired assets, development of our acquired assets or our overall business strategy, and regulatory, market, and economic environment and trends.

If the associated research and development effort is abandoned, the related asset will be written-off, and the Company will record a non-cash impairment loss on its consolidated statements of operations and comprehensive loss. For those products that reach commercialization, the IPR&D asset will be amortized over its estimated useful life. Refer to *Note 8. Fair Value Measurements – Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis* for additional discussion.

Leases

The Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset's economic benefits in accordance with ASU 2016-02, *Leases (Topic 842),* as codified in ASC 842, *Leases*. Lease right-of-use assets and liabilities are initially recorded on the lease commencement date based on the present value of lease payments over the lease term. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term. Leases may include renewal, purchase, or termination options that can extend or shorten the term of the lease. The exercise of those options is at the Company's sole discretion and is evaluated at inception and throughout the contract to determine if a modification of the lease term is required.

In addition to rent, the leases may require the Company to pay additional amounts for taxes, insurance, maintenance, and other expenses, which are generally referred to as non-lease components. The Company has elected to not separate lease and non-lease components. Only the fixed costs for lease components and their associated non-lease components are accounted for as a single lease component and recognized as part of a right-of-use asset and liability. Rent expense is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expenses in the consolidated statements of operations and comprehensive loss.

The Company has made an accounting policy election providing that leases with an initial term of 12 months or less are not recorded as a lease right-of-use asset and corresponding liability in accordance with ASC 842, *Leases*; those lease payments are recognized in the consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term. Refer to *Note 10. Commitments – Operating Leases* for additional discussion.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is determined on a straight-line basis over the estimated useful lives of the assets, which range from three to five years. Repairs and maintenance that do not improve or extend the useful life of the respective asset are charged to expense as incurred. Refer to *Note 6. Property and Equipment, Net* for additional discussion.

Patents and Intellectual Property

As the Company’s products are currently under research and development and are not currently approved for market, costs incurred in connection with patent applications are expensed as incurred due to the uncertainty of the future economic benefits of the underlying patents and intellectual property.

Fair Value of Financial Instruments

The accounting standard for fair value measurements provides a framework for measuring fair value and requires disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on the Company’s principal or, in absence of a principal, most advantageous market for the specific asset or liability.

The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires the Company to use observable inputs when available, and to minimize the use of unobservable inputs, when determining fair value.

The three tiers are defined as follows:

- Level 1 – Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2 – Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities; and
- Level 3 – Unobservable inputs that are supported by little or no market data, which require the Company to develop its own assumptions.

The Company's financial instruments consist primarily of cash, cash equivalents, short term investments, accounts payable, and accrued liabilities. The Company's cash, cash equivalents, accounts payable, and accrued liabilities approximate fair value due to their relatively short maturities. Refer to *Note 8. Fair Value Measurements* for additional discussion.

Revenue Recognition

The Company records revenue based on a five-step model in accordance with ASC 606, *Revenue from Contracts with Customers*. To date, the Company has not generated any product revenue. The Company's ability to generate product revenues, which the Company expects to commence in the upcoming year(s), if ever, will depend heavily on the successful development, regulatory approval, and eventual commercialization of the Company's product candidates.

Net Loss per Share

Basic net loss attributable to common stockholders per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock and pre-funded warrants outstanding during the period without consideration of common stock equivalents. Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods presented as the inclusion of all potential dilutive securities would have been antidilutive. Refer to *Note 13. Net Loss per Share* for additional discussion.

Stock-Based Compensation

The Company recognizes the cost of stock-based awards granted to employees based on the estimated grant-date fair value of the awards. The value of the portion of the award is recognized as expense ratably over the requisite service period. The Company recognizes the compensation costs for awards that vest over several years on a straight-line basis over the vesting period. Forfeitures are recognized when they occur, which may result in the reversal of compensation costs in subsequent periods as the forfeitures arise. In addition, the Company accounts for any modifications to stock-based awards in accordance with ASC Topic 718, *Compensation – Stock Compensation*. Refer to *Note 11. Stock-Based Compensation* for additional discussion.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates on deferred tax assets and liabilities will be recognized in the period that includes the enactment date. A valuation allowance is established against the deferred tax assets to reduce their carrying value to an amount that is more-likely-than not to be realized. Refer to *Note 12. Income Taxes* for additional discussion.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09 (Topic 740), Income Taxes—Improvements to Income Tax Disclosures ("ASU 2023-09"), in order to enhance the transparency and decision usefulness of income tax disclosures. ASU 2023-09 requires greater disaggregation of income tax disclosures related to the income tax rate reconciliation and income taxes paid. The Company adopted this new standard for the year ended December 31, 2025. These amendments have been applied on a prospective basis in the financial statements. The required disclosure enhancements of ASU 2023-09 did not have a material impact on the Company's consolidated financial statements. See *Note 12. Income Taxes* for further details.

Recent Accounting Pronouncements (Not Yet Adopted)

In March 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("*ASU 2024-03"), to improve the disclosures about a public business entity's expenses and to provide more detailed information about the types of expenses in commonly presented expense captions. The amendments in this update should be applied either prospectively or retrospectively, and are effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027. We began an assessment of the impact that this guidance will have on our consolidated financial statements and related disclosures, and our analysis is currently ongoing.

3. Prepaid Expenses and Other Current Assets

Prepaid expenses, consisted of (in thousands):

	December 31, 2025	2024
Prepaid contracted research and development costs	$ 3,159	$ 4,179
R&D tax credit receivable	864	768
VAT receivable	390	275
Prepaid insurance	215	131
Royalty purchase and sale agreement derivative	394	—
Deposits and other	892	455
Total prepaid expenses and other current assets	**$ 5,914**	**$ 5,808**

Prepaid Contracted Research and Development Costs

As of December 31, 2025, *Prepaid contracted research and development costs* are primarily comprised of contractual prepayments associated with the Company's clinical trial for MOLBREEVI for the treatment of autoimmune PAP and for CMC related activities. This includes prepaid amounts paid under agreements with CROs, CMOs, and other outside service providers that provide services in connection with the Company's research and development activities.

R&D Tax Credit Receivable

The Company has recorded a Danish R&D tax credit receivable earned by its subsidiary, Savara ApS, as of December 31, 2025. Under Danish tax law, Denmark remits a research and development tax credit equal to 22% of qualified research and development expenditures, not to exceed established thresholds. During the year ended December 31, 2024, the Company generated a Danish R&D tax credit receivable of $0.8 million which was received in the fourth quarter of 2025. During the year ended December 31, 2025, the Company generated a Danish R&D tax credit receivable of $0.9 million which is expected to be received in the fourth quarter of 2026.

4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other liabilities, consisted of (in thousands):

	December 31, 2025	2024
Accrued compensation	$ 6,552	$ 5,017
Accrued contracted research and development costs	6,380	3,912
Accrued general and administrative costs	1,338	1,134
Royalty agreement derivative liability	362	—
Lease liability	7	116
Total accrued expenses and other current liabilities	**$ 14,639**	**$ 10,179**

Accrued Compensation

As of December 31, 2025, *Accrued compensation* includes amounts to be paid to employees for salary, vacation and non-equity performance-based compensation. At the end of any period, the amount accrued for such compensation may vary due to many factors including, but not limited to, timing of payments to employees and vacation usage.

Accrued Contracted Research and Development Costs

As of December 31, 2025, *Accrued contracted research and development costs* are primarily comprised of costs associated with MOLBREEVI for the treatment of autoimmune PAP, including expenses resulting from obligations under agreements with CROs, CMOs, and other outside service providers that provide services in connection with the Company's research and development activities.

5. Short-term Investments

Short-term Investments in Available-for-Sale Securities

The Company's investment policy seeks to preserve capital and maintain sufficient liquidity to meet operational and other needs of the business. The following table summarizes, by major security type, the Company's investments (in thousands):

As of December 31, 2025	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments				
U.S. government securities	$ 202,290	$ 232	$ —	$ 202,522
Total short-term investments	**$ 202,290**	**$ 232**	**$ —**	**$ 202,522**

As of December 31, 2024	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments				
U.S. government securities	$ 180,961	$ 255	$ (17)	$ 181,199
Total short-term investments	**$ 180,961**	**$ 255**	**$ (17)**	**$ 181,199**

The Company has classified its investments as available-for-sale securities. These securities are carried at estimated fair value with the aggregate unrealized gains and losses related to these investments reflected as a part of Accumulated other comprehensive loss in the consolidated balance sheet. Classification as short-term or long-term is based upon whether the maturity of the debt securities is less than or greater than twelve months, as further discussed in *Note 8. Fair Value Measurements.*

There were no significant realized gains or losses related to investments for the years ended December 31, 2025 and 2024.

6. Property and Equipment, Net

Property and equipment, net consisted of (in thousands):

	December 31, 2025	2024
Research and development equipment	$ 1,102	$ 1,102
Equipment	878	772
Furniture and fixtures	120	120
Leasehold improvements	333	333
Total property and equipment	2,433	2,327
Less accumulated depreciation	(2,333)	(2,162)
Property and equipment, net	**$ 100**	**$ 165**

Depreciation expense for the years ended December 31, 2025 and 2024 was minimal.

7. Debt Facility

On March 26, 2025 (the "Closing Date"), the Company, as borrower, entered into a Loan and Security Agreement (the "Hercules Loan Agreement") with the lenders party thereto (the "Lenders") and Hercules Capital, Inc., as administrative agent and collateral agent. The Hercules Loan Agreement provides for the Company to borrow up to $200 million of term loans (the "Term Loan") that may be advanced in multiple tranches.

The initial advance of $30 million under the Hercules Loan Agreement was drawn on the Closing Date and used to repay all outstanding obligations under the Company's prior term loan with Silicon Valley Bank ("SVB Loan"), to pay the Company's expenses in connection with the Hercules Loan Agreement, and for general corporate purposes. The Hercules Loan Agreement provides the Company may make further draws in the following tranches: (i) subject to FDA approval of the Company's MOLBREEVI product candidate for the treatment of autoimmune PAP (the "Approval Milestone"), (a) up to $40 million on or prior to March 15, 2026 and (b) up to $40 million on or prior to December 15, 2026; (ii) subject to the Company achieving a trailing six months' net product revenue from the sale of MOLBREEVI of at least seventy-five percent of an agreed upon revenue plan for any reporting period following March 31, 2027 (the "Revenue Milestone"), up to $20 million on or prior to December 31, 2027; and (iii) subject to approval by the Lenders' investment committees, up to $70 million.

The Term Loan will mature April 1, 2030 (the “Maturity Date”). Amounts outstanding under the Term Loan bear interest at a floating rate equal to (i) the greater of (a) the prime rate reported in The Wall Street Journal or (b) 6.0%, plus (ii) 1.45%, or, subject to the Company meeting the Revenue Milestone, a 25 bps reduction in the interest rate after the full fiscal quarter following such achievement. The Term Loan has an interest-only monthly payment through March 2028 (the “Interest-Only Period”), and beginning April 1, 2028, requires equal monthly installments of principal plus interest until the Maturity Date. If the Company achieves the Approval Milestone, the Interest-Only period will extend until the Maturity Date.

The Company's obligations under the Hercules Loan Agreement are secured, subject to customary permitted liens and other agreed-upon exceptions, by a first-priority perfected security interest in all of the tangible and intangible assets of the Company, other than intellectual property, on which there is a negative pledge. The Hercules Loan Agreement includes customary affirmative and negative covenants, repayment terms, prepayment terms subject to a 1.0% or 2.0% penalty of the amount prepaid as determined when payment occurs following the Closing Date, a contingent prepayment requirement, with any prepayment penalties waived, upon the acquisition or change of control of the Company as defined within the Hercules Loan Agreement, representations and warranties, and events of default, consisting of some events not related to the creditworthiness of the Company, which if triggered, permit the Lenders to accelerate repayment of any outstanding loan amount at the Lenders' discretion. In the event any payment is not paid on the scheduled payment date or upon an aforementioned non-creditworthiness event of default, which may trigger a call feature by the Lenders, an amount equal to 4.0% of such past due amount shall be payable on demand (collectively, the "Default Penalty").

The Hercules Loan Agreement contains an affirmative covenant requiring the Company to maintain unrestricted cash under an account control agreement equal to 50% of the outstanding principal of the Term Loan beginning April 1, 2026 (the “Cash Requirement”), which will decrease to 35% upon achievement of the Revenue Milestone and compliance with the Conditional Minimum Revenue Covenant (defined below). However, if the Approval Milestone has not been achieved, the Cash Requirement increases to 70% of the outstanding principal until the Approval Milestone is achieved. Notwithstanding the foregoing, the Cash Requirement will not apply during any period when the Company’s market capitalization exceeds $600 million.

Additionally, if the Company draws more than $50 million under the Term Loan, beginning nine months after achievement of the Approval Milestone, the Company will be required to have achieved, and to maintain, trailing six months of net product revenue of at least (i) 65% of a provided sales forecast or (ii) $100 million (“Conditional Minimum Revenue Covenant”). If the Company raises at least $75 million in net cash proceeds from the issuance of equity and/or upfront business development proceeds before June 30, 2026, the Conditional Minimum Revenue Covenant will not apply until 15 months after achievement of the Approval Milestone. Notwithstanding the foregoing, the Conditional Minimum Revenue Covenant will not apply during any period when the Company’s market capitalization exceeds $500 million and the Company maintains minimum unrestricted cash under an account control agreement equal to 50% of the outstanding principal amount of the Term Loan.

The Company is obligated to pay customary closing fees, a facility charge equal to 0.5% of the initial tranche at the Closing Date and upon any additional tranches drawn by the Company during the term of the Hercules Loan Agreement, and an end of term charge based upon the outstanding principal balance equal to 3.95% if repayment occurs within 24 months of the Closing Date, 4.95% if repayment occurs after 24 months and before 36 months of the Closing Date, 5.95% if repayment occurs after 36 months and before 48 months of the Closing Date, and 6.95% if repayment occurs after 48 months from the Closing Date.

As of December 31, 2025, approximately $0.4 million of fees consisting of legal, commitment and facility charges, paid to the Lenders were capitalized and will be amortized over the term of the Hercules Loan Agreement.

The Company has identified certain embedded features within the Hercules Loan Agreement. The Company assessed these features and determined the one feature related to Default Penalty interest due upon an event of default is required to be bifurcated from the debt and accounted for separately at fair value. As of December 31, 2025, the Default Penalty does not have a discernable fair value and no amounts are recorded.

The Company accounted for the repayment of the SVB Loan as an extinguishment in accordance with the guidance in ASC 470-50 and recognized a loss associated with the extinguishment of approximately $0.5 million in other income(expense) in the accompanying consolidated statements of operations and comprehensive loss for the twelve months ended the year ended December 31, 2025.

On January 26, 2026, the “Company entered into a First Amendment (the “First Amendment”) to the Hercules Loan Agreement, with Lenders and Hercules Capital, Inc., as administrative agent and collateral agent. As amended, the Loan Agreement provides for the Company to borrow up to an aggregate of $105 million of term loans.

The First Amendment reset the timing and conditions to the Company's ability to draw up to $75 million of additional term loans under the Hercules Loan Agreement, subject in each case to achievement of the Approval Milestone.

Pursuant to the First Amendment, upon achievement of the Approval Milestone, the Company may borrow up to $75 million of additional term loans under the Hercules Loan Agreement, as amended, as follows:

- Up to $45 million through the earlier of (i) 120 days following the Approval Milestone or (ii) June 30, 2027 (the "First Post-Approval Tranche").
- Beginning upon the earlier of the full draw or expiration of the First Post-Approval Tranche, up to $30 million through the earlier of (i) 120 days following the Approval Milestone or (ii) June 30, 2027.

Refer to *Note 16. Subsequent Events* in the notes to our consolidated financial statements in this annual report on Form 10-K for additional discussion.

Summary of Carrying Value

The following table summarizes the components of the long-term debt carrying value, which approximates the fair value (in thousands):

Future minimum payments due during the year ended December 31,	
2026	$ —
2027	—
2028	11,297
2029	14,747
2030	6,041
Total future minimum payments	32,085
Unamortized end of term charge	(1,767)
Debt fees	(411)
Total debt	29,907
Current portion of long-term debt	—
Long-term debt	$ 29,907

8. Fair Value Measurements

The Company measures and reports certain financial instruments at fair value on a recurring basis and evaluates its financial instruments subject to fair value measurements on a recurring and nonrecurring basis to determine the appropriate level in which to classify them in each reporting period.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company categorizes its financial assets and liabilities measured and reported at fair value in the financial statements on a recurring basis based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels, which are directly related to the amount of subjectivity associated with the inputs used to determine the fair value of financial assets and liabilities, are as follows:

- Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.
- Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the assets or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life
- Level 3—Inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

Each major category of financial assets and liabilities measured at fair value on a recurring basis is categorized based upon the lowest level of significant input to the valuations. The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company determined that certain investments in debt securities classified as available-for-sale securities were Level 1 financial instruments.

Additional investments in corporate debt securities, commercial paper, and asset-backed securities are considered Level 2 financial instruments because the Company has access to quoted prices but does not have visibility to the volume and frequency of trading for all of these investments. For the Company's investments, a market approach is used for recurring fair value measurements and the valuation techniques use inputs that are observable, or can be corroborated by observable data, in an active marketplace.

The fair value of these instruments as of December 31, 2025 and 2024 was as follows (in thousands):

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
As of December 31, 2025				
Cash equivalents:				
U.S. Treasury money market funds	$ 32,210	$ —	$ —	$ 32,210
Short-term investments:				
U.S. government securities	202,522	—	—	202,522
Current liabilities:				
Royalty purchase and sale agreement derivative	—	—	362	362
As of December 31, 2024				
Cash equivalents:				
U.S. Treasury money market funds	$ 13,802	$ —	$ —	$ 13,802
Short-term investments:				
U.S. government securities	181,199	—	—	181,199

The Company did not transfer any assets measured at fair value on a recurring basis to or from Level 1, Level 2, and Level 3 during the years ended December 31, 2025 and 2024.

Royalty Purchase and Sale Agreement Derivative Liability

The derivative liability arose from the royalty purchase and sale agreement entered on October 29, 2025, as further described in *Note 10. Commitments*, under which the seller has the option to prepay the buyer and the buyer may require the seller to remunerate proceeds of $4.0 million upon a change of control, as further defined, prior to approval of MOLBREEVI by the FDA on or before March 31, 2027. The fair value of the derivative liability is estimated utilizing a probability-adjusted discounted cash flow approach and is performed quarterly with gains and losses included within *change in fair value of the derivative liability* in the consolidated statements of comprehensive loss. This obligation would be settled in cash. As of October 29, 2025 and December 31, 2025, the Company assessed a 20% probability that a change of control would occur prior to the closing date of the royalty purchase and sale agreement and a 50% probability that the purchaser would exercise its right to the prepayment, which would terminate the royalty purchase and sale agreement. After taking into consideration the probability of repayment, the time value of money, and the counterparty credit risk, the estimated fair value of the put option derivative liability as $363 thousand and $362 thousand as of the October 29, 2025 and December 31, 2025 measurement dates, respectively.

The derivative liability has been classified as a Level 3 recurring liability as its valuation requires substantial judgment and estimation of factors that are not currently observable in the market. If different assumptions were used for the inputs to the valuation approach, the estimated fair value could be significantly different than the fair value the Company determined. The derivative liability is expected to either be settled or absolved within twelve months and is therefore classified as a current liability in the consolidated balance sheet.

Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis

Certain assets and liabilities are measured at fair value on a nonrecurring basis. These assets and liabilities are not measured at fair value on an ongoing basis but are subject to fair value adjustments annually or whenever events or circumstances indicate that the carrying value of those assets may not be recoverable. These assets and liabilities can include acquired IPR&D and other long-lived assets that are written down to fair value if they are impaired.

As of December 31, 2025 and 2024, the Company had IPR&D of approximately $11.6 million and $10.3 million, respectively. For the years ended December 31, 2025 and 2024, the Company experienced an increase of approximately $1.3 million and an decrease of approximately $0.6 million, respectively, in the carrying value of IPR&D, which was due to foreign currency translation.

9. Stockholders' Equity

Underwritten Offering of Common Stock

October 2025

On October 31, 2025, the Company sold pursuant to an underwritten public offering (i) an aggregate of 28,452,381 shares of the Company's common stock for $4.20 per share, including 4,642,857 shares of common stock sold pursuant to the exercise in full by the underwriters of their option to purchase additional shares, and (ii) pre-funded warrants to purchase an aggregate of 7,142,857 shares of common stock at an exercise price of $0.001 per share (the "2025 Pre-Funded Warrants") for $4.199 per pre-funded warrant (collectively, the "October 2025 Offering"). The October 2025 Offering was offered by the Company pursuant to the 2024 Registration Statement, and a prospectus supplement filed with the SEC on October 30, 2025.

The Company determined that the securities issued in the October 2025 Offering were free-standing and that the 2025 Pre-Funded Warrants meet the equity classification requirements pursuant to ASC 480, *Distinguishing Liability from Equity*, ASC 815, *Derivatives and Hedging* and Subtopic 815-40, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*.

The October 2025 Offering resulted in net proceeds to the Company of approximately $140.2 million, after deducting final underwriting discounts, commissions, and other estimated offering expenses, as follows (in thousands):

Financial instruments		**Proceeds**
Common stock	$	119.5
2025 Pre-funded warrants		30.0
Total	$	149.5
Estimated offering expenses		(9.3)
Net proceeds	$	140.2

July 2024

On July 1, 2024, the Company sold an aggregate of 26,246,720 shares of the Company's common stock, par value $0.001 per share, pursuant to an underwritten offering of its common stock (the "July 2024 Offering") at an offering price of $3.81 per share. The July 2024 Offering was made pursuant to the Registration Statement on Form S-3 (File No. 333-279274), which was filed with the SEC on May 9, 2024 and declared effective on May 21, 2024 (the "2024 Registration Statement"), and a prospectus supplement filed with the SEC on June 28, 2024. The July 2024 Offering resulted in net proceeds of $93.8 million after taking into consideration underwriter commissions, legal fees, and other customary closing costs, as follows (in thousands):

Financial instruments		**Proceeds**
Common stock	$	100,000
Offering expenses		(6,201)
Net proceeds	$	93,799

Evercore Common Stock Sales Agreement Termination

On July 6, 2021, the Company entered into a Sales Agreement with Evercore Group L.L.C. ("Evercore"), as sales agent (the "ATM Agreement"), permitting the Company to offer and sell up to an aggregate of $100.0 million of shares of its common stock, par value $0.001 per share, from time to time through Evercore in "at the market offerings" as defined in Rule 415 under the Securities Act of 1933, as amended. On March 31, 2025, pursuant to Section 12(b) of the ATM Agreement, the Company delivered written notice to Evercore that it was terminating the ATM Agreement, effective April 2, 2025. The Company is not subject to any termination penalties related to the termination of the ATM Agreement.

During the year ended December 31, 2024, the Company sold 6,038,650 shares of the Company's common stock to a single institutional investor pursuant to the Sales Agreement resulting in net proceeds of $24.4 million. The Company did not sell any shares of common stock under the Sales Agreement during the year ended December 31, 2025.

Common Stock

The Company's amended and restated certificate of incorporation, as amended, authorizes the Company to issue 301,000,000 shares of capital stock, consisting of 300,000,000 shares of common stock with $0.001 par value per share and 1,000,000 shares of preferred stock with $0.001 par value per share.

The following is a summary of the Company's common stock at December 31, 2025 and 2024:

	December 31	
	2025	2024
Common stock authorized	300,000,000	300,000,000
Common stock outstanding	204,567,283	172,423,223

The Company's shares of common stock reserved for issuance as of December 31, 2025 and 2024 were as follows:

	December 31,	
	2025	2024
April 2017 Warrants	24,725	24,725
June 2017 Warrants	41,736	41,736
December 2018 Warrants	11,332	11,332
Pre-funded PIPE Warrants	3,615,516	5,780,537
2021 Pre-funded Warrants	32,175,172	32,175,172
2023 Pre-funded Warrants	5,666,667	5,666,667
2025 Pre-funded Warrants	7,142,857	—
Stock options outstanding	13,243,462	13,554,621
Issued and non-vested RSUs	6,905,000	4,677,500
Total shares reserved	**68,826,467**	**61,932,290**

Warrants

The following table summarizes the outstanding warrants for the Company's common stock as of December 31, 2025:

Expiration Date	Shares Underlying Outstanding Warrants	Exercise Price
April 2027	24,725	$ 2.87
June 2027	41,736	$ 2.87
December 2028	11,332	$ 2.87
None	48,600,212	$ 0.001
	48,678,005	

Accumulated Other Comprehensive Income (Loss) Information

The components of accumulated other comprehensive income (loss) as of the dates indicated and the change during the period were (in thousands):

	Foreign Exchange Translation Adjustment	Unrealized Gain (Loss) on ST Investments	Total Accumulated Other Comprehensive Income (Loss)
Balance, December 31, 2023	$ (461)	$ 190	$ (271)
Change	(523)	44	(479)
Balance, December 31, 2024	$ (984)	234	$ (750)
Change	665	(2)	663
Balance, December 31, 2025	$ (319)	$ 232	$ (87)

10. Commitments

Operating Leases

The Company is obligated under an operating lease, as amended, for commercial real estate located in Langhorne, Pennsylvania, the Company's headquarters. On February 28, 2023, the Company entered into the first amendment (the "Lease Amendment") to its existing lease agreement, dated July 7, 2021 and which originally commenced on October 1, 2021. The Lease Amendment commenced on July 1, 2023, continues through June 30, 2026, or an additional thirty-six

months, expands the existing office space, and increases the average monthly rent to approximately $14.5 thousand, paid over monthly installments during the Lease Amendment term.

As of December 31, 2025, the carrying value of the right-of-use assets for the operating lease was approximately $0.1 million, which is reflected in *Prepaid expenses and other current assets* and the carrying value of the lease liabilities for the operating lease experienced a minimal decrease, which is reflected in *Accrued expenses and other current liabilities.*

The following is a maturity analysis of the annual undiscounted cash flows reconciled to the carrying value of the operating lease liabilities as of December 31, 2025 (in thousands):

Year ending December 31,		
2026	$	87
Total future minimum lease payments	**$**	**87**
Less imputed interest		(2)
Total	**$**	**85**
Operating cash flows from operating leases	$	175
Weighted-average remaining lease term (in months) - operating leases		6
Weighted-average discount rate - operating leases		7.8%

Manufacturing and Other Commitments and Contingencies

The Company has entered into a number of contracts for the manufacture of its product candidate, MOLBREEVI. Some of these, as enumerated below entail various royalties and manufacturing and development payments.

FujiFilm Diosynth (“Fuji”)

In February 2024, the Company entered into a master services agreement with Fuji to provide development and manufacturing services related to the active pharmaceutical ingredient (“API”) for the Company’s MOLBREEVI product candidate in accordance with the terms of separate scope of work agreements and to perform a manufacturing campaign for process performance qualification of the API of MOLBREEVI. Under that master services agreement, work orders and subsequent change orders, the Company is currently obligated to pay Fuji, in total, estimated fees of $44.6 million of which $15.6 million and $15.9 million has been recognized as expense during the years ended December 31, 2025 and 2024. Amounts payable for future services are subject to various cancellation fees ranging from ten percent (10%) to one hundred percent (100%) of the cost of the respective activity based upon the timing of the commencement date and status of the activity.

GEMABIOTECH SAU (“GEMA”)

Under a manufacture and supply agreement, as amended, with GEMA related to the API for MOLBREEVI, the Company must make certain payments to GEMA upon achievement of the milestones outlined in the table set forth below. Additionally, upon first receipt of marketing approval by the Company from a regulatory authority in a country for a product containing the API supplied by GEMA for therapeutic use in humans and ending the earlier of (i) ten (10) years thereafter or (ii) the date a biosimilar of such product is first sold in such country, the Company shall pay GEMA a royalty equal to low-single digits of the net sales in that country.

Additionally, the Company is subject to a purchase requirement under which for ten years following the date of receipt of approval by a regulatory authority of the first regulatory filing for the marketing and sale of the first product containing the API supplied by GEMA in any country, the Company will purchase from GEMA the API required to produce a percentage of such product it sells each year (the “Purchase Requirement”); provided, however, that the Purchase Requirement will no longer apply if (i) the price charged by GEMA exceeds a certain price charged by an alternative supplier, (ii) there is a shortage of supply, or (iii) GEMA at any time fails to materially fulfill a purchase order of the Company.

PARI Pharma GmbH (“PARI”)

The Company is also subject to certain contingent milestone payments, disclosed in the table set forth below, payable to PARI, the manufacturer of the proprietary nebulizer used to administer MOLBREEVI. In addition to these milestones, the Company will owe PARI a royalty of three-and one-half percent (3.5%) based on net sales.

Milestone Payments

The following table summarizes manufacturing commitments and contingencies as of the period indicated (in thousands):

	December 31, 2025
MOLBREEVI manufacturer:	
Achievement of certain milestones related to validation of API and regulatory approval of MOLBREEVI	$ 200
MOLBREEVI nebulizer manufacturer:	
Achievement of various development activities and regulatory approval of nebulizer utilized to administer MOLBREEVI	587
Total manufacturing and other commitments	**$ 787**

The milestone commitments disclosed above reflect the activities that have (i) not been met or incurred; (ii) not been remunerated; and (iii) not accrued, as the activities are not deemed probable or reasonably estimable, as of December 31, 2025.

Contract Research

As part of its development of MOLBREEVI for the treatment of autoimmune PAP, the Company entered into a Master Services Agreement (“MSA”) with Parexel International (IRL) Limited (“Parexel”) pursuant to which Parexel provides contract research services related to clinical trials. Contemporaneously with entering the MSA in January 2021, a work order was executed with Parexel, under which they provide services related to the IMPALA-2 trial. From inception of the original work order and subsequent change orders through trial close-out activities, the Company is obligated to pay Parexel service fees, pass-through expenses, and investigator fees estimated to be approximately $51.3 million over the course of the IMPALA-2 clinical trial and trial close-out activities of which $8.0 million and $9.2 million has been recognized as expense during the years ended December 31, 2025 and 2024, respectively.

In the second quarter of 2024, the Company initiated an open-label, multicenter clinical trial of MOLBREEVI in pediatric subjects with autoimmune PAP ("IMPACT") under a separate work order with Parexel. Pursuant to the IMPACT trial, Parexel currently has the opportunity to earn up to approximately $5.6 million in various milestone payments primarily dependent upon patient enrollment, site management, project oversight and the compliance with defined study protocols of which $1.1 million and 1.3 million was recognized in the years ended December 31, 2025 and 2024, respectively.

Royalty Purchase and Sale Agreement

On October 29, 2025, the Company entered into a purchase and sale agreement (the “Purchase Agreement”) with funds managed by RTW Investments, LP (the “Purchaser”). Under the terms of the Purchase Agreement, the Purchaser has agreed to pay the Company $75.0 million (the “Purchase Price”) upon approval of MOLBREEVI by the FDA on or before March 31, 2027 (the date of such payment, the "Closing Date") and subject to satisfaction of other customary closing conditions, in exchange for a true sale of assigned interests, including the right to receive royalty payments equal to a percentage of Net Sales (as defined in the Purchase Agreement) of MOLBREEVI in the U.S. The royalty rate is tiered, with the payments ranging from 7.0% to 1.0% of Net Sales in each calendar year, with the 7.0% tier increasing to 9.5% for a calendar year if the prior year’s Net Sales do not achieve a specified level. The royalty payments commence in the first calendar quarter in which there is a commercial sale of MOLBREEVI in the United States and end upon the receipt by the Purchaser of $187.5 million (the “Maximum Payment”). The Purchase Agreement includes a buy-back option that may allow the Company to pay a specified amount up to the Maximum Payment to terminate the Purchase Agreement and all obligations in the event of certain changes of control within two years of receipt of the Purchase Price. Unless otherwise agreed with the Purchaser, the Company is required to use a portion of the Purchase Price to repay all outstanding indebtedness. The Purchase Agreement contains customary affirmative and negative covenants, including covenants that limit or restrict the Company’s ability to, among other things, incur indebtedness (which restrictions are eliminated after the achievement by the Company of a specified amount of Net Sales), and other provisions customary for transactions of this nature, in each case subject to certain exceptions set forth in the Purchase Agreement.

Under the Purchase Agreement, upon the occurrence of a Change of Control of the Company (as defined in the Purchase Agreement) the Company has the option to prepay (“Company Call”) and the Purchaser has the option to demand the prepayment (“Buyer Put”) of a specified amount and terminate the Purchase Agreement. The revenue-based repayments to the Buyer (“Revenue-Based Payment”) will be established on a schedule of royalty rates as a factor of Annual Net Sales, including applicable ratchets in the definition of a Royalty Rate, until the Royalty Cap is reached.

The Company has identified the embedded features in the Purchase Agreement and concluded that the Buyer Put Option and the Company Call Option are embedded derivatives that must be bifurcated under ASC 815-10-15-83 and ASC 815-15-25-1, Derivatives and Hedging.

Accordingly, the Company has recorded the royalty agreement derivative as of the date of issuance and determined its fair value to be approximately $0.4 million as of the issue date and December 31, 2025. The Company has also capitalized the amount as deferred issuance costs, subject to straight line amortization up until the Closing Date, which is reflected in Prepaid expenses and other current assets and recorded a derivative liability reflected in Accrued expenses and other current liabilities, subject to periodic fair value remeasurement

In addition, direct and incremental Company issuance costs as well as reimbursed Buyer expenses have been capitalized by the Company and amortized over the expected term of the arrangement. Upon the Purchase Agreement closing, the remaining balance will be applied against the proceeds received and subsequently amortized using the effective interest method.

Risk Management

The Company maintains various forms of insurance that the Company's management believes are adequate to reduce the exposure to these risks to an acceptable level.

Employment Agreements

On December 8, 2020, the Company entered into an employment agreement with the Chief Executive Officer ("CEO"), which was amended and restated on December 13, 2022, whereby the CEO is entitled to payments and benefits upon certain events. Upon (i) termination without cause, (ii) termination due to the CEO's death or disability, or (iii) the CEO's resignation for good reason, the CEO is entitled to receive (i) a lump sum payment equal to 18 months of base salary, (ii) a lump sum payment equal to 100% of his target bonus, (iii) a pro-rated portion of the unpaid target bonus based upon the number of days he was employed by the Company during the relevant performance period, (iv) reimbursement for continued coverage under medical benefit plans for 18 months or until covered under a separate plan from another employer, and (v) the immediate and full vesting of outstanding non-vested Company equity awards. Additionally, all of the CEO's outstanding stock options will be exercisable through the earlier of (x) the 18-month anniversary of the termination date or (y) the original expiration date.

Upon a termination other than for cause, death or disability or upon resignation for good reason within three months prior to or 12 months following a change in control, the CEO is entitled to receive (i) a lump sum payment of an amount equal to 24 months of base salary, (ii) 100% of the unpaid target bonus, (iii) a pro-rated portion of the unpaid target bonus based on the number of days he was employed by the Company during the relevant performance period, (iv) reimbursement for continued coverage under medical benefit plans for 24 months or until covered under a separate plan from another employer, and (v) the immediate and full vesting of outstanding non-vested Company equity awards. Additionally, all of the CEO's outstanding stock options will be exercisable through the earlier of (x) the 24-month anniversary of the termination date or (y) the original expiration date.

Each of the Company's Chief Financial & Administrative Officer ("CFO"), Chief Medical Officer ("CMO"), Chief Operating Officer ("COO"), Chief Business Officer ("CBO"), Chief Commercial Officer ("CCO") and Chief Legal Officer ("CLO") has entered into an employment agreement with the Company that entitles them to payments and benefits if the CFO, CMO, COO, CBO, CCO or CLO, respectively, is (i) terminated without cause, (ii) terminated due to death or disability, or (iii) resigns for good reason, which includes (i) a lump sum payment equal to 12 months of base salary and a pro-rated portion of their unpaid bonus, (ii) reimbursement for continued coverage under medical benefit plans for 12 months or until covered under a separate plan from another employer, and (iii) accelerated vesting of outstanding non-vested Company equity awards that would have otherwise vested had the executive remained employed by the Company for an additional 12 months. Upon a termination other than for cause, death or disability or upon resignation for good reason within three months prior to or 12 months following a change in control, the CFO, CMO, COO, CBO, CCO or CLO is entitled to receive (i) a lump sum payment of an amount equal to 18 months of base salary, plus 100% of their target bonus, plus a pro-rated portion of their unpaid target bonus, (ii) a lump sum payment equal to the amount required to continue coverage under medical benefit plans for 18 months, and (iii) the immediate and full vesting of outstanding non-vested options at the time of such termination.

Litigation

On September 8, 2025, a putative securities class action complaint, *Ho, et al. v. Savara Inc., et al.*, was filed against the Company and certain of our executive officers in the United States District Court for the Eastern District of Pennsylvania. The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder in connection with various public statements made by the Company regarding its regulatory filings for MOLBREEVI as a therapy to treat patients with autoimmune PAP. The plaintiffs seek unspecified damages, costs and expenses, including attorneys' fees. On each of December 4, 2025 and January 16, 2026, a stockholder derivative complaint was filed in the United States District Court for the Eastern District of Pennsylvania against our directors, certain of our officers, and the Company as a nominal defendant, *Norman v. Pauls, et al.* and *Lasky v. Pauls, et*

al., respectively. The derivative complaints arise out of similar allegations as the securities class action and were consolidated and stayed pending further proceedings in the securities class action. In each of the derivative complaints, the plaintiffs seek changes to the Company's corporate governance and internal procedures, as well as unspecified monetary damages, costs and expenses, including attorneys' fees.

On February 6, 2026, the co-lead plaintiffs in the securities class action voluntarily dismissed the action without prejudice as to all defendants. On February 12, 2026, the plaintiffs in the stockholder derivative action voluntarily dismissed the action without prejudice as to all defendants.

From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. Although the results of litigation and claims cannot be predicted with certainty, the Company does not believe it is party to any claim or litigation the outcome of which, if determined adversely to the Company, would individually or in the aggregate be reasonably expected to have a material adverse effect on its business. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors.

11. Stock-Based Compensation

The Company's 2024 Omnibus Incentive Plan (the "2024 Plan") was adopted by the Company's board of directors in March 2024, was approved by the Company's stockholders on June 6, 2024, and became effective on June 7, 2024. The 2024 Plan was intended to replace the Company's Amended and Restated 2015 Omnibus Incentive Plan (the "2015 Plan"), and upon the effectiveness of the 2024 Plan, no further grants may be made under the 2015 Plan. All outstanding awards under the 2015 Plan will continue in accordance with the 2015 Plan and any award agreement executed in connection with such outstanding awards. The 2024 Plan provides for the grant of stock options (both incentive stock options and non-statutory stock options), stock appreciation rights, restricted stock, restricted stock units ("RSUs"), performance stock units ("PSUs"), and other stock-based awards. Stock-based awards are subject to terms and conditions established by the board of directors or the compensation committee of the board of directors. As of December 31, 2025, the number of shares of common stock available for grant under the 2024 Plan was 3,134,152 shares.

The Company's 2021 Inducement Equity Incentive Plan (the "Inducement Plan") was adopted by the Company's board of directors in May 2021 and subsequently amended to increase the shares available for grant. The Inducement Plan provides for the grant of non-statutory stock options, restricted stock, RSUs, stock appreciation rights, PSUs, and performance shares. Each award under the Inducement Plan is intended to qualify as an employment inducement grant in accordance with Nasdaq Listing Rule 5635(c)(4). As of December 31, 2025, the number of shares of common stock available for grant under the Inducement Plan was 1,098,321 shares.

The Savara Inc. Stock Option Plan (the "2008 Plan") was adopted in 2008, and the Company no longer issues awards under the 2008 Plan. As of December 31, 2025, the Company had options outstanding to purchase 127,612 shares of common stock under the 2008 Plan. The outstanding awards granted under the 2008 Plan are fully vested and generally have a maximum contractual term of ten years.

The Company values stock options using the Black-Scholes-Merton option pricing model, which requires the input of subjective assumptions, including the risk-free interest rate, expected life, expected stock price volatility, and dividend yield. The risk-free interest rate assumption is based upon observed interest rates for constant maturity U.S. Treasury securities consistent with the expected term of the Company's employee stock options. The expected life represents the period of time the stock options are expected to be outstanding and is based on the simplified method. The Company uses the simplified method due to the lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected life of the stock options. Expected volatility is based on historical volatilities for publicly traded stock of comparable companies over the estimated expected life of the stock options. The Company assumes no dividend yield because dividends are not expected to be paid in the future, consistent with the Company's history of not paying dividends. The valuation of stock options is also impacted by the valuation of common stock.

Restricted stock units, including PSUs, are valued at the closing market price of the Company's common stock on the date of grant.

During the year ended December 31, 2025, the Company granted 4,545,000 PSUs (the "2025 PSUs") to certain of its employees and non-employee service providers. The 2025 PSUs are subject to certain performance conditions and a service condition. The performance conditions range from (i) FDA approval of the Company's BLA for MOLBREEVI for the treatment of autoimmune PAP, of which 225,000 PSUs require approval on or before a specified date, (ii) the European Medicines Agency approval of the Company's marketing authorisation application for MOLBREEVI for the treatment of autoimmune PAP, (iii) the achievement of a certain revenue target, or (iv) a combination of some the aforementioned performance conditions. The service condition is continuous employment or service with the Company through the date

the performance obligations may be achieved. The potential payout of the award ranges from 0% to 100% of the target, dependent on the achievement of the performance conditions and their respective weighting towards the vesting of the 2025 PSUs as predetermined by the Company. The Company began recognizing and recording compensation cost on a straight-line basis in the consolidated statements of comprehensive loss upon the grant date of the 2025 PSU grants as the performance conditions were deemed probable by the Company. Any forfeitures of unvested awards that occurs after the recognition of compensation cost will result in the cumulative reversal of expense in the period in which the forfeiture occurs.

The following table summarizes the assumptions used for estimating the fair value of stock options granted to employees for the years ended December 31, 2025 and 2024:

	2025	2024
Risk-free interest rate	3.67% - 4.51%	3.58% - 4.55%
Expected term (years)	6.44 - 6.71	6.06 - 9.26
Expected volatility	114.3%	90.9% - 114.6%
Dividend yield	0%	0%

Stock-Based Award Activity

The following tables provide a summary for stock option and RSU activity for the year ended December 31, 2025:

Stock Options:

	Shares Underlying Option Awards	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value (in 000's)
Outstanding at December 31, 2024	**13,554,621**	**$ 2.79**	**7.89**	**$ 11,586**
Granted	409,500	3.26	6.06	
Exercised	(192,159)	1.85		$ 324
Expired/cancelled/forfeited	(528,500)	1.92		
Outstanding at December 31, 2025	**13,243,462**	**$ 2.82**	**6.94**	**$ 46,078**
Options exercisable at December 31, 2025	**8,364,040**	**$ 2.56**	**5.99**	**$ 32,198**

The weighted-average grant date fair values for the Company's stock options granted during the years ended December 31, 2025 and 2024 were $2.82 per share and $3.47 per share, respectively. The total compensation cost related to non-vested stock options not yet recognized as of December 31, 2025 was $13.1 million, which will be recognized over a weighted-average period of approximately 2.7 years.

During the years ended December 31, 2025 and 2024, the Company did not grant any options to purchase shares of common stock to non-employees. The Company recorded a minimal amount of stock-based compensation expense for options issued to non-employees for the years ended December 31, 2025 and 2024, respectively.

RSUs:

	Shares Underlying Stock Awards	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2024	**4,677,500**	**$ 3.83**
Granted	5,080,500	6.11
Vested	(2,148,000)	4.03
Expired/cancelled/forfeited	(545,000)	—
Vested and deferred settlement	(160,000)	3.35
Outstanding at December 31, 2025	**6,905,000**	**$ 5.40**

RSUs with deferred settlement are considered equity-classified awards as the Company does not have an obligation to settle the awards in cash and the participant cannot accelerate settlement. The Company recognizes compensation expense on a straight-line basis over the requisite service period based on the grant-date fair value of the awards. As of December 31, 2025, the Company had 160,000 vested RSUs with deferred settlement outstanding, representing deferred shares to be issued in future periods. These shares are reflected as issued and outstanding for accounting purposes only upon physical delivery of the shares. The total compensation cost related to unvested RSUs not yet recognized as of December 31, 2025 was $32.1 million, which will be recognized over a weighted-average period of 1.9 years.

Stock-Based Compensation

Stock-based compensation expense is included in the following line items in the accompanying consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024 (in thousands):

	Year ended December 31, 2025	2024
Research and development	$ 4,055	$ 4,453
General and administrative	10,366	5,407
Total stock-based compensation	**$ 14,421**	**$ 9,860**

12. Income Taxes

The components of loss before income taxes for the years ended December 31, 2025 and 2024 are as follows (in thousands):

	December 31, 2025	2024
Domestic	$ (84,300)	$ (63,256)
Foreign	(34,537)	(32,625)
Total	**$ (118,837)**	**$ (95,881)**

The Company did not record a federal tax benefit or expense for the years ended December 31, 2025 and 2024. The Company recorded a minimal state provision for income taxes for the year ended December 31, 2024 and no state provision for income taxes for the year ended December 31, 2025 due to revenues below the minimum tax threshold. The components of the income tax expense are as follows for the years ended December 31, 2025 and 2024 (in thousands):

	December 31, 2025	2024
Current:		
Federal	$ —	$ —
State	—	9
Foreign	—	—
Total Current	—	9
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total Deferred	—	—
Total income tax expense	**$ —**	**$ 9**

As noted above, we adopted ASU 2023-09 on a prospective basis effective January 1, 2025. The following table presents required disclosure pursuant to ASU 2023-09 and reconciles the U.S. federal statutory tax amount and rate to our actual global effective amount and rate for the year ended December 31, 2025:

	December 31, 2025	
Federal	$ (24,956)	21.00%
Other States	—	0.00%
Foreign		
Income taxes, net of amounts refunded		
Statutory tax rate difference between DK and US	(345)	0.29%
Change in valuation allowance	6,968	-5.86%
Other	630	-0.53%
Tax credits		
Orphan drug tax credit	(8,033)	6.76%
Change in valuation allowance	23,375	-19.67%
Nontaxable or Nondeductible Items		
Imputed Interest Income	1,810	-1.52%
162(m) Limitation	1,150	-0.97%
Other	(604)	0.50%
Other adjustments		
Other	5	0.00%
Total	**$ —**	**0.00%**

(a) The company does not have any state income tax in current year.

A reconciliation of the expected income tax results computed using the federal statutory income tax rate to the Company's effective income tax rate is as follows for the year ended December 31, 2024 (in thousands):

	December 31, 2024
Income tax benefit computed at federal statutory tax rate	$ (20,135)
State taxes, net of federal	7
Change in valuation allowance	29,911
Orphan drug & research credits generated	(9,659)
Impact of foreign operations	(338)
Foreign deferred tax asset - true up	(750)
Actualization and deferred tax asset - true up	(214)
Imputed interest	1,498
Permanent differences	(311)
Other	—
Total	**$ 9**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company has established a valuation allowance due to uncertainties regarding the realization of deferred tax assets based upon the Company's lack of earnings history. During the years ended December 31, 2025 and 2024, the valuation allowance increased by $35.4 million and $33.5 million, respectively.

Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31, 2025	2024
Deferred tax liabilities:		
ROU assets	$ 23	$ 67
Other	397	687
Total deferred tax liabilities	420	754
Deferred tax assets:		
Net operating loss carryforwards	85,643	58,384
Intangible assets	111	379
Amortization	—	1,263
Credit carryforwards	30,656	22,624
Section 174 research and development expenses	20,007	20,058
ROU liabilities	2	56
Depreciation	315	272
Stock-based compensation	4,448	3,618
Accrued liabilities & other	1,969	1,456
Total deferred tax assets	143,151	108,110
Subtotal	142,731	107,356
Valuation allowance	(142,731)	(107,356)
Net deferred taxes	**$ —**	**$ —**

The Company completed a Section 382 analysis to determine the amount of losses that are currently available for potential offset against future taxable income. Based on the analysis, it was determined that the utilization of the Company's NOLs and tax credit carryforwards generated in tax periods up to and including December 2019 are substantially limited and may result in the expiration of such carryforwards prior to utilization. In general, an ownership change, as defined by Section 382, results from transactions that increase the ownership of 5% shareholders in the stock of a corporation by more than 50 percentage points in the aggregate over a three-year period. Since the Company's formation, it has raised capital through public and private issuance of common stock on several occasions which have ultimately resulted in multiple changes in ownership, as defined by Section 382. As of December 31, 2025 and 2024, the Company still has $53.9 million of federal Section 382 NOLs, collectively, which are included in the federal NOL carryforwards below, that are severely limited in future years.

As of December 31, 2025 and 2024, the Company had foreign NOL carryforwards of approximately $177.1 million and $137.7 million, respectively, which have an indefinite carryforward period. After taking the Section 382 limitations discussed into account, as of December 31, 2025 and 2024, the Company had NOLs for federal income tax purposes of approximately $195.3 million and $126.0 million, respectively. Federal NOL carryforwards of $5.2 million begin to expire in 2037, with $190.1 million not having an expiration date. As of December 31, 2025 and 2024, the Company had state NOL carryforwards of approximately $96.0 million and $25.3 million, respectively. The state NOL carryforwards begin to expire in 2037.

As of December 31, 2025 and 2024, the Company also had available research and orphan drug tax credit carryforwards for federal income tax purposes of approximately $30.2 million and $22.1 million, respectively. If not utilized, these carryforwards expire at various dates beginning in 2039. As of December 31, 2025 and 2024, the Company had state research and development tax credit carryforwards of approximately $0.5 million and $0.5 million, respectively, which will begin to expire in 2034 if not utilized.

Law Changes

On July 4, 2025, H.R. 1 – OBBBA, the One Big Beautiful Bill Act ("OBBBA"), was signed into law. Effective beginning in 2025, OBBBA provides for US tax law changes and modifications including the ability to deduct US based research and development expenditures, a more favorable interest expense limitation, the reinstatement of 100% bonus depreciation on qualified property and several changes to the US taxation of foreign activity. Given the Company's history of net operating losses, OBBBA did not have a significant impact on the Company's financial statements.

The Company applies the accounting guidance in ASC 740 *Income Taxes* related to accounting for uncertainty in income taxes. The Company's reserves related to taxes are based on a determination of whether, and how much of, a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. As of December 31, 2025 and 2024, the Company had no unrecognized tax benefits. During the years ended December 31, 2025 and 2024, the Company had no interest and penalties related to income taxes.

The Company files income tax returns in the U.S. federal, state, and foreign jurisdictions. As of December 31, 2025, the statute of limitations for assessment by the Internal Revenue Service ("IRS") is open for the 2020 and subsequent tax years, although carryforward attributes that were generated for tax years prior to then may still be adjusted upon examination by the IRS if they either have been, or will be, used in a future period. The 2020 and subsequent tax years remain open and subject to examination by the state taxing authorities. The 2021 and subsequent tax years remain open and subject to examination by the foreign taxing authorities. There are currently no federal, state, or foreign income tax audits in progress.

New Accounting Pronouncement Adoption

We adopted ASU 2023-09 on a prospective basis for the year ended December 31, 2025 and have included the following table as a result of our adoption, which presents income taxes paid (net of refunds received) for the year ended December 31, 2025:

	December 31, 2025
Federal	$ —
Other States	—
Foreign	—
Income taxes, net amounts refunded	**$ —**

13. Segment Reporting

We follow the accounting guidance of ASC Topic 280, *Segment Reporting*, which establishes standards for companies to report in their financial statement information about operating segments, products, services, geographic areas, and major customers. Operating segments are defined as components of an enterprise engaging in business activities for which separate financial information is available that is regularly evaluated by the Company's chief operating decision-makers in deciding how to allocate resources and assess performance. The Company's chief operating decision maker ("CODM") has been identified as the Chief Executive Officer, who reviews consolidated results including operating expenses and operating losses at a consolidated level only. The Company and its CODM do not distinguish between potential markets for the purpose of making decisions about resource allocation and performance assessment of its sole pre-revenue development program, MOLBREEVI, for the treatment of autoimmune PAP. Therefore, the Company has only one operating segment and one reportable segment, specialty pharmaceuticals within the respiratory system. The Company's only significant long-lived asset, IPR&D, is located in Denmark, and the Company currently does not generate any revenues and its operating expenses and losses are viewed on a consolidated basis by the CODM. Therefore, no geographical segments are presented. In addition to the significant expense categories included on the Company's

consolidated statements of operations, refer below for disaggregated amounts that comprise research and development expenses and the segment net loss (in thousands):

	Year Ended December 31, 2025	2024
Operating expenses:		
Research and development operating costs and expenses excluding non-cash stock-based compensation:		
Primary program research and development expenses [(a)]	$ 61,744	$ 59,325
Other research and development expenses:		
Payroll and benefits	13,549	11,933
Occupancy and other overhead and operating costs	2,056	2,318
Total other research and development expenses	15,605	14,251
Research and development operating costs and expenses excluding non-cash stock-based compensation:	77,349	73,576
General and administrative expense excluding non-cash stock-based compensation	31,690	19,630
Other segment income (expense), net [(b)]	9,798	2,675
Segment net loss	$ (118,837)	$ (95,881)

(a) *Primary program research and development expenses are comprised primarily of costs paid to third parties for clinical trials and product development manufacturing, nonclinical, regulatory, and quality assurance activities, and the portion of related research and development expenses incurred by our collaborators and third-party service providers, including contract research and manufacturing organizations that we are obligated to reimburse.*

(b) *Other segment income (expense), net includes interest income, interest expense, foreign currency exchange gain or loss, depreciation and amortization, non-cash stock-based compensation, loss on extinguishment of debt (for the year ended December 31, 2025) and tax credit income.*

14. Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding. Diluted net loss per share is computed similarly to basic net loss per share except the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. Diluted net loss per share is the same as basic net loss per common share since the effects of potentially dilutive securities are antidilutive.

As of December 31, 2025 and 2024, potentially dilutive securities include:

	Year ended December 31, 2025	2024
Awards under equity incentive plan	13,243,462	13,554,621
Non-vested restricted shares and restricted stock units	6,905,000	4,677,500
Warrants to purchase common stock	77,793	77,793
Total	**20,226,255**	**18,309,914**

The following table calculates basic net loss per share of common stock and diluted net loss per share of common stock for the years ended December 31, 2025 and 2024 (in thousands, except share and per share amounts):

	Year ended December 31, 2025	2024
Net loss	$ (118,837)	$ (95,881)
Net loss attributable to common stockholders	$ (118,837)	$ (95,881)
Undistributed earnings and net loss attributable to common stockholders, basic and diluted	$ (118,837)	$ (95,881)
Weighted-average common shares outstanding, basic and diluted	222,387,531	198,191,936
Basic and diluted net loss per share	**$ (0.53)**	**$ (0.48)**

15. Employee Benefits

The Company offers a defined contribution 401(k) plan for its employees. Employees are eligible to participate in the plan beginning on the first day following ninety days of the anniversary date of hire. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation. The Company makes discretionary contributions to the 401(k) plan equal to 100 percent of each employee's pretax contributions up to eighteen thousand dollars. The Company's total contributions to the 401(k) plan were $0.9 million and $0.6 million for the years ended December 31, 2025 and 2024, respectively.

16. Subsequent Events

The Company has evaluated subsequent events through the date these consolidated financial statements were issued. The Company determined there were no events, other than as described below, that required disclosure or recognition in these condensed consolidated financial statements.

Loan Agreement

On January 26, 2026, the Company entered into a First Amendment (the "First Amendment") to the Hercules Loan Agreement as described in *Note 7. Debt Facility*, with the Lenders. As amended, the Hercules Loan Agreement provides for the Company to borrow up to an aggregate of $105 million of term loans.

The First Amendment reset the timing and conditions to the Company's ability to draw up to $75 million of additional term loans under the Hercules Loan Agreement, subject in each case to FDA approval of the Company's MOLBREEVI product candidate for the treatment of autoimmune PAP (the "Approval Milestone").

Pursuant to the Hercules Loan Agreement, as amended by the First Amendment, upon achievement of the Approval Milestone, the Company may borrow up to $75 million of additional term loans under the Hercules Loan Agreement, as follows:

- Up to $45 million through the earlier of (i) 120 days following the Approval Milestone or (ii) June 30, 2027 (the "First Post-Approval Tranche").
- Beginning upon the earlier of the full draw or expiration of the First Post-Approval Tranche, up to $30 million through the earlier of (i) 120 days following the Approval Milestone or (ii) June 30, 2027.

The First Amendment extended the dates by which the Company may be required to comply with two financial covenants, extending the initial date for compliance with the Cash Requirement to April 1, 2027, and the date for compliance with the Conditional Minimum Revenue Covenant to September 30, 2027, if its market capitalization falls below the previously reported thresholds for each respective covenant.

The Hercules Loan Agreement, as amended by the First Amendment, grants the Lenders a first-priority perfected security interest in the Company's intellectual property that will convert to a negative pledge if the Company terminates the Purchase Agreement dated as of October 29, 2025 with funds managed by the Purchaser, as described in *Note 10. Commitments* prior to receiving funds under the Purchase Agreement and so long as the Company maintains $50 million or more in unrestricted cash.

Litigation

On February 6, 2026, the co-lead plaintiffs of the securities class action claim filed against the Company on September 8, 2025, as described in *Note 10. Commitments* to our consolidated financial statements in this Annual Report on Form 10-K, voluntarily dismissed the action without prejudice as to all defendants. On February 12, 2026, the plaintiffs in the stockholder derivative action described in *Note 10. Commitments* to our consolidated financial statements in this Annual Report on Form 10-K voluntarily dismissed the action without prejudice as to all defendants.

New Lease Agreement

On March 10, 2026, the Company entered into a lease agreement (the "New PA Lease") for its office headquarters in Yardley, Pennsylvania. The New PA Lease shall commence on July 1, 2026 and continues through November 30, 2031.

Concurrent with the New PA Lease, the Company is not renewing its current operating lease for its office space in Langhorne Pennsylvania with termination of the Langhorne Pennsylvania lease effective June 30, 2026.