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, 2020

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.)**
6836 Bee Cave Road, Building III, Suite 200	
Austin, TX	**78746**
(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. ☐

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, 2020, (the last business day of the registrant's most recently completed second fiscal quarter), was $116,495,337.

The number of shares of Registrant's Common Stock outstanding as of March 8, 2021 was 54,235,926.

Portions of the Registrant's Definitive Proxy Statement relating to the Annual Meeting of Shareholders, scheduled to be held on June 10, 2021, are incorporated by reference into Part III of this Report.

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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 "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "expect," "indicate," "seek," "should," "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 and prospects for regulatory approval of our product candidates, including timing and outcomes of clinical trials;*
- *our beliefs regarding the therapeutic benefits of our product candidates;*
- *our beliefs regarding the treatment of conditions related to the indications targeted by our product candidates; and*
- *prospects for market success of our product candidates, including competition, intellectual property protection and infringement, third party payor coverage and reimbursement.*

For a discussion of the factors that may cause our actual results, performance or achievements to differ materially from any future results, or performance or achievements expressed or implied in such forward-looking statements, see Part I, Item 1A, "Risk Factors," in this report.

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.

PART I

Item 1. Business.

Business Overview

Savara is an orphan lung disease company. Our lead program, molgramostim nebulizer solution ("molgramostim," formerly referred to as Molgradex), is an inhaled granulocyte-macrophage colony-stimulating factor ("GM-CSF") in Phase 3 development for autoimmune pulmonary alveolar proteinosis ("aPAP"). Our management team has significant experience in orphan drug development and pulmonary medicine, identifying unmet needs, and effectively advancing product candidates to approval and commercialization.

Corporate Strategy

Our goal is to become a leader in orphan lung disease 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:

- **Advancing the molgramostim aPAP program and the Phase 3 IMPALA 2 clinical trial.** The IMPALA 2 trial design has been endorsed by regulatory authorities in approximately 14 countries across North America, Europe, and Asia and is expected to initiate by the end of the second quarter of 2021.
- **Ensuring all aspects of our manufacturing are validated and can produce product at commercial scale.** As is good practice, we are pursuing the development of a second source manufacturer of molgramostim to ensure drug substance supply and mitigate approvability risk.
- **Outsourcing capital-intensive operations.** We will continue to pursue the development and manufacturing of our product candidates 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.

Molgramostim – aPAP

Our lead product candidate, molgramostim, an inhaled formulation of recombinant human GM-CSF, is being developed for the treatment of aPAP. Pulmonary alveolar proteinosis ("PAP") is a rare lung disease characterized by the build-up of surfactant in the alveoli (or air sacs) of the lungs. There are different types of PAP, of which aPAP is the most common.

In June 2019, we announced that IMPALA, the Phase 3 clinical trial of molgramostim for the treatment of aPAP, did not meet its primary endpoint of alveolar-arterial oxygen gradient, or (A-a)DO_2, improvement compared to placebo and that the U.S. Food and Drug Administration ("FDA") indicated data from the IMPALA trial did not provide sufficient evidence of efficacy and safety. The totality of data from the IMPALA trial – which extends beyond the primary endpoint – gives us confidence that molgramostim has the potential to address a significant unmet need in this rare disease. These data include:

- Multiple key secondary and exploratory endpoints that either achieved nominal statistical significance 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 molgramostim. Additionally, patients who had been on placebo during the double-blind period of the trial and switched to treatment with molgramostim during the open-label period, showed improvements that eventually caught up with those seen in patients who received molgramostim during the double-blind period; and
- Molgramostim being generally well tolerated.

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

We consider molgramostim to have a favorable risk-benefit profile and remain confident in the future of the program, including the upcoming Phase 3 IMPALA 2 trial.

In May 2019, the FDA granted Fast Track Designation to molgramostim for the treatment of aPAP. 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, although the IMPALA data did not meet the regulatory requirement for approval, the FDA granted a Breakthrough Therapy Designation ("BTD") for molgramostim in aPAP based on data from the 24-week double-blind treatment period from our IMPALA trial. Additionally, molgramostim was granted Orphan Drug Designation for the treatment of aPAP 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 PARI eFlow® Nebulizer System for this indication along with a proprietary cell bank for molgramostim, a non-glycosylated form of GM-CSF.

Molgramostim – NTM

Molgramostim was also being investigated in cystic fibrosis ("CF") and non-CF patients for the treatment of nontuberculous mycobacterial ("NTM") lung infection, a rare and serious lung disorder. The most common types of NTM lung infection involve *Mycobacterium avium* complex ("MAC") and *Mycobacterium abscessus* ("MABSC").

Savara has conducted two exploratory clinical trials of molgramostim in patients with persistent pulmonary NTM lung infection.

- OPTIMA: An open-label, non-controlled, Phase 2a trial in non-CF patients
- ENCORE: An open-label, non-controlled, Phase 2a clinical trial in patients with CF

The OPTIMA trial investigated the efficacy of molgramostim on reduction of NTM bacterial load in sputum, NTM sputum culture conversion to negative, exercise capacity, patient reported outcomes, and safety. The primary endpoint was sputum culture conversion during the treatment period. In March 2020, we disclosed top line microbiology results showing that OPTIMA did not meet the primary endpoint. Data showed five out of 24 patients (21%) with MAC infection achieved a sputum culture conversion, defined as at least three consecutive sputum samples without growth of nontuberculous mycobacteria by week 48.

The ENCORE trial investigated the efficacy of molgramostim on reduction of NTM bacterial load in sputum, NTM sputum culture conversion to negative, and other microbiological indicators, pulmonary measures, and patient reported outcomes. In September 2020, we announced the decision to discontinue the ENCORE trial based on confounding factors that compromised the ability of the trial to achieve its primary purpose of investigating the efficacy of molgramostim on NTM sputum culture conversion to negative. Such factors included the impact of COVID-19 on patient recruitment and continued participation in the trial as well as the availability of the new triple-combination CFTR modulator, approved during the treatment period of ENCORE, which became a preferred treatment option for many CF patients. Trial recruitment was terminated at the end of March 2020 with 14 patients enrolled out of a target of 30. Ten out of 14 patients were on the triple-combination CFTR modulator, nine patients started it during the trial, and one patient was on the triple-combination modulator from baseline. The decision to discontinue the trial was not based on safety concerns. Due to the early discontinuation of the trial, not all patients completed the planned 48-week treatment period. Based on preliminary data as of September 2020 from 12 patients who progressed at least beyond 20 weeks of treatment, five patients on the triple-combination CFTR modulator achieved a sputum culture conversion, defined as at least three consecutive sputum samples without growth of NTM. All of those patients had started the triple-combination modulator during the trial prior to culture conversion. Sputum culture conversions were not observed in patients who were on molgramostim without the triple-combination modulator. Data disclosed from the ENCORE trial have not been validated and are subject to the final trial report.

Based on the results of the exploratory ENCORE and OPTIMA trials, we decided to continue focusing molgramostim development efforts on our lead indication, aPAP, and do not plan to conduct further development activities related to molgramostim in NTM.

Vancomycin hydrochloride inhalation powder

Vancomycin inhalation powder ("vancomycin," formerly referred to as AeroVanc) was the first inhaled antibiotic in development for the treatment of persistent methicillin-resistant *Staphylococcus aureus* ("MRSA") lung infection in individuals living with CF and was being investigated in a randomized, double-blind, placebo-controlled Phase 3 clinical trial called AVAIL. The primary endpoint was the absolute change from baseline in Forced Expiratory Volume in one second (FEV_1) percent predicted at weeks 4, 12, and 20. Secondary endpoints included: (i) time-to-first pulmonary exacerbation requiring use of another antibiotic, (ii) frequency of pulmonary infection, (iii) patient reported outcome measures Cystic Fibrosis Questionnaire-Revised (CFRQ-R) and Cystic Fibrosis Respiratory Symptom Diary-Chronic Respiratory Infection Symptom Score (CFRSD-CRISS), and (iv) relative change in FEV_1 and area under the curve FEV_1.

In December 2020, we announced the AVAIL trial did not meet the primary endpoint of mean absolute change from baseline in FEV_1 percent predicted analyzed sequentially at week 4, 12, and 20. According to statistical hierarchy, if the trial did not show a statistically significant improvement in FEV_1, the sequence of analysis would end. Data from the trial showed a mean change from baseline in FEV_1 percent predicted compared to placebo of 1.4 at week 4 (p=0.33), 1.3 at week 12 (p=0.33), and 3.0 at week 20 (p=0.07) in the primary analysis population of patients 6-21 years of age. Additionally, treatment with vancomycin did not result in a reduction in the frequency of pulmonary exacerbations versus placebo. The exacerbation rate per year was 2.3 for both groups (risk ratio 1.0, 95% CI 0.7, 1.4). Vancomycin was generally well tolerated.

Based on the AVAIL results, we have discontinued further development of the vancomycin program.

Inhaled liposomal ciprofloxacin ("Apulmiq")

In March 2020, we entered into an exclusive license and collaboration agreement with Grifols, S.A. ("Grifols") for Apulmiq (inhaled liposomal ciprofloxacin). Apulmiq is a late-stage (Phase 3-ready) investigational inhaled antibiotic for the treatment of non-cystic fibrosis bronchiectasis ("NCFB"). Under the terms of the agreement, Savara obtained the worldwide rights to develop and

commercialize Apulmiq. However, as part of our December 2020 pipeline simplification strategy that focused resources on molgramostim in aPAP and the IMPALA 2 trial, we discontinued the Apulmiq clinical development program.

Detailed Program Descriptions

Molgramostim

Background on aPAP

Autoimmune PAP, known as aPAP, 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 prevalence of PAP is seven cases per million people in the U.S.[1], with similar or higher prevalence reported elsewhere in the world. For example, Japan, a country that undertakes a more centralized approach to diagnosing and treating aPAP, has seen a consistent increase in patients being diagnosed with the disease. It is now estimated the prevalence in Japan could be four times the original estimate of seven cases per million.[2] PAP is characterized by the build-up 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 aPAP, the macrophages fail to clear the surfactant from the alveoli, leading to gradual accumulation of surfactant in the alveoli. The root cause of aPAP is an autoimmune response against GM-CSF, a naturally occurring protein in the body. Pulmonary macrophages need to be stimulated by GM-CSF to function properly, but in aPAP, GM-CSF is neutralized by antibodies against GM-CSF, rendering the macrophages unable to perform their tasks, including the clearance of surfactant from the alveoli.

aPAP most commonly affects men in early middle age, but both sexes and patients of any age can be affected. As a result of the accumulation of surfactant, gas exchange in the lungs is obstructed, and patients start to experience shortness of breath 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, as well as episodes of fever, especially if secondary lung infection develops. In the long-term, the disease can lead to serious complications, including lung fibrosis and the need for lung transplant.

Current treatment options for aPAP

The current standard-of-care for aPAP is a procedure called Whole Lung Lavage (“WLL”), which entails washing out the lungs with saline, one lung at a time, under general anesthesia. WLL is an invasive and inconvenient procedure that is performed by highly experienced physicians at specialist sites and necessitates hospitalization and admission to intensive care afterwards. In many patients, WLL may only provide temporary symptomatic relief. Once the lungs refill with surfactant, the WLL procedure needs to be repeated.

As there are no approved pharmaceutical treatments available for aPAP, there is a high need for a convenient and efficacious medicinal treatment. We believe that inhalation of molgramostim activates macrophages in the lung alveoli, thus potentially restoring the surfactant clearing activity of the alveolar macrophages and considerably improving oxygenation and exercise tolerance. Sargramostim, an injectable form of GM-CSF, is approved in the U.S. for intravenous (“IV”) and subcutaneous administration (“SC”) treatment of neutropenia caused by cancer chemotherapy and other related indications. Currently, there are no approved inhalation formulations of GM-CSF. GM-CSF products administered systemically (e.g., by injection), including molgramostim, are unlikely to benefit patients with aPAP because autoimmune PAP patients have circulating antibodies against GM-CSF. These antibodies would likely neutralize systemically administered GM-CSF before reaching the alveolar space in the lung, unless a very large (perhaps impractical) amount of GM-CSF is injected to overwhelm the circulating anti-GM-CSF antibody.

1 Trapnell BC, Avetisyan R, Carey B, Zhang W, Kaplan P, Wang H. Prevalence of pulmonary alveolar proteinosis (PAP) determined using a large health care claims database. Am J Respir Crit Care Med. 2014;VOL:abstract A6582.

2 Kitamura N, Ohkouchi S, Tazawa R, Ishi H, Takada T, Sakagami T, Tanaka T, Nakata K. Incidence of autoimmune pulmonary alveolar proteinosis estimated using Poisson distribution. ERJ Open Res. 2019 Mar. 18;5(1).

The potential benefits of inhaled GM-CSF in aPAP, together with the availability of sargramostim for off-label compounding, have prompted independent clinicians and academic researchers in the U.S., Europe, and Japan to study the safety and efficacy of inhaled GM-CSF in aPAP patients. In addition to our Phase 3 IMPALA trial of molgramostim, the largest placebo-controlled trial in this patient population (n=138), 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.[3,4,5] In total, treatment of nearly 150 aPAP patients with inhaled GM-CSF have been reported in open-label trials or retrospective cohorts, as well as several individual case reports. In PAGE, a randomized, double-blind, placebo-controlled, 25-week clinical trial of inhaled sargramostim in 64 patients with mild-to-moderate disease, a significant effect was observed in the primary endpoint, which was change from baseline in (A-a)DO_2. Secondary endpoints, including changes from baseline in diffusing capacity for carbon monoxide ("DLCO"), six-minute walk distance ("6MWD"), and aPAP serum biomarkers, showed directional, but in most cases not statistically significant, treatment effects over placebo. Overall, for the first time, the PAGE trial showed in a placebo-controlled setting, proof-of-concept for GM-CSF inhalation therapy in aPAP. Results from these investigator-sponsored clinical trials and case studies indicate that GM-CSF may have a positive impact on oxygenation and clinical symptoms in aPAP patients. For details on the results of the IMPALA trial, please see the "Clinical Development of Molgramostim—aPAP: Phase 3 IMPALA Trial" section included in this report.

According to our review of published literature, few safety issues related with GM-CSF inhalation in patients with aPAP have been reported. However, there is still limited information available on the long-term safety of inhaled GM-CSF. In indications other than aPAP, more than 100 patients, mainly with a cancer diagnosis, have received inhaled sargramostim in doses up to 4000 µg/day. Pulmonary adverse event was the most frequently reported adverse event at high doses. An increase in both the number and severity of adverse events with an increasing dose has been observed. However, due to the underlying diseases, it was often difficult for investigators to assess causality of the adverse event cases.

Product Description

Molgramostim is a non-glycosylated form of recombinant human GM-CSF that we are developing as an inhaled formulation for the treatment of aPAP. GM-CSF is an endogenous growth factor that stimulates the proliferation and differentiation of hematopoietic cells (blood immune cells), mainly granulocytic and monocytic cell lines, which defend against bacteria and viruses, and clear cellular debris and waste substances from the body. Molgramostim 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 nebulizer solution (drug component) and a nebulizer (device component). Molgramostim nebulizer solution is vialed as a sterile formulation containing 300 µg of molgramostim in 1.2 mL solution. Molgramostim nebulizer solution is administered once daily by inhalation via a high efficiency nebulizer, the eFlow® Nebulizer System (PARI Pharma GmbH). The eFlow® Nebulizer System is a reusable electronic inhalation system that has been optimized for administration of molgramostim nebulizer solution. The eFlow® consists of a controller unit (AC or battery powered), a nebulizer handset, and a connection cord. The controller unit has a life span of multiple years and the handset is replaced monthly with a new unit.

Molgramostim was granted Orphan Drug Designation by the FDA (October 2012) and by the EMA (July 2013) for the treatment of aPAP. It was also granted Fast Track Designation and Breakthrough Therapy Designation by the FDA in May 2019 and December 2019, respectively. Since 2014, molgramostim has been available in several European countries for the treatment of aPAP for named patients following unsolicited physician requests.

We anticipate that molgramostim will be used as a long-term therapy in patients with aPAP. The optimal duration of treatment is currently not known and is likely to vary between patients depending on disease severity and the natural course of their disease. Treatment with molgramostim may not entirely eliminate the need for WLL in all patients. In the IMPALA trial, we observed a reduced number of WLL procedures in the active treatment arms, but the difference was not statistically significant due to the relatively low number of the procedures (approximately 10%). In the open-label extension period (Period 2) of the trial, when all patients received active drug, there was a further reduction of WLL procedures. This suggests that prolonged treatment with molgramostim may reduce the need for WLL.

3 Tazawa R, Trapnell BC, Inoue Y, Arai T, Takada T, Nasuhara Y, et al. Inhaled Granulocyte/Macrophage–Colony Stimulating Factor as Therapy for Pulmonary Alveolar Proteinosis. Am J Resp Crit Care Med 181: 1345-1354, 2010.

4 Wylam ME, Ten R, Prakash UB, Nadrous HF, Clawson ML and Anderson PM (2006). Aerosol granulocyte-macrophage colony-stimulating factor for pulmonary alveolar proteinosis. Eur Respir J 27(3): 585-93.

5 Papiris SA, Tsirigotis P, Kolilekas L, Papadaki G, Papaioannou AI, Triantafillidou C, et al. (2014). Long-term inhaled granulocyte macrophage-colony-stimulating factor in autoimmune pulmonary alveolar proteinosis: effectiveness, safety, and lowest effective dose. Clin Drug Investig 34(8): 553-64.

Molgramostim Key Advantages

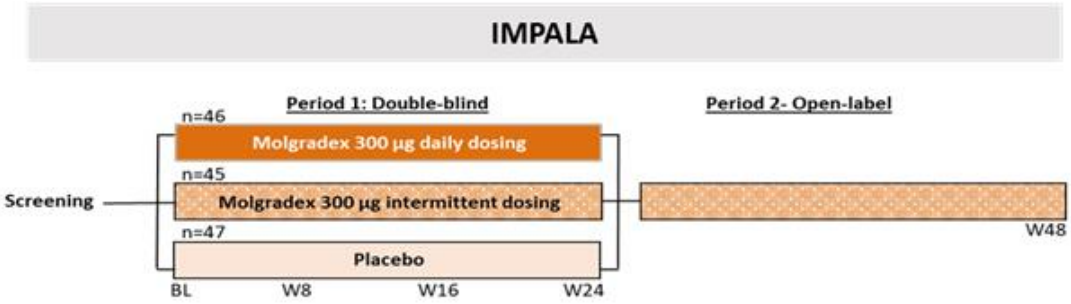
Based on data from the completed Phase 3 IMPALA trial and building upon the published investigator-sponsored treatment experience with inhaled GM-CSF, we believe molgramostim has the potential to become the treatment of choice for aPAP. Molgramostim has the following characteristics that may contribute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

Specifically, molgramostim 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 function deficiency, which could result in high clinical efficacy with limited systemic adverse effects.
- A high-efficiency nebulizer that provides a fast and convenient method of administration. This is highly desirable for long-term treatment in a chronic disease, such as aPAP.
- Eligibility for strong market protection via orphan drug status, potential eligibility for biologic exclusivity in the U.S., and Fast Track and Breakthrough Therapy Designations.
- A proprietary cell bank used in the production of the drug substance.
- An exclusive agreement for a device that is optimized for administration of molgramostim nebulizer solution.

Clinical Development of Molgramostim – aPAP

Phase 3 IMPALA Trial



IMPALA was a Phase 3 randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of molgramostim in patients with aPAP. Conducted in 18 countries including the U.S., Japan, and various European countries, it was the largest controlled clinical trial of molgramostim for the treatment of aPAP. Patients were randomized to receive treatment for up to 24 weeks in one of three treatment arms: 1) molgramostim 300 µg administered once daily ("continuous dosing arm"), 2) molgramostim 300 µg and matching placebo administered daily every other week ("intermittent dosing arm"), or 3) inhaled placebo administered once daily. At the end of the 24-week double-blind period, all patients received molgramostim 300 ug administered daily in every other week intermittent cycles in a 24-week open-label follow up period. The primary endpoint of the trial was (A-a)DO_2, a commonly used measure of oxygenation impairment. In addition, three key secondary endpoints—St. George's Respiratory Questionnaire ("SGRQ"), 6MWD, and time to/requirement for WLL— along with multiple other secondary and exploratory endpoints were assessed to determine improvement in the disease pathology, pathophysiology, clinical symptoms, and function.

The pathogenesis of aPAP is well known and GM-CSF's effect on the disease, as evaluated by (A-a)DO_2, dyspnea, 6MWD, pulmonary function tests, computed tomography ("CT") scores, and biomarkers, is well documented through published clinical trials. While IMPALA did not meet its primary endpoint, when looking at the totality of evidence, we believe that data from the IMPALA trial demonstrate reversal of lung pathology and pathophysiology, improvement in clinical outcomes, and reduction of the need for rescue treatment, with a clear dose-frequency dependency in favor of the continuous dosing arm. Such results are detailed below:

- Lung Pathology—Reversal of disease pathology and reduction of surfactant accumulation was demonstrated in the Full Analysis Set ("FAS") population with improvement in CT scans as measured by Ground Glass Opacity ("GGO") scores. Results from IMPALA also demonstrated positive biomarker data, with improvements seen in most of the key biomarkers known to be associated with the severity of aPAP.
- Lung Pathophysiology—In the FAS population, an average (A-a)DO_2 improvement of 12.1 mmHg was observed in the continuous dosing arm, compared to an average (A-a)DO_2 improvement of 8.8 mmHg in the placebo arm. With an

estimated 4.6 mmHg treatment difference, the trial did not meet its primary endpoint. Notably, one-third of patients in IMPALA were prescribed supplemental oxygen, continuously or as necessary, during the trial. The trial protocol recommended that supplemental oxygen not be used immediately before or during arterial blood sampling to minimize influence on (A-a)DO_2 values. The protocol did allow patients to remain on supplemental oxygen during blood sampling if they could not tolerate discontinuation due to the severity of their respiratory condition. This was conditionally allowed only if they received the same oxygen flow rate used at baseline at all subsequent visits (n=4 patients, two in the placebo arm and one in each of the active arms).

In these four patients, (A-a)DO_2 values distributed quite differently compared to the remaining trial population—ranging from highly negative to highly positive. In a revised analysis that excluded these four patients, a statistically significant average (A-a)DO_2 improvement was observed in the continuous dosing arm compared with the placebo arm.

Impaired gas transfer and oxygenation are key pathophysiologic features of aPAP and are associated with symptoms of shortness of breath and limitations in exercise capacity. In addition to (A-a)DO_2, DLCO was assessed in the FAS as a secondary endpoint to evaluate the efficacy of molgramostim on gas transfer. Patients in the continuous dosing arm showed a mean improvement of 11.6% predicted in DLCO, whereas the intermittent dosing and placebo arms showed a 7.7% predicted and 3.9% predicted improvement, respectively. The estimated treatment difference of 7.9% predicted (p=0.007) between the continuous dosing arm and placebo was statistically significant, and in keeping with the (A-a)DO_2 improvement, and suggests improved gas exchange in the lungs.

- Clinical Outcomes—In the FAS population, an average improvement of 12.3 points in the SGRQ, a patient-reported outcomes/health status measure and a key secondary endpoint, was observed in the continuous dosing arm compared to an average improvement of 4.7 points in the placebo arm. The estimated treatment difference was 7.6 points which was statistically significant ($p < 0.05$). The 6MWD, another key secondary endpoint, was numerically in favor of the continuous dosing arm, but the difference to placebo was not statistically significant. Patients in the continuous dosing arm showed a mean improvement of 39.6 meters in the 6MWD, while the intermittent and placebo arms showed improvements of 11.3 meters and 6.0 meters, respectively. The third key secondary endpoint was the requirement for WLL. Four patients in each of the active arms, and six patients in the placebo arm underwent at least one WLL procedure during the treatment period. Given that some patients received more than one WLL, the total number of WLLs observed in the continuous dosing arm was 9, with 7 observed in the intermittent dosing arm and 17 in the placebo arm.
- Consistency of Endpoints in the FAS—A range of primary and secondary endpoints were selected to determine the potential treatment effect of molgramostim on aPAP. Patients in the continuous dosing arm demonstrated consistent improvements across all the key endpoints compared to placebo, with the majority of the measures achieving statistical significance. A dose-frequency dependency was observed, with continuous daily administration of molgramostim generally resulting in higher efficacy than intermittent dosing.
- Safety and Tolerability—The percentage of patients with adverse events were similar in the treatment arms, except for the percentage of patients with chest pain, which was higher in the continuous dosing arm compared to placebo.

Results from the open-label period of the IMPALA trial, announced in March 2020, demonstrated a sustained treatment effect, or continued improvement, after longer term exposure to molgramostim. A summary of the results can be found below.

During the double-blind period, a dose frequency dependency was observed with continuous administration of molgramostim resulting in higher efficacy than intermittent dosing. Results from the open-label period noted below, therefore, focus on the group that had received a continuous dose of molgramostim during the double-blind period versus those that had received placebo, both of which received intermittent dosing during the open-label period.

- Patients who had been in the continuous dosing group during the double-blind period:

  (A-a)DO_2 improvement from baseline continued in these patients during the open-label period of the trial, with progressively larger improvements at weeks 48 and 72. Likewise, progressively larger improvements from baseline were observed in DLCO and SGRQ at weeks 48 and 72.

- Patients who had been in the placebo group during the double-blind period:

  Placebo patients that transitioned to active drug showed similar average improvements in (A-a)DO_2, DLCO, and SGRQ in the open-label period as compared to the continuous dosing group during the double-blind period, reaching similar levels of improvement to the continuous dosing group by week 72.

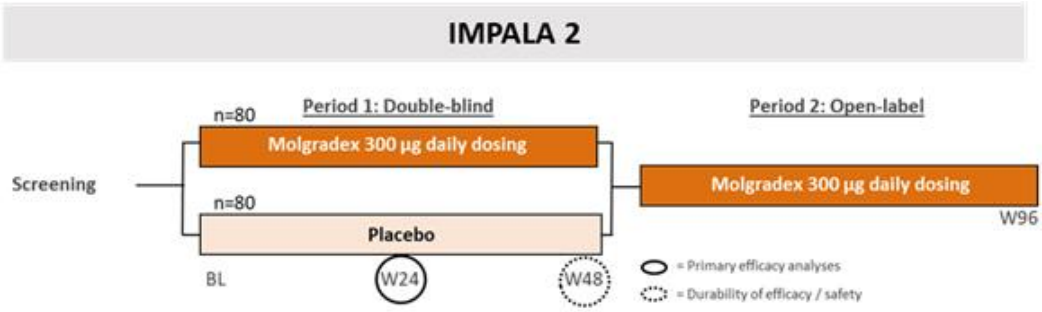
Similar trends were seen in the 6MWD at weeks 48 and 72, but the data were less conclusive.

During the double-blind period of the trial, 33 WLL procedures were required, with nine in the continuous group compared to 17 in the placebo group. During the 48-week open-label period of the trial, during which time all patients received active drug, only five WLL procedures were conducted.

IMPALA-X Extension Trial

In March 2018, the IMPALA-X clinical trial was initiated. IMPALA-X was an open-label extension trial that allowed patients who completed the IMPALA trial to continue treatment for up to three additional years. In August 2020, we disclosed that we were stopping the IMPALA-X trial in which approximately 60 patients were being treated with molgramostim 300 µg according to the intermittent, every other week dosing regimen. Some patients from IMPALA-X may be eligible to enroll in the Phase 3 IMPALA 2 trial.

Phase 3 IMPALA 2 Trial



IMPALA 2 is a Phase 3, 48-week, randomized, double-blind, placebo-controlled clinical trial designed to compare the efficacy and safety of molgramostim 300 µg administered once daily by inhalation with matching placebo in patients with aPAP. The primary endpoint is the change from baseline in percent predicted DLCO, a gas exchange measure. Three secondary endpoints will evaluate clinical measures of direct patient benefit: SGRQ Total Score, SGRQ Activity Component Score, and exercise capacity using a treadmill test. Other efficacy endpoints will include (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 CT scan to assess lung opacity, blood biomarkers, etc. IMPALA 2 is expected to enroll a total of 160 patients who will be randomized to receive treatment for up to 48 weeks in one of two arms: molgramostim 300 µg administered once daily or inhaled placebo administered once daily. The primary time point for efficacy assessment will be at week 24, however, efficacy will be assessed through week 48 to show durability of effect. Safety will be assessed through week 48. Following the 48-week double-blind treatment period, patients will roll over to a 48-week open-label period and will receive molgramostim 300 µg administered once daily.

The IMPALA 2 trial design has been endorsed by regulatory authorities in approximately 14 countries across North America, Europe, and Asia and is anticipated to start by the end of the second quarter of 2021. The trial will be conducted at approximately 50 sites and is expected to fully enroll in approximately 20 months following initiation. Top line data are anticipated in the second quarter of 2024. While we are working to initiate IMPALA 2 as quickly and as safely as possible, the impact of the COVID-19 pandemic continues to evolve and may adversely impact trial timelines, even with mitigation strategies in place.

In January 2021, we engaged Parexel International (IRL) Limited (“Parexel”), a global contract research organization (“CRO”) to support our IMPALA 2 clinical trial development activities.

Manufacturing and Supply

We do not own or operate manufacturing facilities to produce clinical or commercial quantities of our molgramostim product candidate. We have fee-for-service contracts with a well-established drug substance manufacturer and drug product manufacturer that covers all steps of the manufacturing process of molgramostim. We expect to continue with this outsourcing model for the foreseeable future and plan to pursue a second source manufacturer to reduce production risks and ensure drug substance supply. All of our manufacturing and supply vendors conduct their operations under current Good Manufacturing Practices (“cGMP”), a regulatory standard for the manufacture of pharmaceuticals.

Molgramostim drug substance is currently manufactured by GEMA Biotech S.A. in Buenos Aires, Argentina (“GEMA”). All clinical and nonclinical trials to-date have used material sourced from GEMA and validation activities are ongoing to prepare for commercial manufacturing.

Patheon UK Limited in Ferentino, Italy (“Patheon”), a division of Thermo Fisher Scientific Inc., has been selected as the commercial drug product manufacturer. Technology transfer and process validation activities with Patheon UK Limited are complete.

Molgramostim is administered to the lungs using the eFlow® Nebulizer System, manufactured by PARI Pharma GmbH in Stamberg, 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) approval 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 recombinant human GM-CSF.

Commercialization

Savara owns exclusive rights to molgramostim in the U.S. and all other major markets. We continue to pursue clinical and regulatory approvals for molgramostim in the U.S., EU, and Japan and to independently commercialize molgramostim in the U.S. In doing so, 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. Pending European Medicines Agency ("EMA") approval, we expect to commercialize molgramostim in the EU and may engage with strategic partners to optimize sales and promotion activities in other EU territories.

Key License and Other Agreements

Parexel

We entered into a Master Services Agreement ("MSA") with Parexel on March 5, 2021, pursuant to which Parexel will provide contract research services related to our clinical trials. The MSA has an initial term of five years. We may terminate the MSA and/or any work order without cause on 60 days' prior written notice to Parexel, and either party may terminate the MSA or any work order (i) upon 30 days' notice in the event of the other party's uncured breach, or (ii) immediately upon the occurrence of any of the following: (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. Contemporaneously with entering the MSA, we executed a work order with Parexel, under which Parexel will provide services related to the IMPALA 2 trial. Under that work order, we expect to pay Parexel service fees and pass-through expenses estimated to be approximately $31 million over the course of the IMPALA 2 clinical trial.

PARI Pharma GmbH

We have a license and collaboration agreement related to molgramostim with PARI Pharma GmbH (the "PARI License Agreement"). Under the PARI License Agreement, we have a worldwide, exclusive license to commercialize PARI's eFlow Nebulizer System for the pulmonary delivery of any liquid formulation containing human GM-CSF ("hGM-CSF") as the sole active pharmaceutical ingredient for nebulization for aPAP. Additionally, we have the option to change the device, subject to certain conditions, to PARI's eFlow Technology Nebulizer Closed System ("CS") and, until marketing approval, the option to negotiate an extension to the license to cover commercialization of the drug for pulmonary delivery via the PARI eFlow Inline device for the treatment of certain other indications. 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 until (i) in the European Economic Area, marketing approval of the product in Europe or the U.S., whichever is later, or (ii) in the rest of the world, the term of the PARI License Agreement.

In consideration of rights granted by PARI, our predecessor paid a one-time upfront fee and we pay an hourly rate for work performed by PARI. Additionally, we are obligated to make future milestone payments to PARI based upon (i) the successful completion of certain clinical trials, (ii) submissions for regulatory approval in the U.S, the EU or Japan, and (iii) 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 in a country, 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 molgramostim 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.

We also have a commercial supply agreement with PARI (the "PARI Supply Agreement") related to the supply of the PARI eFlow Nebulizer 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.

GEMA Biotech S.A.

In April 2019, we entered into a Manufacture and Supply Agreement with GEMA pursuant to which GEMA will supply the active pharmaceutical ingredient ("API") for molgramostim 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 right, title, 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 per vial of 1 gram 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 an audit by the FDA, 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.

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 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.

Patheon UK Limited

We have entered into an agreement and related work orders with Patheon under which Patheon manufactures our molgramostim 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) pursuant to the Master Manufacturing Agreement to govern the terms and conditions of Patheon's manufacture of commercial supplies of molgramostim. Under the terms of the Master Manufacturing Agreement, we have agreed to order from Patheon at least a certain percentage of our commercial requirements.

The Master Manufacturing Agreement has 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 of our timely payment of invoices, or if we forecast zero volume for six months.

Inhaled liposomal ciprofloxacin (Apulmiq)

In March 2020, we entered into an exclusive license and collaboration agreement with Grifols for Apulmiq for the treatment of NCFB. Under the terms of the agreement, Savara obtained an exclusive, worldwide, royalty-bearing license, with rights to sublicense, patent rights and know-how owned or controlled by Grifols to develop and commercialize Apulmiq. The term of the license continues until the Royalty Term (as defined in the license agreement) expires in all countries for all products containing Apulmiq. Grifols may terminate the license immediately if (1) we or one of our affiliates files a challenge to a patent owned by Grifols or (2) we fail to develop Apulmiq for 12 consecutive months. Either party can terminate for the other party's material breach following a cure period or upon certain insolvency events.

As part of our December 2020 pipeline optimization strategy that focused our resources on molgramostim in aPAP and the IMPALA 2 trial, we discontinued the Apulmiq clinical development program.

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 those 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 candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Government Regulation of Drugs

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 ("GLP") regulation.
- Submission to the FDA of an 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, purity and potency of the proposed product candidate for its intended purpose.
- Preparation of and submission to the FDA of a Biologics License Application ("BLA"), after 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 preserve the product's continued safety, purity and potency, and of selected clinical investigational sites to assess compliance with current Good Clinical Practices ("cGCP"); 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 candidates 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 cGCPs, 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, potency, 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 labeling.
- *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 does not undergo unacceptable deterioration 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. A waiver of user fees may be obtained under certain limited circumstances.

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 application relates to an unmet medical need in a serious or life-threatening indication, six months after 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 facility 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 clinical 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 cGCP. 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 products. After the FDA evaluates a

BLA and conducts inspections of manufacturing facilities where the investigational product and/or our drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. 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 Phase 4 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 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 breakthrough therapy designation. 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 a 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 a breakthrough therapy, 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. Breakthrough designation also allows the sponsor to file sections of the BLA for review on a rolling basis.

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

The review and approval process with respect to our drug candidates may also be significantly delayed in the event of government shutdowns, if any.

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 the 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 candidates 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 Designation

In December 2019, the FDA granted the use of molgramostim for the treatment of aPAP program Breakthrough Therapy Designation 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.

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, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as 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 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 candidates under development will be regulated as combination products, which means that they are 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 candidates include 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 inhaler component of our product candidates.

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 per se illegal 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. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $179,495 per year (or up to an aggregate of $1,176,638 per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. On October 24, 2018, former 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 (with reporting requirements going into effect in 2022 for payments made in 2021). 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 candidates, 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 candidates 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 potential drug candidates 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;
- 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 candidates, 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. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case to the District Court to determine whether the remaining provisions of the ACA are invalid. The decision was appealed, and the case is currently under consideration by the U.S. Supreme Court. It is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA 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.

Foreign Regulation

In addition to regulations in the U.S., 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 candidates and our processes. We seek patent protection in the U.S. and internationally for our products, their methods of use and processes of manufacture 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.

We own issued patents and additional pending patent applications worldwide for a proprietary formulation of vancomycin. The patents and pending applications are derived from a PCT application (Pub. No. WO2012159103) entitled "Dry Powder Vancomycin Compositions and Associated Methods." In February 2017, the United States Patent and Trademark Office issued United States Patent No. 9,572,774 for "Dry Powder Vancomycin Compositions and Associated Methods" that will expire no earlier than 2032. We also have corresponding patent applications for vancomycin in different stages of prosecution in other key markets throughout the world. However, in connection with our decision to discontinue the development of the vancomycin program, we may choose to abandon certain vancomycin-related applications in the future.

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 the 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. 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 candidates 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.

We are not aware of any other companies developing an inhaled form of GM-CSF. A glycosylated GM-CSF product, sargramostim (Leukine®), is available on the market in the U.S., intended for IV or SC delivery in patients with neutropenia following cancer chemotherapy. Leukine® has not been approved for the treatment of aPAP or any other acute or chronic lung disease but is sometimes used as a 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 aPAP. No clinical trials have been conducted to date under this collaboration project. We are aware of a multicenter clinical trial of inhaled Leukine®, using a standard commercially available nebulizer, which was conducted by a consortium of independent clinical investigators[6]. It is not known to us if this trial, together with other possibly available related clinical or nonclinical information, may be, or will be, used to support a potential new product approval in Japan. If such a new product would be approved and launched in Japan, we believe it has the potential to present a material competitive threat to the commercial success of molgramostim in Japan. In addition, in November 2018, Partner Therapeutics, Inc., a commercial biotechnology company, was granted Orphan Drug Designation to Leukine® for the treatment of PAP by the FDA.

Employees and Human Capital

We are committed to attracting and retaining the best possible talent. As of March 8, 2021, we had 27 employees as well as several consultants. Of our employees, 14 are located in Denmark and 13 are located in the U.S. 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. In 2020, we 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, such as our LEAD2020 program administered during 2020. This program helped employees assess their strengths and identify areas of improvement while also allowing a 360 assessment of their managers.

6 Tazawa R, Ueda T, Abe M, Tatsumi K, Eda R, Kondoh S, et al. (2019) Inhaled GM-CSF for Pulmonary Alveolar Proteinosis.
N Engl J Med. 2019 Sep 5;381(10):923-932. doi: 10.1056/NEJMoa1816216.

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. Currently, women represent approximately 63% of our employees and 50% of our leadership team. 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. In dealing with the COVID-19 pandemic, we have provided our employees the ability to work virtually in order to best manage business and personal responsibilities and halted non-essential travel. We have enhanced our internal communications with regular "town hall" meetings to ensure connectivity to our workforce. We have set specific guidelines for our employees to follow when they determine they need to use our facilities. These guidelines include, among others, limiting the number of people in our office at one time and social distancing. We will continue to manage this situation with a focus towards the safety of our employees.

Merger and Corporate Information

On April 27, 2017, Savara completed its business combination through a reverse merger with Mast Therapeutics, Inc. ("Mast"), a publicly held company, in accordance with the terms of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), dated January 6, 2017 (the "Merger"). In connection with the Merger, Mast changed its name to Savara Inc. Pre-Merger Savara was formed as a corporation in Delaware in 2007. Mast was originally incorporated in Delaware in December 1995.

Our website is located at 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." and the Savara logo are unregistered trademarks of Savara Inc. 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.

Summary Risk Factors

The risk factors described below are a summary of the principal risk factors associated with an investment in us.

Risks Relating 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 will require additional financing to obtain regulatory approval for molgramostim and a failure to obtain this necessary capital could force us to delay, limit, reduce, or terminate our product development efforts or other operations.

- Our loan agreement contains covenants which may adversely impact our business; the failure to comply with such covenants could cause our outstanding debt to become immediately payable or accelerate principal payments.
- Any future acquisitions that we make could disrupt our business and harm our financial condition.
- We have significant IPR&D and future impairment of IPR&D may have a significant adverse impact on our future financial condition and results of operations. Our goodwill was fully impaired during the year ended December 31, 2019.

Risks Related to Our Business Strategy and Operations

- We are substantially dependent upon the clinical, regulatory, and commercial success of our product candidate, molgramostim.
- If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop and commercialize our product candidate.
- 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.
- We rely significantly on third parties to conduct our nonclinical testing and clinical trials and other aspects of our molgramostim development program.
- Our molgramostim 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.
- We may not achieve our projected development goals in the time frames we have announced.
- We are substantially dependent upon our primary CRO, Parexel, for conducting our IMPALA 2 clinical trial.
- Our employees, independent contractors and consultants, principal investigators, CROs, CMOs and other vendors, and any future commercial partners may engage in misconduct or other improper activities.
- 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 cyber-security.
- If we or our vendors fail to comply with data protection laws and regulations, we could be subject to government enforcement actions, private litigation and/or adverse publicity.
- Our operations might be interrupted and financial results could be adversely impacted by the occurrence of a natural disaster, war, system malfunction, terrorism, telecommunication and electrical failures or other catastrophic event.
- We currently have limited marketing capabilities and no sales organization.
- 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.

Risks Related to Drug Development and Commercialization

- We depend on the successful completion of clinical trials of our molgramostim product candidate, and any positive results in prior clinical trials do not ensure that ongoing or future clinical trials will be successful.
- Molgramostim has received Orphan Drug Designation by the FDA and in Europe. While orphan designation provides certain benefits, there are also associated risks.
- Delays in commencement and completion of clinical trials are common and have many causes.
- Clinical trials are very expensive, difficult to design and implement, often take many years to complete, and the outcome is inherently uncertain.
- There is significant uncertainty regarding the regulatory approval process for any investigational new drug, substantial further testing and validation of our primary product candidate and related manufacturing processes may be required.
- Even if we receive regulatory approval for our primary product candidate, we may face regulatory difficulties that could materially and adversely affect our business, financial condition, and results of operations.
- If our primary product candidate 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.

- Even if we receive regulatory approval to market our primary 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 our full commercial potential.
- We must comply with the U.S. Foreign Corrupt Practices Act and similar foreign anti-corruption laws.

Risks Related to Our Intellectual Property

- Our success will depend on obtaining and maintaining effective patent and other intellectual property protection for our primary product candidate and proprietary technology.
- Our success depends on our ability to prevent competitors from duplicating or developing and commercializing equivalent versions of our primary product candidate, but patent protection may be difficult to obtain and any issued claims may be limited.
- Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies.
- Third parties may claim that our product, if approved, infringe on their proprietary rights and may challenge the approved use or uses of a product or its patent rights through litigation or administrative proceedings.

Risks Related to Our Industry

- We expect competition in the marketplace for our molgramostim product candidate.
- We are subject to uncertainty relating to healthcare reform measures and reimbursement policies.
- 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.

Risks Related to our Common Stock

- Our stock price is expected to continue to be volatile.
- 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.
- We will continue to incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.
- We do not expect to pay any cash dividends in the foreseeable future.
- We have completed certain transactions that likely have resulted in an ownership change under Section 382 of the Internal Revenue Code limiting the use of our net operating loss carryforwards and certain other tax attributes.

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. To date, we have not obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates, 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, 2020, we incurred a net loss of $49.6 million, and net cash used in operating activities was $39.8 million. At December 31, 2020, our cash, cash equivalents and short-term investment securities were approximately $82.2 million, and working capital was approximately $76.9 million. At December 31, 2020, we had an accumulated deficit of $257.5 million. We expect to continue to incur substantial operating losses for the next several years as we seek to advance our molgramostim product candidate through clinical development (IMPALA 2 trial), global regulatory approvals, and commercialization. No revenue from operations will likely be available until, and unless, our current product candidate, molgramostim, 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 are also continuously and critically reviewing our liquidity and anticipated capital requirements in light of the significant uncertainty created by the COVID-19 global pandemic.

We will require additional financing to obtain regulatory approval for molgramostim 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, molgramostim, vancomycin hydrochloride inhalation powder ("vancomycin") and Apulmiq. On December 10, 2020, based upon our analysis of the clinical data from the Phase 3 trial of vancomycin, we concluded and announced that the trial missed its primary endpoint, ceasing further development of vancomycin. Our priority remains the continued development of molgramostim for the treatment of aPAP and preparation for an additional Phase 3 trial. 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.

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 primary 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
- negative impacts from the scope and spread of COVID-19.

Additional capital may not be available when we need it, on terms that are acceptable to us or at all. If adequate funds are not available to us on a timely basis, we will 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.

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 candidates, 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.

Our loan agreement contains covenants which may adversely impact our business; the failure to comply with such covenants could cause our outstanding debt to become immediately payable or accelerate principal payments.

On April 28, 2017, we entered into a Loan and Security Agreement, as subsequently amended on October 31, 2017, December 4, 2018, and January 31, 2020 between us and Aravas, as co-borrowers, and Silicon Valley Bank (the "Amended Loan Agreement"). The Amended 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, subject to certain exceptions. Collectively, these covenants could constrain our ability to grow our business through acquisitions or engage in other transactions. In addition, the Amended Loan Agreement includes covenants requiring, among other things, that we provide financial statements, comply with all laws, pay all taxes, maintain insurance, and satisfy an equity-based milestone. If we are not able to comply with these covenants, the outstanding loans under the Amended Loan Agreement could become immediately due and payable and 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. The Amended Loan Agreement requires us to have an ongoing Phase 3 or Phase 4 clinical trial evaluating our molgramostim product for the treatment of aPAP in which the first patient has been dosed by the end of the first quarter of 2021. This milestone, if not met, will cease the interest only period and principal plus interest payments will be due in equal monthly installments over 24 months beginning April 1, 2021. In February 2021, Silicon Valley Bank agreed to extend the requirement for the date of the first patient dosed in our Phase 3 IMPALA 2 trial to the end of the second quarter of 2021.

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 or equity, 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 significant IPR&D and future impairment of IPR&D may have a significant adverse impact on our future financial condition and results of operations. Our goodwill was fully impaired during the year ended December 31, 2019.

As of December 31, 2020, we had IPR&D of approximately $12.2 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. We test our goodwill, if any, and IPR&D for impairment annually, or more frequently if an event or change in circumstances indicates that the asset may be impaired. If an impairment is identified, we would be required to record an impairment charge with respect to the impaired asset to our condensed consolidated statements of operations and comprehensive loss. A significant impairment charge could have a material negative impact on our financial condition and results of operations. We will continue to evaluate our intangible assets for potential impairment in accordance with our accounting policies.

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 goodwill and 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, 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 market and economic environment changes or trends, such as the ultimate scope and scale of the COVID-19 global pandemic and the impact of COVID-19 on patient enrollment in our IMPALA 2 trial. 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.

Risks Related to Our Business Strategy and Operations

We are substantially dependent upon the clinical, regulatory, and commercial success of our product candidate, molgramostim. Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and trials may not be predictive of future trial results, and our clinical trials may fail to adequately demonstrate to the satisfaction of regulatory authorities the safety and efficacy of our molgramostim product candidate.

The success of our business is dependent on our ability to advance the clinical development of molgramostim for the treatment of patients with aPAP.

The topline results of the molgramostim Phase 3 clinical trial for the treatment of aPAP, designated as IMPALA, were announced on June 12, 2019. The trial did not meet its primary endpoint of change in alveolar-arterial oxygen gradient ("A-aDO2") compared to placebo. The continuous treatment arm (molgramostim 300 µg administered once daily continuously over 24 weeks) did show a 12.1 mmHG improvement which is similar to what has been observed in previously published trials, but a larger-than-expected placebo effect was also seen (8.8 mmHg improvement). However, results from IMPALA did show statistically significant improvement in two secondary endpoints: the St. George's Respiratory Questionnaire ("SGRQ") and diffusing capacity of the lungs for carbon monoxide ("DLCO"). Two other secondary endpoints were numerically in favor of the continuous dosing arm of molgramostim but were not statistically significant (six-minute walk distance and time to WLL), while adverse event frequencies were similar between the treatment arms and placebo.

On October 1, 2019, we received a written response from the FDA in connection with a Type C meeting regarding the molgramostim development program for aPAP and results from the IMPALA trial in which the FDA indicated that the data provided in the briefing package for the Type C meeting did not provide sufficient evidence of efficacy and safety.

On December 23, 2019, the FDA granted us Breakthrough Therapy designation for molgramostim for the treatment of aPAP, a process designed to expedite the development and review of drugs that are intended to treat a serious condition and for which preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). During the year ended December 31, 2020, we worked with the FDA and EMA regarding the protocol and design of an additional Phase 3 trial of molgramostim for the treatment of aPAP, or the IMPALA 2 trial. IMPALA 2 will be a 48-week, double-blind, placebo-controlled trial, with efficacy endpoints assessed at week 24 for the primary analyses and a sample size of 160 patients. However, the placebo-controlled period will be 48 weeks to better support the durability of treatment effect, as well as long-term safety of the drug, which is intended to be administered chronically. At the end of the placebo-controlled period, both the placebo and non-placebo treatment arms will rollover into a 48-week open-label follow-on period in which all patients will receive molgramostim 300 micrograms administered once-daily and provide useful information on the long-term safety of the drug. The primary endpoint of the IMPALA 2 trial will be the gas exchange measure of DLCO. Three secondary endpoints designed to measure direct patient benefit will be evaluated which include the SGRQ Total Score, SGRQ Activity Component score, and exercise capacity using a treadmill test.

Additionally, as we work to initiate the IMPALA 2 trial, there remains a general uncertainty regarding the impact of COVID-19 on the aPAP patient population and physicians. Patients suffering from aPAP lung disease are prone to underlying lung conditions and are often treated by infectious disease specialists and pulmonologists. These treating physicians are on the front lines in addressing this global pandemic and must now, understandably, focus their attention on COVID-19.

Clinical testing is expensive, can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process as demonstrated by our IMPALA trial results in June 2019. The results of preclinical and early clinical trials of our product candidate may not be predictive of the results of later-stage clinical trials. There is a high failure rate for drugs proceeding through clinical trials, and product candidates in later stages of clinical trials may fail to show the required safety and efficacy despite having progressed through preclinical and initial clinical trials. 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. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidate.

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, including:

- slow implementation, enrollment, and completion of the clinical trials;

- inability to enroll enough patients in the clinical trials;
- low patient compliance and adherence to dosing and reporting requirements, for example, incomplete reporting of patient reported outcomes in the clinical trials or missed doses;
- lack of safety and efficacy in the clinical trials;
- delays in manufacture of supplies for both drug and device components due to delays in formulation, process development, or manufacturing activities;
- requirements for additional nonclinical or clinical trials based on changes to formulation and/or changes to regulatory requirements;
- poor quality or missing data from the clinical trials; and
- requirements for additional clinical trials based on inconclusive or negative clinical results or changes in market, standard of care, and/or regulatory requirements.

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:

- FDA rejection of our BLA submissions for our product candidate;
- regulatory rejection in the EU, Japan, and other markets;
- 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 “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 of, commercialize, or generate significant revenue. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

If we fail to attract and retain senior management and key scientific personnel, 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 product candidates 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.

The COVID-19 global pandemic has required us to adapt our operations, such as enabling employees to work remotely, which may adversely affect their employment satisfaction or productivity.

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 molgramostim product candidate and do not plan to establish our own manufacturing facilities. To manufacture our product candidate, we have made numerous custom modifications at contract manufacturing organizations ("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 molgramostim 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, 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. For example, the impacts of the current COVID-19 global pandemic are rapidly evolving. The extent to which the pandemic impacts our ability to procure sufficient supplies for the development and commercialization of our product candidate will depend on the severity and duration of the spread of COVID-19, and the actions undertaken to contain the pandemic or treat its effects.

All manufacturers of our clinical trial material and, if approved, commercial product, including drug substance manufacturers, must comply with current Good Manufacturing Practices ("cGMP") requirements enforced by the FDA through its facilities inspection program and applicable requirements of foreign regulatory authorities. These requirements include 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 shared between us and the third-party manufacturer, 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.

Currently, we do not have alternative vendors to back up our primary vendors of clinical trial material or, if approved, commercial supply material. Identification of and discussions with other vendors 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 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. In addition, the FDA or regulatory authorities outside of the U.S. may require that we have an alternate manufacturer of a drug product before approving it for marketing and sale in the U.S. or abroad and securing such alternate manufacturer before approval of a BLA could result in considerable additional time and cost prior to BLA approval. We are pursuing but have not yet engaged a second source manufacturer for molgramostim.

Any new manufacturer or supplier of finished drug product or its component materials, including drug substance and delivery devices, 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 or equipment is particularly challenging for companies like us, with inhalation products, because any change could alter the performance of the drug product.

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 their commercial value and, accordingly, 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, molgramostim 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 molgramostim development program, and if those third parties do not satisfactorily perform their contractual obligations or meet anticipated deadlines, the development of our molgramostim 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, contract research organizations (“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. Specifically, in early 2021, we engaged Parexel to support our IMPALA 2 clinical trial development activities. As a result, 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 good clinical practice (“GCP”), good laboratories practice (“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, including as a result of an outbreak of COVID-19 or another infectious disease, 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. Additionally, the COVID-19 global pandemic may pose significant risks to our development and commercialization of our product candidate as our third-party service providers, manufacturers, and suppliers are experiencing restrictions and challenges which could negatively impact our supply-chain and progress of our development pipeline.

Our molgramostim 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 molgramostim 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. For example, patients in earlier stage trials may be more sick, compliant, or otherwise motivated than patients in larger trials. 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.

If our product candidate receives marketing approval and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- regulatory authorities may withdraw their approval of the product;
- 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.

We may not achieve our projected development goals in the time frames we have announced.

We have set goals for accomplishing certain objectives material to the successful development of our molgramostim product candidate. The actual timing of these events may vary due to many factors, including delays or failures in our nonclinical testing, clinical trials, and manufacturing and regulatory activities and the uncertainties inherent in the regulatory approval process. From time to time, we create estimates for the completion of enrollment of or announcement of data from clinical trials of our product candidate. However, predicting the rate of enrollment or the time from completion of enrollment to announcement of data for any clinical trial requires us to make significant assumptions that may prove to be incorrect. As an example, due to the COVID-19 pandemic, we ceased enrollment in our discontinued AVAIL and ENCORE trials. Our estimated enrollment rates and the actual rates may differ materially, and the time required to complete enrollment of any clinical trial may be considerably longer than we estimate. Such delays may adversely affect our financial condition and results of operations.

Even if we complete a clinical trial with successful results, we may not achieve our projected development goals in the time frames we initially anticipate or announce. If a development plan for a product candidate becomes more extensive and costly than anticipated, we may determine that the associated time and cost are not financially justifiable and, as a result, may discontinue development in a particular indication or of the product candidate as a whole. In addition, even if a trial did complete with successful results, changes may occur in regulatory requirements or policy during the period of product development and/or regulatory review of a BLA that relate to the data required to be included in BLAs, which may require additional studies that may be costly and time consuming. Any of these actions may be viewed negatively, which could adversely impact our financial condition.

Further, throughout development, we must provide adequate assurance to the FDA and other regulatory authorities that we can consistently develop and produce our product candidate in conformance with GLP, GCP, cGMP, and other regulatory standards. As discussed above, we rely on CMOs for the manufacture of clinical, and future commercial, quantities of our product candidate. If future FDA or other regulatory authority inspections identify cGMP compliance deficiencies at these third-party facilities, production of our clinical trial material or, in the future, commercial product, could be disrupted, causing potentially substantial delay in or failure of development or commercialization of our product candidate.

We are substantially dependent upon our primary CRO, Parexel, for conducting our IMPALA 2 clinical trial.

We do not employ personnel or possess the facilities necessary to conduct many of the activities associated with our IMPALA 2 clinical trial. We have engaged a CRO, Parexel, to assist in the conduct of the trial. As a result, many important aspects of our development programs are, and will, continue to be outside our direct control. Parexel may not perform their activities as required or expected, including the maintenance of GCP and GLP. Further, Parexel may not be as committed to the success of our program as our own employees would. To the extent we are unable to successfully manage the performance of Parexel, our business may be adversely affected.

Our employees, independent contractors and consultants, principal investigators, CROs, CMOs and 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 and 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 them, 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.

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 cyber-security.

We rely on information technology (“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 and 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.

In response to COVID-19, we have modified our business practices with a majority of our employees working remotely from their homes to have our operations uninterrupted as much as possible. Technology in employees' homes may not be as robust as in our offices 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. The continuation of these work-from-home measures also introduces additional operational risk, including increased cybersecurity risk. 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 and the operations of any impacted customers.

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.

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.

If we 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, or if we or our vendors fail to comply with applicable data privacy laws, including the GDPR or the CCPA, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted.

A number of state, national, and foreign laws and regulations apply to the collection, use, retention, protection, disclosure, transfer, and other processing of personal data. Due to our Danish subsidiary, Savara ApS, our clinical trial activities, and operations in Europe, we are subject to data protection laws in the EU, including the General Data Protection Regulation ("GDPR"). The GDPR, which became effective on May 25, 2018, has caused the EU requirements for the protection of personal data to become more stringent and increased the penalties for noncompliance. Penalties can consist of fines up to €20 million or 4% of global annual revenues, whichever is higher. As a result, we have been required to implement additional mechanisms to ensure compliance with the new EU data protection rules, which may cause us to incur additional costs. Similarly, in June 2018, California enacted the California Consumer Privacy Act of 2018 (the "CCPA"), which became effective in January 2020. The CCPA, among other things, requires covered companies to provide new disclosures to California consumers and afford such consumers new rights to opt-out of certain sales of personal information. The CCPA creates a private right of action for statutory damages for certain breaches of information and the California Attorney General has proposed regulations under the CCPA which became effective on July 1, 2020. In addition, the California Privacy Rights Act was passed in November 2020 expanding CCPA regulations and will have an impact on our future privacy obligations. Other states have enacted or proposed legislation that regulates the collection, use, and sale of personal information, and such regimes might not be compatible with either the GDPR or the CCPA. We may be required to implement additional mechanisms to comply with the CCPA or such other state laws, which may be difficult to implement and may require us to incur additional costs. If we or our vendors fail to comply with applicable data privacy laws, including the GDPR, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted.

Our operations might be interrupted and financial results could be adversely impacted by the occurrence of a natural disaster, war, system malfunction, terrorism, telecommunication and electrical failures or other catastrophic event, or public health crises, such as the COVID-19 pandemic.

Our corporate headquarters is located in a single commercial facility in Austin, Texas, USA. We maintain a second office in a single commercial facility in Denmark where many of our product development staff are located. 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, terrorist attacks, public health crises, or severe weather conditions could significantly disrupt our operations and result in additional, unplanned expense. We are currently preparing a formal business continuity/disaster recovery plan; however, 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.

During the first quarter of 2020, COVID-19 was declared a pandemic by the World Health Organization, resulting in significant disruptions to U.S. and international manufacturing and supply chains or operations as well as travel restrictions in the U.S., Denmark, and many other countries. While the continued impact of the current COVID-19 pandemic on our business and financial results is

uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a negative impact on our business, financial condition, and operating results. As a result of the COVID-19 pandemic, there could be delays in the manufacturing supply chain for our product candidate, including delays in procurement of materials for certain of our clinical trials due to the outbreak, delays in clinical trials or recruitment, or in a more severe scenario, our business, financial condition, and operating results could be more severely affected. Given the dynamic nature of these circumstances, the duration of any business disruption or potential impact to our business of the COVID-19 pandemic is difficult to predict.

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 primary product candidate, if approved, or generate product revenue.

To commercialize our molgramostim 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 molgramostim 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 of March 8, 2021, we had 27 employees including 17 employees engaged in research and development. As we advance our molgramostim 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 Drug Development and Commercialization

We depend on the successful completion of clinical trials of our molgramostim product candidate, and any positive results in prior clinical trials do not ensure that ongoing or future clinical trials will be successful.

Pharmaceutical products are subject to stringent regulatory requirements covering quality, safety, and efficacy. The burden of proof is on the manufacturer, such as us, to show with substantial clinical data that the risk/benefit profile for any new drug is favorable. 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, they can take many years to complete, and outcomes are inherently uncertain. A drug product may fail to demonstrate positive results at any stage of testing despite having progressed satisfactorily through nonclinical testing and initial clinical trials. There is significant risk in clinical development where later stage clinical trials are designed and powered based on the analysis of data from earlier trials, with these earlier trials involving a smaller number of patients, and the results of the earlier trials being driven primarily by a subset of responsive patients. In addition, interim results of a clinical trial do not necessarily predict final results. Further, clinical trial data frequently are susceptible to varying interpretations. Medical professionals and/or regulatory authorities may analyze or weigh trial data differently than the sponsor company, resulting in delay or failure to obtain marketing approval for a product candidate. Additionally, the possible lack of standardization across multiple investigative sites may induce variability in the results which can interfere with the evaluation of treatment effects.

If we license rights to develop our product candidate to independent third parties or otherwise permit third parties to evaluate our product candidate in clinical trials, such as an investigator-sponsored clinical trial, we may have limited control over those clinical

trials. For example, we have provided molgramostim and placebo for an investigator-sponsored clinical trial by the University of Giessen in Germany that will assess the potential efficacy of molgramostim in preventing progression of COVID-19 pneumonia to acute respiratory distress syndrome. Any safety or efficacy concern identified in a third-party sponsored trial could adversely affect our or another licensee's development of our product candidate and prospects for its regulatory approval, even if the data from that trial are subject to varying interpretations and analyses. If serious adverse events are observed in such third-party sponsored trials, it could delay or cause the discontinuation of the development of the product candidate and have a material adverse effect on our business.

There are significant risks that ongoing and future clinical trials of our product candidate will not be successful. 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. For example, as a result of our IMPALA trial results and related correspondence from the FDA, we are planning an additional Phase 3 trial of molgramostim for the treatment of aPAP. Failure to complete a clinical trial of a product candidate or an unsuccessful result of a clinical trial could have a material adverse effect on our business.

Molgramostim has received Orphan Drug Designation by the FDA and in Europe. If a competitor obtains Orphan Drug exclusivity for a product with the same active ingredient and route of delivery as molgramostim for aPAP, we may be unable to market our product candidate until the exclusivity of the competing product expires.

Molgramostim has received Orphan Drug Designation in the U.S. by the FDA and in Europe by the EMA for the treatment of aPAP. Orphan Drug Designation will not shorten the regulatory review or reduce the clinical data requirements needed to obtain approval. If approval is received to market molgramostim, the FDA will not approve a similar product, with the same active ingredient, to molgramostim for seven years and the EMA will not approve a similar product to molgramostim 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 of the respective products, 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 one or more product candidate due to a competitor's Orphan Drug exclusivity, this would have a material adverse effect on our business.

Delays in commencement and completion of clinical trials are common and have many causes. Delays in clinical trials of our molgramostim product candidate would likely increase overall development costs and jeopardize our ability to obtain regulatory approval and successfully commercialize any approved product.

Clinical testing typically is expensive, can take many years to complete, and its outcome is inherently uncertain. Clinical trials may not commence on time or be completed on schedule, if at all. The commencement and completion of 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 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 regulatory approval in a prospective country;
- delays in obtaining ethics committee approval to conduct 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 administration 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 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;
- invalidation of clinical data caused by mixing up of the active drug and placebo through randomization or manufacturing errors;
- delays on the part of our CROs, CMOs, and other third-party contractors in developing procedures and protocols or otherwise 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, including returning for post-treatment follow-up;
- 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; and
- delays in enrollment and the treatment of patients caused by COVID-19.

Patient enrollment, a critical component to successful completion of a clinical trial, is affected by many factors, including the size and nature of the trial population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, ongoing trial competing for the same patient population and clinicians, and patients' perceptions as to the potential advantages of the drug being studied in relation to available alternatives, including therapies being investigated by other companies which may be viewed as more beneficial or important to study, fear of being randomized to the placebo arm, and changes in standard of care. Challenges to complete enrollment can be exacerbated in orphan indications, like those being pursued by us, with a limited number of qualifying patients and the lack of clinical sites with the necessary expertise and experience to conduct our trials. Further, completion of a clinical trial and/or its results may be adversely affected by failure to retain patients who enroll in a trial but withdraw due to adverse side effects, perceived lack of efficacy, belief that they are on placebo, improvement in condition before treatment has been completed, for personal reasons, without reason, or by patients who fail to return for or complete post-treatment follow-up.

For example, although we are not aware of any companies developing an inhaled form of GM-CSF for the treatment of aPAP, Leukine® (sargramostim), a yeast-derived recombinant human granulocyte-macrophage colony stimulating factor (rhu-GM-CSF) which is a product of Partner Therapeutics, Inc., is being utilized by some patients, domestically and internationally, for the off-label treatment of aPAP. Additionally, Partner Therapeutics, Inc. is working with the Pharmaceuticals and Medical Devices Agency and the Ministry of Health, Labour, and Welfare in Japan for regulatory approval of Leukine® for the treatment of aPAP. We cannot assess the likelihood of formal regulatory approval of Leukine®, the effectiveness of its off-label administration to patients with aPAP, or the number of aPAP patients using Leukine® for off-label treatment. However, the current off-label administration of Leukine® could adversely affect the enrollment of patients in our IMPALA 2 trial.

Additionally, as we work to initiate the IMPALA 2 trial, there remains a general uncertainty regarding the impact of COVID-19 on the aPAP patient population and physicians. Patients suffering from aPAP lung disease are prone to underlying lung conditions and are often treated by infectious disease specialists and pulmonologists. These treating physicians are on the front lines in addressing this global pandemic and must now, understandably, focus their attention on COVID-19.

Additionally, on March 30, 2020, due to the COVID-19 pandemic and out of an abundance of caution for people living with CF and clinical trial staff, we announced the close-out of enrollment in our discontinued Phase 3 AVAIL and Phase 2a ENCORE trials. With patient safety at the forefront of the decision and in accordance with guidelines established by the FDA, efforts have been made to allow enrolled patients to continue with trial treatments and site visit protocols, where possible. However, the COVID-19 pandemic may cause further delays in our clinical trials and have a negative impact on our business, financial condition, and operating results.

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.

Clinical trials are very expensive, difficult to design and implement, often take many years to complete, and the outcome is inherently uncertain.

Clinical development of pharmaceutical products for humans is generally very expensive, takes many years to complete, and failures can occur at any stage of clinical testing. We estimate that clinical development of our product candidate will take several additional years to complete; however, because of the variety of factors that can affect the design, timing and outcome of clinical trials, we are unable to estimate the exact funds required to complete research and development, obtain regulatory approval, and commercialize our product candidate. We will need significant additional capital to continue to advance our products as per current business plans.

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 Independent Review Board ("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.

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.

There is significant uncertainty regarding the regulatory approval process for any investigational new drug, substantial further testing and validation of our primary 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 primary product candidate and substantially harm our business.

Pharmaceutical products generally are subject to rigorous nonclinical testing and clinical trials and other approval procedures mandated by the FDA and foreign regulatory authorities. 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. Molgramostim is currently in Phase 3 clinical testing. The top line results from our first Phase 3 clinical trial, IMPALA, 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 molgramostim development program for aPAP and results from the IMPALA Phase 3 trial in which the FDA indicated that the data provided in the briefing package for the Type C meeting did not provide sufficient evidence of efficacy and safety for the treatment of aPAP.

On December 23, 2019, the FDA provided communication to us regarding the granting of Breakthrough Therapy designation, a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on clinically significant endpoint(s), for molgramostim for the treatment of aPAP. As such, we have worked with the FDA and EMA and determined the scope and design of an additional Phase 3 trial for the molgramostim development program for the treatment of aPAP, the IMPALA 2 trial. The scope, powering, cost, and timing of IMPALA 2 will require us to expend substantial additional resources. Additional clinical trials, and/or other costly trials, could require us to expend substantial additional resources and could significantly extend the timeline for clinical development prior to market approval.

Significant uncertainty exists with respect to the regulatory approval process for any investigational new drug, including molgramostim. 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 BLA or the equivalent foreign regulatory approval submission for review or before approving the BLA or its equivalent, the FDA or foreign regulatory agencies may request that we provide additional information that may require significant resources and time to generate and there is no guarantee that our product candidate will be approved for any indication for which we may apply. 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. For example, U.S. federal government shut-downs or budget sequestrations, such as ones that occurred during January 2018 and December 2018 through January 2019, 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. Further, regulatory oversight and actions may be disrupted or delayed in regions particularly impacted by COVID-19 if regulators and industry professionals are expending significant and unexpected resources addressing the outbreak.

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, molgramostim 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. They may limit the label of molgramostim 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 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.

Regulations may be changed prior to submission of a marketing application that require higher hurdles than currently anticipated. These may occur as a result of drug scandals, recalls, or a political environment unrelated to our products.

Even if we receive regulatory approval for our primary product candidate, we may face regulatory difficulties 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 molgramostim 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 untitled 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;
- 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 or require a product recall.

If our primary product candidate 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 a product's approved labeling;
- reimbursement and coverage policies of government and other third-party payers;
- pricing and cost-effectiveness of our product relative to alternative treatments;
- availability of 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 a 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 primary 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 primary 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. Conversely, if the product candidate does receive approval outside the U.S. in the future, we may not meet the FDA requirements in the U.S. for approval.

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

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is 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. Other countries, such as the U.K., have similar laws with which we must comply. 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. Such an accusation, even if unwarranted, could prove disruptive to our developmental and commercialization efforts.

Risks Related to Our Intellectual Property

Our success will depend on obtaining and maintaining effective intellectual property protection for our primary product candidate and proprietary technology.

We have no patent protection for molgramostim for the treatment of aPAP, and primarily rely on the Orphan Drug exclusivity as our primary barrier to competition. Molgramostim utilizes proprietary delivery devices with exclusive supply agreements and receives additional protection via 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.

The patent and intellectual property positions of biopharmaceutical companies generally are highly uncertain, involve complex legal and factual questions, and have been and continue to be the subject of much litigation. There is no guarantee that we have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any pending applications or that claims allowed will be sufficient to protect the technology we develop or have developed or that is used by us, our CMOs, or our other service providers. In addition, any patents that are issued to us may be limited in scope or challenged, invalidated, infringed, or circumvented, including by our competitors, and rights we have under issued patents may not provide competitive advantages to us. If competitors can develop and commercialize technology and products similar to ours, our ability to successfully commercialize our technology and products may be impaired.

Patent applications in the U.S. are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months. As a result, we cannot be certain that the inventors listed in any patent or patent application owned by us were the first to conceive of the inventions covered by such patents and patent applications (for U.S. patent applications filed before March 15, 2013), or that such inventors were the first to file patent applications for such inventions outside the U.S. and, after March 15, 2013, in the U.S. In addition, changes in or different interpretations of patent laws in the U.S. and foreign countries may affect our patent rights and limit the number of patents we can obtain, which could permit others to use our discoveries or to develop and commercialize our technology and products without any compensation to us.

While we are no longer pursuing the development of our vancomycin program, we hold a patent specific to the formulation of the vancomycin powder. While this may prevent identical products from entering the market, it may not preclude someone skilled in the art from inventing an alternate formulation approach with comparable or improved characteristics.

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 also intend to rely on regulatory exclusivity for protection of our 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 molgramostim, which is administered via nebulization, we may rely on regulatory exclusivity for the combination of molgramostim and its delivery system. However, there is no assurance that our molgramostim product and its delivery system, if approved, will benefit from this type of market protection.

We may rely on trademarks, trade names, and brand names to distinguish our molgramostim product, if approved for commercial sale, from the products of our competitors. We intend to seek approval for a new name for molgramostim that meets the FDA’s and foreign regulatory requirements. 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. In the event that 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 our trademarks or we may not have adequate resources to enforce our trademarks.

Our success depends on our ability to prevent competitors from duplicating or developing and commercializing equivalent versions of our primary product candidate, but patent protection may be difficult to obtain and any issued claims may be limited.

Patents may not provide us with significant competitive advantages, because the validity or enforceability of the patents may be challenged and, if instituted, one or more of the challenges may be successful. Patents may be challenged in the U.S. under post-grant review proceedings, *inter partes* re-examination, *ex parte* re-examination, or challenges in district court. Patents issued in foreign jurisdictions may be subjected to comparable proceedings lodged in various foreign patent offices, or courts. These proceedings could result in either loss of the patent or loss or reduction in the scope of one or more of the claims of the patent. Even if a patent issues and is held valid and enforceable, competitors may be able to design around our patents, such as by using pre-existing or newly developed technology, in which case competitors may not infringe our issued claims and may be able to market and sell products that compete directly with us before and after our patents expire.

The patent prosecution process is expensive and time-consuming. We and any future licensors and licensees may not apply for or prosecute patents on certain aspects of our product candidate at a reasonable cost, in a timely fashion, or at all. We may not have the

right to control the preparation, filing, and prosecution of some patent applications related to our product candidate or technology. As a result, these patents and patent applications may not be prosecuted and enforced in a manner consistent with our best interests. It is also possible that we or any future licensors or licensees will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Further, it is possible that defects of form in the preparation or filing of our patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, assignment, or claim scope. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid or unenforceable. In addition, one or more parties may independently develop similar technologies or methods, duplicate our technologies or methods, or design around the patented aspects of our products, technologies, or methods. Any of these circumstances could impair our ability to protect our products, if approved, in ways which may have an adverse impact on our business, financial condition, and operating results.

Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in and outside of the U.S. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to use our patents to stop others from using or commercializing similar or identical products or technology, or limit the duration of the patent protection of our technology and drugs. Given the amount of time required for the development, testing, and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

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.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and applications are required to be paid to the United States Patent and Trademark Office (“USPTO”), and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process and after a patent has been issued. There are situations in which non-compliance can result in decreased patent term adjustment or in abandonment or lapse of the patent or patent application, leading to partial or complete loss of patent rights in the relevant jurisdiction.

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 products and product candidates 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 many years to publish and issue, there currently may be pending applications, unknown to us, that may later result in issued patents that our product, 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, 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, product candidate, and/or technology infringe its patents and/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, product candidate, or technology, infringe its patents and/or other intellectual property rights. If a third-party patent or other intellectual property right is found to cover our product, 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 expect competition in the marketplace for our molgramostim product candidate should it receive regulatory approval.

Molgramostim has received Orphan Drug Designation from the FDA and the EMA. Orphan Drug Designation will provide market exclusivity in the U.S. for seven years and ten years in Europe, but only if (i) molgramostim receives market approval before a competitor using the same active compound for the same indication, (ii) we are able to produce sufficient supply to meet demand in the marketplace, and (iii) another product with the same active ingredient is not deemed clinically superior.

The industries in which we operate (biopharmaceutical, specialty pharmaceutical, biotechnology, and pharmaceutical) are highly competitive and subject to rapid and significant change. Developments by others may render potential application of our molgramostim product candidate in a particular indication obsolete or noncompetitive, even prior to completion of its development and approval for that indication. 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.

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 primary 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 from those products. The commercial success of our product candidate, if approved, will depend on the extent to which the costs of such products 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 orphan diseases) thus requiring us to charge very high prices in order to recover development costs and achieve a profit on our revenue. If these third-party payers do not consider our products to be cost-effective compared to other therapies, we may not obtain coverage for our products 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 products 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 products 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 products may be adversely affected if the amount of payment for our products proves to be unprofitable for healthcare providers or less profitable than alternative treatments or if administrative burdens make our products less desirable to use. Third-party payer reimbursement to providers of our products, if approved, may be subject to a bundled payment that also includes the procedure of administering our products or third-party payers may require providers to perform additional patient testing to justify the use of our products. To the extent there is no separate payment for our product(s), 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 products;
- 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 products 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 products. The containment of healthcare costs has become a priority of federal and state governments worldwide and the prices of drug products have been a focus in this effort. For example, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs, and former President Trump signed four executive orders on July 24, 2020 aimed at bringing down pharmaceutical prices. 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. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue, attain profitability, or commercialize our product candidate, especially in light of our plans to price our product candidate at a high level.

Furthermore, we expect that 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 primary 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 primary 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 primary 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.

Risks Related to our Common Stock

Our stock price is expected to continue to be volatile.

The market price of our common stock has experienced substantial declines since we announced the top-line results of our IMPALA Phase 3 trial of molgramostim for aPAP on June 12, 2019, and our stock price has been and is expected to 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:

- impact of the COVID-19 pandemic on the global economy, financial markets, and liquidity and availability of capital;
- failed or inconclusive data results from our clinical trials;
- our ability to obtain regulatory approvals for our primary 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 primary 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 primary product candidate;
- any inability to obtain adequate supply of our primary 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 aPAP 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. 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. 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 our common stock trades at closing bid prices below $1.00 for 30 consecutive business days, or if we are unable to satisfy any of the other 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 and fewer business development opportunities, and adversely affect our ability to obtain financing for the continuation of our operations.

For example, on November 15, 2019, we received written notice from The Nasdaq Stock Market LLC indicating that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Global Select Market under Nasdaq Listing Rule 5550(a)(2). However, on December 10, 2019, we received written notice from The Nasdaq Stock Market LLC stating that because our shares had a closing bid price at or above $1.00 per share for a minimum of ten consecutive business days, our stock had regained compliance with the minimum bid price requirement of $1.00 per share for continued listing on the Nasdaq Global Select Market, as set forth in NASDAQ Listing Rule 5450(a)(1).

We will continue to incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

As a public company, we will continue to incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We will also continue to incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the U.S. Securities and Exchange Commission ("SEC") and Nasdaq. These rules and regulations may also make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers, which may adversely affect investor confidence in us and cause our business or stock price to suffer.

In March 2020, the SEC amended the definitions of accelerated filer and large accelerated filer to exclude smaller reporting companies that have not yet begun to generate significant revenue. Accordingly, we are changing our status from a smaller reporting company, accelerated filer, to a smaller reporting company, non-accelerated filer, effective for this annual report on Form 10-K. In accordance with the SEC amendments, we no longer require an integrated independent audit of our internal controls under Sarbanes-Oxley 404(b) but will continue to comply with Sarbanes-Oxley 404(a) and (c).

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 have completed certain transactions that likely have resulted in an ownership change under Section 382 of the Internal Revenue Code limiting the use of our net operating loss carryforwards and certain other tax attributes.

If a corporation undergoes an "ownership change" within the meaning of Sections 381, 382, and 383 of the Internal Revenue Code, the corporation's net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state tax laws. Our net operating loss carryforwards and certain other tax attributes will be subject to limitations on use. Additional ownership changes in the future could result in additional limitations on our net operating loss carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

Item 1B. Unresolved Staff Comments.

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

Item 2. Properties.

Our corporate headquarters are located in Austin, Texas, where we sublease approximately 6,151 square feet of office space pursuant to a sublease that expires in July 2021. Additionally, we lease office space in Copenhagen, Denmark where approximately 50% of our workforce is located.

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.

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 8, 2021, we had approximately 125 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. 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 an orphan lung disease company. Our lead program, molgramostim nebulizer solution ("molgramostim"), is an inhaled granulocyte-macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis ("aPAP"). Savara and its wholly owned subsidiaries operate in one segment with its principal office in Austin, Texas, USA.

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, 2020, we have raised net cash proceeds of approximately $268.2 million, primarily from public offerings of our common stock, private placements of convertible preferred stock, and debt financings.

We have never been profitable and have incurred operating losses in each year since inception. Our net losses were $49.6 million and $78.2 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $257.5 million. Substantially all of our operating losses resulted from expenses incurred in connection with 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 primary 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, 2020, we had cash and cash equivalents of $22.9 million and short-term investments of $59.3 million. We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. 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 candidates.

Recent Events

Parexel Master Services Agreement

We entered into a Master Services Agreement ("MSA") with Parexel on March 5, 2021, pursuant to which Parexel will provide contract research services related to our clinical trials. Contemporaneously with entering the MSA, we executed a work order with Parexel, under which Parexel will provide services related to the IMPALA 2 trial. Under that work order, we will pay Parexel service fees and pass-through expenses estimated to be approximately $31 million over the course of the IMPALA 2 clinical trial.

GSK

On December 10, 2020, we announced that our Phase 3 trial of vancomycin hydrochloride inhalation powder in people living with cystic fibrosis who have MRSA lung infection did not meet the primary endpoint. Subsequently, on January 7, 2021, we issued a termination notice to GlaxoSmithKline Trading Services Limited ("GSK"), who manufactures the drug product from bulk vancomycin powder. On January 26, 2021, we and GSK entered a change order for termination costs associated with the closeout and winddown of vancomycin activities. Termination costs were less than $1 million.

COVID-19

The continuing COVID-19 global pandemic poses significant risks to our business. As we commence enrollment of our additional Phase 3 trial for the use of molgramostim for the treatment of aPAP, there remains a general uncertainty regarding the impact of COVID-19 on the aPAP patient population and physicians. Patients suffering from aPAP lung disease are prone to underlying lung conditions and are often treated by infectious disease specialists and pulmonologists. These treating physicians are on the front lines in addressing this global pandemic and must now, understandably, focus their attention on COVID-19.

Additionally, we are unable to quantify the impact this situation will have on our future financial performance, but the public health actions being undertaken to the reduce spread of the virus have created, and may continue to create, challenges and disruptions to our operations. Accordingly, we are adhering to government restrictions and operating out of an abundance of caution for the safety of our personnel and patients, including social distancing protocols and requiring remote working for our personnel. Additionally, management, on an on-going basis, is evaluating our liquidity position, communicating with and monitoring the actions of our service providers, manufacturers, and suppliers and reviewing our near-term financial performance as we manage Savara through the uncertainty related to COVID-19.

As of the date of this report:

- our personnel have restrictions on traveling, both in the interests of their health as well as federal, state, local, and international travel restrictions;
- due to government guidance, social restrictions, and out of abundance of caution for our employees' health, our office-based employees are primarily working remotely;
- our third-party service providers, manufacturers, and suppliers are experiencing similar restrictions which could negatively impact our supply chain and progress of our development pipeline; and
- government restrictions enacted as a result of COVID-19 and related safety concerns have and could delay recruitment of our clinical trials.

The COVID-19 pandemic remains extremely fluid and we are continuing to re-assess the impact on our operations by monitoring the spread of COVID-19 and the actions implemented to combat the virus in various regions throughout the world. Where appropriate, we are making necessary operational and strategic decisions where possible, in an attempt to mitigate the negative impact of the virus on our operations.

Income Taxes

The Cares Act

In response to the COVID-19 pandemic, many governments are taking measures to provide aid and economic stimulus. These measures include deferring the due dates of tax payments or other changes to their income and non-income-based tax laws. The CARES Act, which was enacted on March 27, 2020 in the U.S., includes many measures to assist companies, including temporary changes to income and non-income-based tax laws. Some of the key tax-related provisions of the bill include:

- eliminating the 80% of taxable income limitations by allowing corporate entities to fully utilize net operating loss ("NOL") carryforwards to offset taxable income in 2018, 2019 or 2020. The 80% limitation is reinstated for tax years after 2020;
- allowing NOLs originating in 2018, 2019 or 2020 to be carried back five years;
- increasing the net interest expense deduction limit to 50% of adjusted taxable income from 30% for tax years beginning January 1, 2019 and 2020;
- allowing taxpayers with alternative minimum tax credits to claim a refund in 2020 for the entire amount of the credit instead of recovering the credit through refunds over a period of years, as originally enacted by the Tax Cut and Jobs Act in 2017; and
- allowing companies to deduct more of their cash charitable contributions paid during calendar year 2020 by increasing the taxable income limitation from 10% to 25%.

In addition to the income tax provisions noted above, the CARES Act provides for non-income tax provisions, such as allowing payments of the employer share of Social Security payroll taxes that would otherwise be due from the date of enactment through December 31, 2020 to be paid over the following two years. Other provisions will allow eligible employers subject to closure due to the COVID-19 pandemic to receive a 50% credit on qualified wages against their employment taxes each quarter with any excess credits eligible for refunds.

On August 8, 2020, former President Trump issued a COVID-19 relief executive order ("EO") intending to help alleviate the hardships experienced by American workers as a result of the pandemic. The EO focuses on four key areas of relief including the deferral of payroll tax obligations for certain workers.

We have assessed the provisions of the CARES Act and EO and do not believe the measures mentioned above materially impact us or are relevant to our tax reporting.

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.

Accrued Research and Development Expenses

We record accrued expenses for estimated costs of our research and development activities conducted by external service providers, which include the conduct of clinical trials and contract formulation and manufacturing activities. We record the estimated costs of development activities based upon the estimated amount of services provided but not yet invoiced, and include these costs in accrued liabilities in the consolidated balance sheet and within research and development expense in the consolidated statement of operations and comprehensive loss. These costs are a significant component of our research and development expenses. We record accrued expenses for these costs based on the estimated amount of work completed and in accordance with agreements established with these external service providers.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates.

Business Combinations

We account for business combinations in accordance with Accounting Standards Codification ("ASC") Topic 805, "Business Combinations," and as further defined by Accounting Standards Update ("ASU") 2017-01, "Business Combinations (Topic 805)," which requires the purchase price to be measured at fair value. When the purchase consideration consists entirely of shares of our common stock, we calculate the purchase price by determining the fair value, as of the acquisition date, of shares issued in connection with the closing of the acquisition and, if the transaction involves contingent consideration based on achievement of milestones or earn-out events, the probability-weighted fair value, as of the acquisition date, of shares issuable upon the occurrence of future events or conditions pursuant to the terms of the agreement governing the business combination. If the transaction involves such contingent consideration, our calculation of the purchase price involves probability inputs that are highly judgmental due to the inherent unpredictability of drug development, particularly by development-stage companies such as ours. We recognize estimated fair values of the tangible assets and intangible assets acquired, including in process research and development ("IPR&D"), and liabilities assumed as of the acquisition date, and we record as goodwill any amount of the fair value of the tangible and intangible assets acquired and liabilities assumed in excess of the purchase price.

Goodwill and Acquired In-Process Research and Development

Although we did not have any goodwill as of December 31, 2020, we adopted the following accounting policy. In accordance with Accounting Standards Codification ("ASC") Topic 350, "Intangibles – Goodwill and Other," our goodwill and acquired in-process research and development ("IPR&D") are determined to have indefinite lives and, therefore, are not amortized. Instead, they are 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. For instance, based upon the ultimate scope and scale of the COVID-19 global pandemic, there may be materially negative impacts to the assumptions made with respect to our IPR&D assets that could result in an impairment of such assets.

Accounting Standards Update ("ASU") 2017-04, "Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment," outlines an impairment model providing us the option to implement a one-step method for determining impairment of goodwill, thereby simplifying the subsequent measurement of goodwill by eliminating Step 2 (quantitative calculation of measuring a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill) from the goodwill impairment test. Under the amendments in this guidance, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable.

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.

If 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 30, utilizing a qualitative approach and determining if it was more-likely-than not that the fair value was impaired. We evaluate potential impairment of our acquired goodwill, if any, annually on June 30, performing the quantitative analysis based upon market capitalization. While we continue to evaluate opportunities to monetize our acquired assets, we can provide no assurances that we will be able to do so. However, we believe that our approach is a more appropriate method for assessing fair value in the context of our current business.

Our determinations as to whether, and if so, the extent to which goodwill and 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.

Share-based Compensation Expenses

We recognize the cost of stock-based awards granted to employees based on the estimated grant-date fair value of the awards. The value of the award is recognized as expense ratably over the requisite service period. We recognize 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.

We estimate the grant-date fair value of a stock option award using the Black-Scholes-Merton option pricing model (“Black-Scholes model”). In determining the grant-date fair value of a stock option award under the Black-Scholes model, we must make a number of assumptions, including the term of the award, the volatility of the price of our common stock over the term of the award, and the risk-free interest rate. Changes in these or other assumptions could have a material impact on the compensation expense we recognize.

Product Revenue

We record revenue based on a five-step model in accordance with ASC 606, “Revenue from Contracts with Customers.” To date, we have not generated any product revenue from our product candidates.

Milestone Revenue

With respect to the license agreement related to molgramostim, which includes certain milestone payments to be remunerated to us by the licensee, we identify the performance obligations, determine the transaction price, allocate the contract transaction price to the performance obligations, and recognize the revenue when (or as) the performance obligation is satisfied. We identify the performance obligations included within the license agreement and evaluate which performance obligations are distinct.

The milestone payments are a form of variable consideration as the payments are contingent upon achievement of a substantive event. The milestone payments are estimated and included in the transaction price when we determine, under the variable consideration constraint, that it is probable that there will not be a significant reversal of cumulative revenue recognized in future periods. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such milestones and any related constraint, and if necessary, adjust the estimate of the overall transaction price.

Income Taxes

We use 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.

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 and generally benefit multiple programs. Where appropriate, these costs are allocated by product candidate. Unallocated internal research and development costs consist primarily of:
  - personnel costs, which include salaries, benefits and stock-based compensation expense;
  - allocated 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.

The largest component of our operating expenses has historically been our investment in research and development activities. The following table shows our research and development expenses by product candidate for the years ended December 31, 2020 and 2019:

	Year ended December 31,	
	2020	2019
	(in thousands)	
Product candidates:		
Molgramostim	$ 19,960	$ 22,404
Vancomycin	9,582	16,348
Other, including Apulmiq	5,496	29
Total research and development expenses	**$ 35,038**	**$ 38,781**

We expect research and development expenses will remain significant in the future as we advance our molgramostim product candidate into and through clinical trials and pursue regulatory approvals, which will require a significant increased investment in regulatory support and contract manufacturing and inventory build-up related costs.

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 candidates. The probability of success of our product candidates 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 molgramostim.

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, and legal; 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 (Expense), 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, 2020 and 2019

	Year ended December 31, 2020	2019	Dollar Change
	(in thousands)		
Milestone revenue	$ 257	$ —	$ 257
Operating expenses:			
Research and development	35,038	38,781	(3,743)
General and administrative	14,264	13,081	1,183
Impairment of goodwill	—	26,852	(26,852)
Depreciation	255	311	(56)
Total operating expenses	49,557	79,025	(29,468)
Loss from operations	(49,300)	(79,025)	29,725
Other income (expense), net	(315)	852	(1,167)
Net loss	$ (49,615)	$ (78,173)	$ 28,558

Research and Development

Research and development expenses decreased $3.7 million, or 9.7%, to $35.0 million for the year ended December 31, 2020 from $38.8 million for the year ended December 31, 2019. The decrease was primarily due to the wind down and conclusion of our non-aPAP trials, primarily vancomycin. During 2019 and part of 2020, our research and development costs included expenses associated with the development of molgramostim for the treatment of NTM and NTM in patients with CF, as well as the enrollment and other Phase 3 trial activities of our vancomycin program. These trials were concluded or terminated as we focus on the development of molgramostim for the treatment of aPAP. The decrease was partially offset by costs incurred related to Apulmiq.

General and Administrative

General and administrative expenses increased $1.2 million, or 9.0%, to $14.3 million for the year ended December 31, 2020 from $13.1 million for the year ended December 31, 2019. The increase was primarily due to increased stock-based compensation expense, insurance expense and costs related to the resignation of our former chief executive officer and former chief business officer. These increases were partially offset by a decrease in commercial costs related to our molgramostim product candidate.

Impairment of IPR&D and Goodwill

During the year ended December 31, 2019, we recognized $26.9 million in goodwill impairment charges following the results of our IMPALA Phase 3 trial of molgramostim for the treatment of aPAP**.**

Other Income (Expense), Net

Other income (expense), net, decreased from $0.9 million income to $0.3 million expense. The decrease was primarily due to an increase in interest expense, net, of $1.4 million. The increase in interest expense, net, was primarily related to moving our available-for-sale securities to money market accounts during 2020, resulting in a decrease in investment income due to lower interest rates.

Liquidity and Capital Resources

Sources of Liquidity

Since inception through December 31, 2020, our operations have been financed primarily by net cash proceeds of approximately $268.2 million, primarily from public offerings of common stock, private placements, and debt financings. As of December 31, 2020, we had $22.9 million in cash, $59.3 million in short-term investments, and an accumulated deficit of $257.5 million. We expect that our research and development expenses will remain significant, and, as a result, we anticipate that we will continue to incur losses in the foreseeable future. Therefore, we will need to raise additional capital to fund our operations, which may be through the issuance of additional equity and potentially through borrowings.

Debt Facility

On April 28, 2017, we entered into a loan and security agreement with Silicon Valley Bank, as amended on October 31, 2017 and December 4, 2018 (the "Loan Agreement"). On January 31, 2020, we executed a third amendment to the Loan Agreement (the "Third Amendment"), which provides for a $25 million term debt facility. The Third Amendment extends the interest only period of the loan repayment through June 30, 2022, with payments thereafter in equal monthly installments of principal plus interest over 18 months. However, if by March 31, 2021, we do not have an ongoing Phase 3 or Phase 4 clinical trial evaluating molgramostim for the treatment of aPAP in which the first patient has been dosed, the interest-only period will end and principal plus interest will be due in

equal monthly installments over 24 months, beginning on April 1, 2021. In February 2021, Silicon Valley Bank agreed to extend the requirement for the date of the first patient dosed in our Phase 3 IMPALA 2 trial to the end of the second quarter of 2021.

Silicon Valley Bank has been granted a perfected first priority lien in all of our assets with a negative pledge on our intellectual property. The Loan Agreement, as amended by the Third Amendment, contains customary affirmative and negative covenants, including among others, covenants limiting our ability and our subsidiaries' ability to dispose of assets, permit a change in control, merge or consolidate, make acquisitions, incur indebtedness, grant liens, make investments, make certain restricted payments, and enter into transactions with affiliates, in each case subject to certain exceptions. In addition, the Third Amendment contains an affirmative covenant requiring us to deliver evidence by June 30, 2021 of the receipt of gross cash proceeds of at least $25 million from the exercise of currently outstanding warrants or the issuance of other equity securities.

Following the effective date of the Third Amendment, the Company was required to pay a portion of the end of period charge equal to $0.5 million under the Loan Agreement to Silicon Valley Bank. The loans bear interest at the greater of (i) the prime rate reported in The Wall Street Journal, plus a spread of 3.0% or (ii) 7.75%. The Loan Agreement, as amended by the Third Amendment will also require a prepayment fee (2.0% of funded amounts in months 13-24, and 1.0% thereafter), and an end of term charge equal to 6.0% of the amount of principal borrowed.

In connection with the execution of the Third Amendment, we entered into amendments to each of the outstanding warrants previously issued to Silicon Valley Bank and its affiliate, totaling 77,793 shares, to amend the exercise price to be $2.87 per share. That amendment results in a minimal incremental increase to the fair value of these warrants, determined in accordance with the Black-Scholes-Merton option pricing model and ASC 718-20-55, which has been recognized as interest expense.

The capital is being utilized to fund our ongoing development programs and for general corporate purposes.

Common Stock Sales Agreement

On April 28, 2017, we entered into a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC ("Wainwright"), as sales agent, which was amended by Amendment No. 1 to the Common Stock Sales Agreement (the "Amendment") on June 29, 2018 (the "Sales Agreement"), pursuant to which we may offer and sell, from time to time, through Wainwright, shares of our common stock, par value $0.001 per share (the "Shares"), having an aggregate offering price of not more than $60.0 million, in addition to the $2.3 million in shares sold prior to the Amendment. The Amendment was effective on July 13, 2018, at the time our Registration Statement on Form S-3, dated June 29, 2018, (the "New Registration Statement") was declared effective by the SEC. The Shares will be offered and sold pursuant to the New Registration Statement. Subject to the terms and conditions of the Sales Agreement, Wainwright will use its commercially reasonable efforts to sell the Shares from time to time, based upon our instructions. We have provided Wainwright with customary indemnification rights, and Wainwright will be entitled to a commission at a fixed commission rate equal to 3.0% of the gross proceeds per Share sold. Sales of the Shares, if any, under the Sales Agreement may be made in transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act of 1933, as amended. We have no obligation to sell any of the Shares and may at any time suspend sales under the Sales Agreement or terminate the Sales Agreement.

During the years ended December 31, 2020 and 2019, we sold 942,825 shares and 4,769,726 shares of common stock under the Sales Agreement for net proceeds of approximately $2.3 million and $29.6 million, respectively.

Recent Public Offering

On July 30, 2018, we completed an underwritten public offering consisting of 4,250,000 shares of our common stock. The net proceeds from the offering, after deducting the underwriting discounts and commissions and offering expenses, were approximately $45.8 million. The July 2018 public offering was executed under the New Registration Statement.

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 candidates, the initiation of molgramostim pre-commercialization activities, and general and administrative expenses.

Private Placement

On December 24, 2019, we completed a private placement in a public entity (the "Private Placement" or "PIPE") under a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional and accredited investors (the "Investors"), pursuant to which we issued and sold to the Investors 9,569,430 shares of our common stock and pre-funded warrants ("Pre-Funded PIPE Warrants") to purchase an aggregate of 5,780,537 shares of our common stock. The gross proceeds before deducting placement fees and offering expenses were approximately $26.8 million. We also issued accompanying warrants (the "Milestone Warrants") to purchase an aggregate of up to 32,577,209 additional shares of our common stock and may receive up to approximately $48.2 million from the exercise of the Milestone Warrants prior to their expiration, totaling potential aggregate gross proceeds of up to approximately $75.0 million from the PIPE before deducting placement agent fees and estimated offering costs. The Milestone Warrants are exercisable at any time prior to the earlier of thirty days following the achievement of a defined clinical milestone or two years after the closing date of the Private Placement. The Pre-Funded PIPE Warrants are exercisable at any time after their original issuance and will not expire.

Cash Flows

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

	Year ended December 31,	
	2020	2019
	(in thousands)	
Cash used in operating activities	$ (39,836)	$ (45,123)
Cash provided by investing activities	9,053	15,740
Cash provided by financing activities	3,689	54,908
Effect of exchange rate changes	170	(22)
Net increase (decrease) in cash	$ (26,924)	$ 25,503

Cash flows from operating activities

Cash used in operating activities for the year ended December 31, 2020 was $39.8 million, consisting of a net loss of $49.6 million, which was partially offset by (1) non-cash, share-based compensation expense of $5.1 million and (2) other non-cash charges related to amortization and depreciation of $0.7 million. In addition, the net loss was impacted by the write-off of acquired in-process research and development of $5.4 million related to the asset acquisition in the first quarter of 2020 of Apulmiq. The cash paid for the acquisition is reflected in cash flows from investing activities for the year ended December 31, 2020.

Cash used in operating activities for the year ended December 31, 2019 was $45.1 million, consisting of a net loss of $78.2 million, which was partially offset by non-cash charges of $32.2 million, mainly comprised of impairment of goodwill, depreciation, non-cash interest, fair value changes, accretion on discount to short-term investments, amortization of debt issuance costs, and stock-based compensation, and further offset by a net decrease in assets and liabilities of $0.8 million. The change in our net operating assets and liabilities was primarily due to an increase in accrued liabilities mostly related to research and development costs for both vancomycin and molgramostim.

Cash flows from investing activities

Cash provided by investing activities for the years ended December 31, 2020 and 2019 was primarily the result of net sale and maturities of short-term investments. In addition, we paid $3.2 million in the first quarter of 2020 related to the acquisition of Apulmiq.

Cash flows from financing activities

Cash provided by financing activities for the year ended December 31, 2020 was primarily related to net proceeds of $2.3 million related to the sales of our common stock through “at the market offerings” under the Sales Agreement and $1.8 million of net proceeds related to the exercise of certain Milestone Warrants issued in the Private Placement. These proceeds were partially offset by the payment of $0.5 million related to the end of period charge following the Third Amendment of our debt facility with Silicon Valley Bank in January 2020.

Cash provided by financing activities for the year ended December 31, 2019 was primarily related to net proceeds of $25.2 million from the Private Placement and $29.6 million in net proceeds from the “at the market offering” under the Sales Agreement.

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 any of our current or future product candidates. At the same time, we expect our expenses to remain significant in connection with our ongoing development and manufacturing activities, particularly as we continue the research, development, manufacture and clinical trials of, and seeking of regulatory approval for, our product candidate.

As of December 31, 2020, we had cash, cash equivalents, and short-term investments of $82.2 million. We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. 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.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to finance our future cash needs primarily through the issuance of additional equity and potentially through borrowings, grants, and strategic alliances with partner companies. To the extent that we raise additional capital through the issuance of additional equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include

covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings 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 our product candidates 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 molgramostim.

For a summary of the contingent milestone payments and commitments, refer to Note 2, “Summary of Significant Accounting Policies - Manufacturing and Other Commitments and Contingencies,” of the consolidated financial statements in this report.

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

See Note 2, “Summary of Significant Accounting Policies - Recent Accounting Pronouncements,” of the consolidated financial statements in this report for a discussion of recent accounting pronouncements and their effect, if any, on us.

Item 6A. Quantitative and Qualitative Disclosures About 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 to 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 had a material impact on our audited 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.

We have ongoing operations in Denmark and pay those vendors in local currency (Danish Krone) or Euros. We seek to limit the impact of foreign currency fluctuations through the use of derivative instruments, and short-term foreign currency forward exchange contracts not designated as hedging instruments. We did not recognize any significant exchange rate losses during the years ended December 31, 2020 and 2019. A 10% change in the Krone-to-dollar or Euro-to-dollar exchange rate on December 31, 2020 would not have had a material effect on our results of operations or financial condition.

We also have interest rate exposure as a result of our Loan Agreement, as amended, with Silicon Valley Bank. As of December 31, 2020, the outstanding gross principal amount of the secured term loan was $25.0 million. The loan bears interest at the prime rate reported in The Wall Street Journal, plus a spread of 3.00%. Changes in the prime rate may therefore affect our interest expense associated with our secured term loan. If a 10% change in interest rates from the interest rates on December 31, 2020 were to have occurred, this change would not have had a material effect on the value of our investment portfolio or on our interest expense obligations with respect to outstanding borrowed amounts.

Inflation generally affects us by increasing our cost of labor 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 7. 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.

Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 8A. 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 Officer, the effectiveness of our disclosure controls and procedures as of December 31, 2020, 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 Officer have concluded that, as of December 31, 2020, 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 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 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, 2020 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, 2020.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during Savara’s quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 8B. Other Information.

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 2021 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 9. 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 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 10. 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 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

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

Item 12. 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 13. 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 14. 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, 2020 and 2019
- Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2020 and 2019
- Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2020 and 2019
- Consolidated Statements of Cash Flows for the years ended December 31, 2020 and 2019
- Notes to Consolidated Financial Statements

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

(3) 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 15. Form 10-K Summary.

Not applicable.

Exhibit Index

2.1	Agreement and Plan of Merger and Reorganization, dated January 6, 2017, by and among the Registrant, Aravas Inc. (formerly Savara Inc.) and Victoria Merger Corp. (Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on January 9, 2017.)
2.2	Business Transfer Agreement, dated May 13, 2016, between Aravas Inc. (formerly Savara Inc.) and Serendex Pharmaceuticals A/S (Incorporated by reference to Exhibit 2.6 to the Registrant's Registration Statement on Form S-4 filed on February 10, 2017.)
2.3	Amendment dated May 27, 2019 to the Business Transfer Agreement Between Savara Inc. and Serendex Pharmaceuticals A/S, dated May 13, 2016, between Savara Inc. and Serendex Pharmaceuticals A/S. (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2019.)
3.1	Amended and Restated Certificate of Incorporation, as amended, of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-3 filed on June 29, 2018.)
3.2	Composite Amended and Restated Bylaws, as amended, of the Registrant (Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K filed on March 26, 2014.)
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 5, 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 5, 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 (Incorporated by reference to Exhibit 4.25 to the Registrant's Annual Report on Form 10-K filed on March 12, 2020).
10.1		Common Stock Sales Agreement, dated April 28, 2017, between Savara Inc. and H.C. Wainwright & Co., LLC (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on April 28, 2017.)
10.2		Loan and Security Agreement, dated April 28, 2017, among Savara Inc., Aravas Inc. and Silicon Valley Bank (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed on May 5, 2017.)
10.3		First Amendment dated October 31, 2017, to Loan and Security Agreement, dated April 28, 2017, among Savara Inc., Aravas Inc. and Silicon Valley Bank. (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on November 8, 2017.)
10.4	#	Savara Inc. Amended and Restated 2015 Omnibus Incentive Plan, as amended (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on June 1, 2020.)
10.5	#	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.)
10.6	#	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.)
10.7	#	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.)
10.8	#	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.)
10.9	#	Form of Incentive Stock Option Grant Agreement – Exempt Employees, in accordance with Danish employment law, under the 2015 Omnibus Incentive Plan.
10.10	#	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.)
10.11	#	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.)
10.12	#	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.)
10.13	#	Executive Employment Agreement, dated March 9, 2017, between Aravas Inc. (formerly Savara Inc.) and David Lowrance (Incorporated by reference to Exhibit 10.58 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed on March 13, 2017.)
10.14	#	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.)

10.15	+	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.)
10.16	+	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.)
10.17		Sublease Agreement between Savara Inc. and Clubessential, LLC dated November 28, 2017 (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 4, 2017.)
10.18		Settlement Agreement between Savara Inc. and Serenova A/S dated September 1, 2017 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 8, 2017.)
10.19		Amendment No. 1 to Common Stock Sales Agreement, dated June 29, 2018, between Savara Inc. and H.C. Wainwright & Co., LLC. (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on June 29, 2018.)
10.20	+	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.)
10.21	#	Amendment to Executive Employment Agreement, dated as of August 3, 2018, by and among Savara Inc. and Dave Lowrance (Incorporated by reference to Exhibit 10.5 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2018.)
10.22		Second Amendment, dated December 4, 2018, to Loan and Security Agreement, dated April 28, 2017, as amended on October 31, 2017, among Savara Inc., Aravas Inc. and Silicon Valley Bank. (Incorporated by reference to Exhibit 10.31 to the Registrant's Annual Report on Form 10-K filed on March 13, 2019.)
10.23		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.)
10.24		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.)
10.25	+	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.)
10.26	+	Master Manufacturing Services Agreement, dated June 26, 2019, between Savara ApS and Patheon UK Limited. (Incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2019.)
10.27		Restricted Stock Unit Agreement (Inducement Grant) between Badrul Chowdhury and Savara Inc. dated November 26, 2019 (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-8 filed on April 17, 2020.)
10.28		Non-statutory Stock Option Agreement (Inducement Award) between Badrul Chowdhury and Savara Inc. dated November 26, 2019 (Incorporated by reference to Exhibit 10.37 to the Registrant's Annual Report on Form 10-K filed on March 12, 2020.)
10.29		Third Amendment, dated January 31, 2020, to Loan and Security Agreement, dated April 28, 2017, as amended on October 31, 2017 and December 4, 2018, among the Registrant, Aravas Inc. and Silicon Valley Bank (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on February 3, 2020.)
10.30		Executive Employment Agreement, dated September 6, 2019, between Savara Inc. and Badrul Chowdhury, Chief Medical Officer (Incorporated by reference to Exhibit 10.39 to the Registrant's Annual Report on Form 10-K filed on March 12, 2020.)
10.31	+	License and Collaboration Agreement between Savara Inc. and Grifols, S.A, dated January 7, 2020, as amended by Amendment No. 1, dated February 18, 2020, and Amendment No. 2, dated March 31, 2020 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 7, 2020.)
10.32		Amended and Restated Executive Employment Agreement, dated December 8, 2020, 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 10, 2020.)

21.1		List of Subsidiaries (Incorporated by reference to Exhibit 21.1 of the Registrant's Annual Report on 10-K filed on March 14, 2018.)
23.1		Consent of RSM US LLP, Independent Registered Public Accounting Firm
24.1		Power of Attorney included on page 63 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
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 Document
101.CAL		Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF		Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB		Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE		Inline XBRL Taxonomy Extension Presentation Linkbase Document
104		Cover Page Interactive Data File (embedded within the Inline XBRL document)

\# Indicates management contract or compensatory plan

\+ Indicates confidential treatment has been granted to certain portions of this exhibit, which portions have been omitted and filed separately with the SEC.

** 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 10, 2021

By: /s/ Matthew Pauls
Mathew Pauls
Chief Executive Officer

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 Chairman (Principal Executive Officer)	March 10, 2021
/s/ Dave Lowrance Dave Lowrance	Chief Financial Officer (Principal Financial and Accounting Officer)	March 10, 2021
/s/ David Ramsay David Ramsay	Director	March 10, 2021
/s/ Joseph McCracken Joseph McCracken	Director	March 10, 2021
/s/ Nevan Elam Nevan Elam	Director	March 10, 2021
/s/ Rick Hawkins Rick Hawkins	Director	March 10, 2021
/s/ An Van Es-Johansson An Van Es-Johansson	Director	March 10, 2021
/s/ Ricky Sun Ricky Sun	Director	March 10, 2021

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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 (collectively, the Company) as of December 31, 2020 and 2019, 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, 2020 and 2019, 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 Matters
The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Accrued 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, and 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 careful analysis with external parties to determine period expenses and potential contractual milestone expenses based on the progress made against benchmarks including, but not limited to, patients enrolled, services performed and equipment purchased.

During 2020, the Company incurred $35.0 million of research and development expenses. The Company recorded an accrued liability of $2.6 million for expenses incurred, but not yet invoiced, and a prepaid expense of $0.6 million for payments made to vendors in excess of costs incurred.

Given the significant judgments and estimates in accounting for accrued research and development costs, we have determined this area, specifically cutoff, a critical audit matter.

Our audit procedures related to the Company's accrued research and development costs included the following among others:

- We obtained an understanding, and evaluated the design and implementation, of controls relating to accrued or prepaid research and development costs, including controls over the review of contracts, and the accumulation of information from external service providers on actual costs incurred.

- We evaluated, on a sample basis, the reasonableness of management’s methods and assumptions used in developing the accrued or prepaid research and development costs by:
  - Agreeing key milestones and completion terms, activities, timing and costs per management-provided schedules to signed and executed CMO and CRO contracts
  - Obtaining evidence from third parties of the research and development activities performed for significant clinical trials and contract manufacturing services
  - Inquiring of financial and clinical personnel on the status of the clinical trials, progress to completion of clinical trials, method of allocating contractual charges to specific tasks performed during the clinical trials and the status of change orders
  - Retrospective review of quarterly analysis to assess the historical accuracy of management’s analysis

/s/ RSM US LLP

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

Austin, Texas
March 10, 2021

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

	As of December 31, 2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 22,880	$ 49,804
Short-term investments	59,308	71,957
Prepaid expenses and other current assets	2,933	2,306
Total current assets	85,121	124,067
Property and equipment, net	156	352
In-process R&D	12,218	11,111
Other non-current assets	250	673
Total assets	$ 97,745	$ 136,203
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,595	$ 3,409
Accrued expenses and other current liabilities	5,579	5,471
Debt facility	—	2,000
Total current liabilities	8,174	10,880
Long-term liabilities:		
Debt facility	25,104	23,112
Other long-term liabilities	84	513
Total liabilities	33,362	34,505
Stockholders' equity:		
Common stock, $0.001 par value, 200,000,000 shares authorized as of December 31, 2020 and 2019; 54,152,955 and 50,790,441 shares issued and outstanding as of December 31, 2020 and 2019, respectively	55	52
Additional paid-in capital	320,893	309,555
Accumulated other comprehensive income (loss)	942	(17)
Accumulated deficit	(257,507)	(207,892)
Total stockholders' equity	64,383	101,698
Total liabilities and stockholders' equity	$ 97,745	$ 136,203

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,	
	2020	**2019**
Milestone revenue	$ 257	$ —
Operating expenses:		
Research and development	35,038	38,781
General and administrative	14,264	13,081
Impairment of goodwill	—	26,852
Depreciation and amortization	255	311
Total operating expenses	49,557	79,025
Loss from operations	(49,300)	(79,025)
Other income (expense), net:		
Interest expense, net	(1,482)	(70)
Foreign currency exchange gain (loss)	158	(78)
Tax credit income	893	1,213
Change in fair value of financial instruments	116	(213)
Total other income (expense), net	(315)	852
Net loss	$ (49,615)	$ (78,173)
Net loss per share:		
Basic and diluted	$ (0.84)	$ (1.95)
Weighted average common shares outstanding:		
Basic and diluted	59,309,090	40,027,758
Other comprehensive income (loss):		
Gain (loss) on foreign currency translation	1,006	(296)
Unrealized gain (loss) on short-term investments	(47)	79
Total comprehensive loss	$ (48,656)	$ (78,390)

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, 2020 and 2019
(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, 2018	**35,146,096**	**$ 36**	**$ 237,702**	**$ (129,719)**	**$ 200**	**$ 108,219**
Issuance of securities in private placement, net closing costs	9,569,430	10	25,237	—	—	25,247
Issuance of common stock upon at the market offerings, net	4,769,726	5	29,587	—	—	29,592
Issuance of common stock upon settlement of contingent liability	1,105,216	1	12,477	—	—	12,478
Issuance of common stock for settlement of RSUs	52,125	—	—	—	—	—
Net issuance of common stock upon cashless exercise of warrants	11,119	—	—	—	—	—
Issuance of common stock upon exercise of stock options	136,729	—	111	—	—	111
Stock-based compensation	—	—	4,441	—	—	4,441
Foreign exchange translation adjustment	—	—	—	—	(296)	(296)
Unrealized gain on short-term investments	—	—	—	—	79	79
Net loss	—	—	—	(78,173)	—	(78,173)
Balance on December 31, 2019	**50,790,441**	**$ 52**	**$ 309,555**	**$ (207,892)**	**$ (17)**	**$ 101,698**
Issuance of common stock for licensing of assets	1,000,000	1	2,119	—	—	2,120
Issuance of common stock upon at the market offerings, net	942,825	1	2,289	—	—	2,290
Issuance of common stock upon exercise of Milestone Warrants, net	1,303,088	1	1,826	—	—	1,827
Issuance of common stock for settlement of RSUs	49,125	—	—	—	—	—
Issuance of common stock upon exercise of stock options	67,476	—	88	—	—	88
Closing costs for previous issuance of securities in private placement	—	—	(120)	—	—	(120)
Incremental cost due to modification of detachable warrants previously issued with debt instrument	—	—	29	—	—	29
Stock-based compensation	—	—	5,107	—	—	5,107
Foreign exchange translation adjustment	—	—	—	—	1,006	1,006
Unrealized loss on short-term investments	—	—	—	—	(47)	(47)
Net loss	—	—	—	(49,615)	—	(49,615)
Balance on December 31, 2020	**54,152,955**	**$ 55**	**$ 320,893**	**$ (257,507)**	**$ 942**	**$ 64,383**

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, 2020	2019
Cash flows from operating activities:		
Net loss	$ (49,615)	$ (78,173)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	255	311
Amortization of right-of-use assets	438	699
Impairment of goodwill	—	26,852
Acquired in-process research and development (Note 8)	5,367	—
Change in fair value of financial instruments	(116)	213
Change in fair value of contingent consideration	—	264
Noncash interest (income) expense	29	(72)
Foreign currency (gain) loss	(158)	78
Amortization of debt issuance costs	507	582
Accretion on discount to short-term investments	55	(1,161)
Gain on short-term investments	—	(4)
Stock-based compensation	5,107	4,441
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(134)	148
Non-current assets	—	131
Accounts payable and accrued expenses and other current liabilities	(1,140)	568
Long-term liabilities	(431)	—
Net cash used in operating activities	$ (39,836)	$ (45,123)
Cash flows from investing activities:		
Purchase of property and equipment	$ (47)	$ (148)
Purchase of in-process research and development (Note 8)	(3,247)	—
Purchase of available-for-sale securities, net	(86,083)	(122,945)
Maturities of available-for-sale securities	89,650	124,700
Sales of available-for-sale securities, net	8,780	14,133
Net cash provided by investing activities	$ 9,053	$ 15,740
Cash flows from financing activities:		
Repayment of debt facility	$ (514)	$ —
Issuance of common stock upon exercise of warrants	1,827	—
Issuance of securities in private financing, net	—	25,247
Issuance of common stock upon at the market offerings, net	2,290	29,592
Proceeds from exercise of stock options	86	110
Capital lease obligation principal payments	—	(41)
Net cash provided by financing activities	$ 3,689	$ 54,908
Effect of exchange rate changes on cash and cash equivalents	170	(22)
Increase (decrease) in cash and cash equivalents	$ (26,924)	$ 25,503
Cash and cash equivalents beginning of period	49,804	24,301
Cash and cash equivalents end of period	$ 22,880	$ 49,804
Non-cash transactions:		
Common stock issued for acquired in-process research and development, net	$ 2,120	$ —
Settlement of contingent consideration	—	12,478
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 2,470	$ 2,099

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," "our," or "us") is an orphan lung disease company. The Company's lead program, molgramostim, is an inhaled granulocyte-macrophage colony-stimulating factor ("GM-CSF") in Phase 3 development for autoimmune pulmonary alveolar proteinosis ("aPAP"). Prior to December 31, 2020, the Company's pipeline also included vancomycin hydrochloride inhalation powder ("vancomycin") for persistent methicillin-resistant *Staphylococcus aureus* ("MRSA") lung infection in people living with cystic fibrosis ("CF") and Apulmiq inhaled ciprofloxacin for non-CF bronchiectasis. The Company and its wholly-owned subsidiaries operate in one segment with its principal offices in Austin, Texas, USA.

Since inception, Savara has devoted substantially all of 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"). Certain prior year amounts have been reclassified for consistency with the current period presentation.

2. Summary of Significant Accounting Policies

Liquidity

As of December 31, 2020, the Company had an accumulated deficit of approximately $257.5 million. The Company used cash from operations of approximately $39.8 million for the year ended December 31, 2020. 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. Accordingly, the Company will need additional capital to further fund the development of, and seek regulatory approvals for, its product candidates and begin to commercialize any approved products.

Currently, the Company is primarily focused on the development of respiratory drugs and believes such activities will result in the Company's continued incurrence of significant research and development and other expenses related to those programs. If the clinical trials for any of the Company's product candidates fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if any of the Company's product candidates, if approved, fail 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 and through a combination of equity offerings, debt financings, government or other third-party funding, and other collaborations and strategic alliances. 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 $22.9 million and short-term investments of $59.3 million as of December 31, 2020, which is sufficient to fund the Company's operations for the twelve months subsequent to the issuance date of its consolidated financial statements for the year ended December 31, 2020. We intend to continue to raise additional capital as needed through the issuance of additional equity and potentially through borrowings, and strategic alliances with partner companies. However, if such financings are not available timely and at adequate levels, the Company will need to re-evaluate its long-term operating plans. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 income (loss)." All intercompany transactions and accounts have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make certain estimates and assumptions that affect the amounts reported in the 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 candidates being developed by the Company require 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 candidates will receive the necessary approvals. If the Company is denied regulatory approval of its product candidates, 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 income (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. Investments in debt securities are considered to be impaired when a decline in fair value is judged to be other than temporary because the Company either intends to sell or it is more-likely-than not that it will have to sell the impaired security before recovery. Once a decline in fair value is determined to be other than temporary, an impairment charge is recorded and a new cost basis in the investment is established.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents and short-term investments held in money market accounts. The Company places its cash and cash equivalents and money market accounts with a limited number of financial institutions and at times may exceed the amount of insurance provided on such deposits.

Accrued 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.

Business Combinations

Assets acquired and liabilities assumed as part of a business acquisition are recorded at their estimated fair value at the date of acquisition. The excess of purchase price over the fair value of assets acquired and liabilities assumed is recorded as goodwill. Determining fair value of identifiable assets, particularly intangibles, and liabilities acquired also requires management to make estimates, which are based on all available information and, in some cases, assumptions with respect to the timing and amount of future revenue and expenses associated with an asset.

License and Collaboration Agreements

The Company entered into a license and collaboration agreement 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 is generally 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.

Goodwill and Acquired In-Process Research and Development

Although the Company does not have any goodwill as of December 31, 2020, it has adopted the following accounting policy. Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill is not amortized but assessed for impairment on an annual basis or more frequently if impairment indicators exist. Current guidance issued by the FASB, as previously adopted by the Company, provides an impairment model whereby the Company has the option to implement a one-step method for determining impairment of goodwill, simplifying the subsequent measurement of goodwill by eliminating Step 2 (quantitative calculation of measuring a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill) from the goodwill impairment test. Under the amendments in this guidance, an entity should perform its annual goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable.

Acquired in-process research and development ("IPR&D") is considered an indefinite-lived intangible asset and is assessed for impairment annually or more frequently if impairment indicators exist. For instance, based upon the ultimate scope and scale of the COVID-19 global pandemic, there may be materially negative impacts to the assumptions made with respect to our IPR&D assets that could result in an impairment of such assets. For the year ended December 31, 2020, the impact of COVID-19 did not trigger any impairment indicators.

The Company adopted accounting guidance related to its annual acquired IPR&D impairment test, a two-step method, which allows the Company to first assess qualitative factors before performing a quantitative assessment of the fair value of a reporting unit. If it is determined on the basis of qualitative factors that the fair value of the IPR&D is more likely than not less than the carrying amount, a quantitative impairment test is required.

If the associated research and development effort is abandoned, the related asset will be written-off, and the Company will record a noncash 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.

The Company performs its annual goodwill impairment test and IPR&D impairment test, as described above, as of June 30th and September 30th, respectively, or whenever an event or change in circumstances occur that would require reassessment of the recoverability of those assets.

For the year ended December 31, 2019, the Company experienced a decrease of approximately $0.3 million in the carrying value of IPR&D, which was due to foreign currency translation. In June 2019, the Company determined that the results from its Phase 3 trial for the use of molgramostim for the treatment of aPAP required an assessment for impairment of both its IPR&D and goodwill. Upon completion of the aforementioned qualitative and quantitative impairment testing of its IPR&D and quantitative impairment testing of its goodwill, the Company concluded that there was no impairment to its IPR&D; however, goodwill was impaired, resulting in an impairment of $7.4 million in the carrying value of goodwill. The Company also determined that a triggering event had occurred during the fourth quarter of 2019 under which the Company's stock price experienced another significant decline requiring the

impairment testing of its goodwill which resulted in an impairment charge of $19.4 million in the fourth quarter of 2019, reducing the Company's carrying value of its goodwill to its fair value, which was determined to be zero. Similarly, the Company completed the aforementioned qualitative and quantitative impairment testing of its IPR&D following this fourth quarter 2019 triggering event and concluded that there was no impairment to its IPR&D. The Company also considered whether a triggering event had occurred during the fourth quarter of 2020 under which the Company's market cap was below carrying value. The Company completed a qualitative and quantitative impairment testing of its IPR&D and concluded that there was no impairment. For the year ended December 31, 2020, the Company experienced an increase of approximately $1.1 million in the carrying value of IPR&D, which was due to foreign currency translation.

Tax Credit Receivable

The Company has recorded a Danish tax credit earned by its subsidiary, Savara ApS, as of December 31, 2020. 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, 2019, the Company generated a Danish tax credit of $0.8 million which was received in the third quarter of 2020. During the year ended December 31, 2020, the Company generated a Danish tax credit of $0.9 million which is recorded in "Prepaid expenses and other current assets" and is expected to be received in the fourth quarter of 2021.

The Company also recorded an Australian tax credit as provided by the Australian Taxation Office for qualified research and development expenditures incurred through our subsidiary, Savara Australia Pty. Limited. Under Australian tax law, Australia remits a research and development tax credit equal to 43.5% of qualified research and development expenditures, not to exceed established thresholds. During the year ended December 31, 2019, the Company generated an Australian tax credit of $0.4 million which was received during the third quarter of 2020. During the year ended December 31, 2020, the Company generated an Australian tax credit of $0.1 million which is recorded in "Prepaid expenses and other current assets" and is expected to be received during the year ended December 31, 2021.

Leases

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, "Leases (Topic 842)" ("ASU 2016-02") as codified in Accounting Standards Codification ("ASC") No. 842 ("ASC 842"). ASU 2016-02, ASC 842, and additional issued guidance are intended to improve financial reporting of leasing transactions by requiring organizations that lease assets to recognize assets and liabilities for the rights and obligations created by leases that extend more than twelve months. This accounting update also requires additional disclosures surrounding the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for financial statements issued for annual and interim periods beginning after December 15, 2018 for public business entities. The Company adopted ASU 2016-02 as of January 1, 2019 using the effective date transition method of implementation offered under ASU 2018-11, "Leases (Topic 842) – Targeted Improvements" issued in July 2018 ("ASU 2018-11"), under which entities may change their date of initial application of ASU 2016-02 to the beginning of the period of adoption, or January 1, 2019, in the case of Savara. Accordingly, the Company is required to apply the prior lease guidance pursuant to ASC Topic 840 "Leases" in the comparative periods, provide the disclosures required by ASC Topic 840 for all periods that continue to be presented in accordance with ASC Topic 840, recognize the effects of applying ASC 842 as a cumulative-effect adjustment to retained earnings as of January 1, 2019, if any, and provide certain disclosures under ASC 842 (see Note 12). The Company has also elected the package of practical expedients, applied by class of underlying asset, permitted in ASU 2018-11. Accordingly, the Company accounted for its existing operating leases as operating leases under the new guidance, without reassessing (a) whether the contracts contain a lease under ASC 842, (b) whether classification of the operating leases would be different in accordance with ASC 842, and (c) whether the unamortized initial direct costs before transition adjustments (as of the period of adoption) would have met the definition of initial direct costs in ASC 842 at lease commencement, and the Company did not separate lease and non-lease components.

As a result of the adoption of the new lease accounting guidance using the effective date transition method, on January 1, 2019, the Company recognized (a) a lease liability of approximately $1.4 million, which represents the present value of the remaining lease payments, as of the date of adoption, of approximately $1.5 million, discounted using the Company's incremental borrowing rate of 8.5%, and (b) a right-of-use asset of approximately $1.4 million. The adoption of the new standard did not result in any adjustment to the Company's retained earnings as of January 1, 2019. The adoption of this standard did not have a material impact on the Company's consolidated balance sheets, cash used/provided from operating, investing, or financing activities in the consolidated statements of cash flows, or on the Company's operating results. The most significant impact was the recognition of right-of-use assets for operating leases, which are reflected in "Other non-current assets," and lease liabilities for operating leases, which are reflected in "Accrued expenses and other current liabilities," for the current portion of the lease liabilities, and in "Other long-term liabilities" for the non-current portion of the lease liabilities, respectively (See Note 12).

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. Our chief operating decision maker is the chief executive officer. We have one operating segment, specialty pharmaceuticals within the respiratory system.

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.

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.

Financial instruments carried at fair value include cash and cash equivalents, short-term investments, and foreign exchange derivatives not designated as hedging instruments.

Financial instruments not carried at fair value include accounts payable and accrued liabilities. The carrying amounts of these financial instruments approximate fair value due to the highly liquid nature of these short-term instruments.

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 does not expect will occur in the next two to three years, if ever, will depend heavily on the successful development, regulatory approval, and eventual commercialization of the Company's product candidates.

Milestone Revenue

The Company entered into a license agreement related to its molgramostim product candidate, which includes certain milestone payments to be remunerated by the licensee to Savara. In exchange, the Company granted the licensee an exclusive right to import, market, sell, distribute and promote molgramostim in Japan for the treatment of aPAP. Pursuant to the license agreement, the Company identifies the performance obligations, determines the transaction price, allocates the contract transaction price to the performance obligations, and recognizes the revenue when (or as) the performance obligation is satisfied. The Company identifies the performance obligations included within the license agreement and evaluates which performance obligations are distinct.

The milestone payments are a form of variable consideration as the payments are contingent upon achievement of a substantive event. The milestone payments are estimated and included in the transaction price when the Company determines, under the variable consideration constraint, that it is probable that there will not be a significant reversal of cumulative revenue recognized in future periods. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price.

In October 2018, the Company achieved a milestone payment pursuant to this license agreement resulting in the receipt of $0.2 million from the licensee which was recorded as deferred revenue in “Accrued expenses and other current liabilities” in the Company’s condensed consolidated balance. On February 21, 2020, the Company received notification from the licensee of its intent to terminate this license agreement. Accordingly, this license agreement terminated on August 21, 2020, upon which the Company recognized revenue related to this $0.3 million milestone payment, increased from $0.2 million due to changes in foreign currency exchange rates, as the Company has determined that all of the performance obligations under this license agreement have been met.

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.

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 (see Note 14). 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.”

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.

Manufacturing and Other Commitments and Contingencies

The Company is subject to various royalties and manufacturing and development payments related to its product candidate, molgramostim. Under a manufacture and supply agreement with the active pharmaceutical ingredients (“API”) manufacturer for molgramostim, Savara must make certain payments to the API manufacturer upon achievement of the milestones outlined in the table set forth below. Additionally, upon first receipt of marketing approval by Savara from a regulatory authority in a country for a product containing the API 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, Savara shall pay the API manufacturer a royalty equal to low-single digits of the net sales in that country.

The Company is also subject to certain contingent milestone payments, disclosed in the following table, payable to the manufacturer of the nebulizer used to administer molgramostim. The change in the amount of the milestone payments from December 31, 2019 to December 31, 2020 was related to changes in foreign currency exchange rate, the accrual of a milestone equal to approximately $0.2 million due to the completion of our Phase 2a trial of the use of molgramostim for the treatment of nontuberculous mycobacterial (“NTM”) in patients not affected by cystic fibrosis, and the elimination of approximately $1.9 million in milestone payments related to the treatment of NTM as the Company is not planning to conduct further development activities related to molgramostim in NTM and instead plans to focus its development efforts of molgramostim on its lead indication, aPAP. In addition, milestone payments totaling $5.2 million reflected in the following table relate to types of nebulizer delivery systems that are not currently being utilized in any of the studies in our development pipeline. In addition to these milestones, the Company will owe a royalty to the manufacturer of the nebulizer based on net sales. The royalty rate ranges from three-and one-half percent (3.5%) to five percent (5%) depending on the device technology used by the Company to administer the product.

Manufacturing, Development, and Other Contingent Milestone Payments (in thousands):

	December 31, 2020
Molgramostim manufacturer:	
Achievement of certain milestones related to validation of API and regulatory approval of molgramostim	$ 2,300
Molgramostim nebulizer manufacturer:	
Achievement of various development activities and regulatory approval of nebulizer utilized to administer molgramostim	6,132
Total manufacturing and other commitments	**$ 8,432**

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, 2020.

Recent Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement (Topic 820): Disclosure Framework- Changes to the Disclosure Requirements for Fair Value Measurement.” The update eliminates, adds, and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. ASU 2018-13 was adopted on January 1, 2020 and did not have a material impact on our consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, “Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606.” The update clarifies that certain transactions between collaborative partners should be accounted for as revenue under the new revenue standard ASC 606 when the collaborative partner is a customer, specifies the unit of account for determining whether a transaction with a customer is a distinct good or service under ASC 606, and precludes a company from presenting transactions with a collaborative partner that are not in the scope of ASC 606 together with revenue from contracts with customers. ASU 2018-18 was adopted on January 1, 2020 and did not impact on our consolidated financial statements.

In March 2019, the FASB issued ASU 2019-01, “Leases (Topic 842): Codification Improvements,” which aims to clarify and revise guidance for certain lessors and clarify interim transition disclosure requirements for ASC 842. ASU 2019-01 was effective on January 1, 2020 and the adoption did not have a material impact on our consolidated financial statements.

In April 2019, the FASB issued ASU 2019-04, “Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments.” The Company has reviewed ASU 2019-01 and concluded that it has no impact on our consolidated financial statements.

In November 2019, the FASB issued ASU 2019-08, “Compensation—Stock Compensation (Topic 718) and Revenue from Contracts with Customers (Topic 606): Codification Improvements—Share-Based Consideration Payable to a Customer” which requires that an entity measure and classify share-based payment awards granted to a customer by applying the guidance in Topic 718 whereby the amount recorded as a reduction of the transaction price is required to be measured on the basis of the grant-date fair value of the share-based payment award in accordance with Topic 718. ASU 2019-08 was effective on January 1, 2020, and the adoption did not impact our consolidated financial statements.

In November 2019, the FASB issued ASU 2019-11, “Codification Improvements to Topic 326, Financial Instruments—Credit Losses” as a separate update for improvements to the amendments in ASU 2016-13 to increase stakeholder awareness of those amendments and to expedite the improvement process. ASU 2019-11 is effective on January 1, 2023. The Company has reviewed ASU 2019-11 and concluded that it does not have a material impact on our consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, “Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes” which aims to simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. ASU 2019-12 is effective for us on January 1, 2021. The Company has reviewed ASU 2019-12 and concluded that it does not have a material impact on our consolidated financial statements.

In January 2020, the FASB issued ASU 2020-01, “Investments—Equity Securities (Topic 321), Investments—Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)—Clarifying the Interactions between Topic 321, Topic 323, and Topic 815 (a consensus of the Emerging Issues Task Force)” which affect all entities that apply the guidance in Topics 321, 323, and 815 and (1) elect to apply the measurement alternative or (2) enter into a forward contract or purchase an option to purchase securities that, upon settlement of the forward contract or exercise of the purchased option, would be accounted for under the equity method of accounting. ASU 2020-01 is effective on January 1, 2021. The Company has reviewed ASU 2020-01 and concluded that it does not have a material impact on our consolidated financial statements.

3. Prepaid Expenses and Other Current Assets

Prepaid expenses, consisted of (in thousands):

	December 31, 2020	2019
R&D tax credit receivable	$ 1,042	$ 1,253
Prepaid contracted research and development costs	591	184
VAT receivable	653	364
Prepaid insurance	453	247
Foreign currency exchange derivative	—	7
Deposits and other	194	251
Total prepaid expenses and other current assets	**$ 2,933**	**$ 2,306**

4. Accrued Expenses and Other Current Liabilities

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

	December 31, 2020	2019
Accrued contracted research and development costs	$ 2,627	$ 2,018
Accrued general and administrative costs	853	1,710
Accrued compensation	1,920	1,303
Lease liability	179	440
Total accrued expenses and other current liabilities	**$ 5,579**	**$ 5,471**

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, 2020	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments				
U.S. government securities	$ 13,296	$ 1	$ —	$ 13,297
Asset backed securities	2,559	—	—	2,559
Corporate securities	19,479	3	(3)	19,479
Commercial paper	23,973	—	—	23,973
Total short-term investments	**$ 59,307**	**$ 4**	**$ (3)**	**$ 59,308**

As of December 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments				
U.S. government securities	$ 15,629	$ 11	$ (2)	$ 15,638
Asset backed securities	8,789	10	—	8,799
Corporate securities	30,556	30	(1)	30,585
Commercial paper	16,935	—	—	16,935
Total short-term investments	**$ 71,909**	**$ 51**	**$ (3)**	**$ 71,957**

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 income (loss)" in the consolidated balance sheets. 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.

There were no significant realized gains or losses related to investments for the years ended December 31, 2020 and 2019.

6. Property and Equipment, Net

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

	December 31, 2020	2019
Research and development equipment	$ 1,102	$ 1,102
Equipment	760	676
Furniture and fixtures	122	105
Leasehold improvements	145	143
Total property and equipment	2,129	2,026
Less accumulated depreciation	(1,973)	(1,674)
Property and equipment, net	**$ 156**	**$ 352**

Depreciation expense for the years ended December 31, 2020 and 2019 was $0.3 million and $0.3 million, respectively.

7. Debt Facility

On April 28, 2017, the Company entered into a loan and security agreement with Silicon Valley Bank, as amended on October 31, 2017 and December 4, 2018 (the “Loan Agreement”). The Company executed a third amendment (the “Third Amendment”) to the Loan Agreement on January 31, 2020, which provides for a $25 million term debt facility. The Third Amendment extends the interest-only period of the loan repayment through June 30, 2022, with payments thereafter in equal monthly installments of principal plus interest over 18 months. However, if by March 31, 2021, the Company does not have an ongoing Phase 3 or Phase 4 clinical trial evaluating its molgramostim product for the treatment of aPAP in which the first patient has been dosed, the interest-only period will cease and principal plus interest will be due in equal monthly installments over 24 months beginning on April 1, 2021. In February 2021, Silicon Valley Bank extended the requirement for the date of the first patient dosed in our Phase 3 IMPALA 2 trial to the end of the second quarter of 2021.

Following the effective date of the Third Amendment, the Company was required to pay a portion of the end of period charge equal to $0.5 million under the Loan Agreement to Silicon Valley Bank. The loan bears interest at the greater of (i) the prime rate reported in The Wall Street Journal, plus a spread of 3.0% or (ii) 7.75%. The Loan Agreement, as amended by the Third Amendment (the “Amended Loan Agreement”), will also require a prepayment fee (2.0% of funded amounts in months 13-24, and 1.0% thereafter), and an end of term charge equal to 6.0% of the amount of principal borrowed. The end of term charge is being accreted through interest expense using the effective interest method through the scheduled maturity date.

Silicon Valley Bank has been granted a perfected first priority lien in all of our assets with a negative pledge on our intellectual property. The Amended Loan Agreement contains customary affirmative and negative covenants, including among others, covenants limiting our ability and our subsidiaries’ ability to dispose of assets, permit a change in control, merge or consolidate, make acquisitions, incur indebtedness, grant liens, make investments, make certain restricted payments and enter into transactions with affiliates, in each case subject to certain exceptions. In addition, the Amended Loan Agreement contains an affirmative covenant requiring Savara to deliver evidence by June 30, 2021, of the receipt of gross cash proceeds of at least $25 million from the exercise of currently outstanding warrants or the issuance of other equity securities.

Pursuant to the execution and funding of the Loan Agreement and subsequent amendments, the Company issued Silicon Valley Bank and its affiliate warrants to purchase (i) 24,725 shares of the Company’s common stock at an exercise price of $9.10 per share, with a ten-year life, expiring April 28, 2027 (“April 2017 Warrants”); (ii) 41,736 shares of the Company’s common stock at an exercise price of $5.39 per share with a ten-year life, expiring June 15, 2027 (“June 2017 Warrants”); and (iii) 11,332 shares of the Company’s common stock at an exercise price of $8.824 per share, with a ten-year life, expiring December 4, 2028 (“December 2018 Warrants”). The warrants were valued using the Black-Scholes option pricing model at the respective issue date, and the collective fair value of the warrants has been recorded as a debt discount which is being amortized through interest expense using the effective interest method through the scheduled maturity date.

In connection with the execution of the Third Amendment, the Company entered into amendments to each of the outstanding warrants previously issued to Silicon Valley Bank and its affiliate, totaling 77,793 shares, to amend the exercise price to be $2.87 per share. That amendment results in a minimal incremental increase to the fair value of these warrants, determined in accordance with the Black-Scholes option pricing model and ASC 718-20-55, which has been recognized as interest expense.

The Company paid minimal legal costs directly attributable to the original issuance of the debt instrument underlying the Loan Agreement and subsequent amendments. Such charges were accounted for as debt issuance costs and are being amortized to interest expense using the effective interest method through the scheduled maturity date.

The carrying value and future minimum payments under the debt facility are as follows (in thousands):

Year ending December 31,	
2021	$ —
2022	8,333
2023	18,167
Total future minimum payments	26,500
Unamortized end of term charge	(1,134)
Debt issuance costs	(149)
Debt discount related to warrants	(113)
Total debt	25,104
Short-term portion	—
Long-term debt facility	$ 25,104

The carrying value of the debt approximates its fair value.

8. License Agreement

Effective March 31, 2020, the Company entered into a license and collaboration agreement (“License”) that provides Savara an exclusive, worldwide, royalty-bearing license to develop and sell or otherwise commercialize pharmaceutical preparations containing a type of inhaled ciprofloxacin (“Licensed Products”).

The Company paid the licensor (i) an upfront cash payment of approximately $3.2 million and (ii) an upfront payment of one million shares of the Company’s common stock valued at approximately $2.1 million on the date of issuance upon effectiveness of the License (collectively the “Upfront Payments”). The Company also agreed to pay the licensor (i) certain developmental milestone payments for the development of the Licensed Products upon regulatory approval for commercial sale and (ii) certain sales milestone payments upon the first achievement of defined annual global net sales (collectively, the “Contingent Consideration”). Additionally, the Company agreed to pay licensor low double-digit tiered royalties based on annual global net sales of all Licensed Products.

The Company has accounted for the License as an asset acquisition in accordance with ASU 2017-01 “Business Combinations (Topic 805) - Clarifying the Definition of a Business” and ASC 805 “Business Combinations.” Since the Licensed Product has not yet achieved regulatory approval and there is deemed to be no alternative future use, the Company has recorded research and development expense of approximately $5.4 million for the Upfront Payments.

The Company has formally announced the termination of any further development of the Licensed Product and, as such, determined that the Contingent Consideration is neither probable nor can the amount be reasonably estimated. Therefore, no related liability has been recorded.

9. 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 basis to determine the appropriate level in which to classify them in each reporting period.

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.

Foreign exchange derivatives not designated as hedging instruments are considered Level 2 financial instruments. The Company’s foreign exchange derivative instruments are typically short-term in nature.

The fair value of these instruments as of December 31, 2020 and 2019 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)
As of December 31, 2020			
Cash equivalents:			
U.S. Treasury money market funds	$ 21,872	$ —	$ —
Short-term investments:			
U.S. government securities	$ 13,297	$ —	$ —
Asset backed securities	—	2,559	—
Corporate securities	—	19,479	—
Commercial paper	—	23,973	—
As of December 31, 2019			
Cash equivalents:			
U.S. Treasury money market funds	$ 13,530	$ —	$ —
Repurchase agreements	—	6,000	—
Short-term investments:			
U.S. government securities	$ 15,638	$ —	$ —
Asset backed securities	—	8,799	—
Corporate securities	—	30,585	—
Commercial paper	—	16,935	—
Other assets:			
Foreign exchange derivatives not designated as hedging instruments	$ —	$ 7	$ —

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instrument, contingent liability that was fully settled during the year ended December 31, 2019 (in thousands):

	Contingent Consideration
Balance at December 31, 2018	**$ 12,214**
Change in fair value	219
Settlement of contingent liability	(12,433)
Balance at December 31, 2019	**$ —**

Prior to its settlement during the year ended December 31, 2019, the Company recorded changes in fair value of the contingent consideration in general and administrative expense.

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, 2020 and 2019.

10. Derivative Financial Instruments

In the normal course of business, the Company is exposed to the impact of foreign currency fluctuations. The Company seeks to limit these risks by following risk management policies and procedures, including the use of derivatives. The Company's derivative contracts, which are not designated as hedging instruments, principally address short-term foreign currency exchange. The estimated fair value of the derivative contracts was based upon the relative exchange rate as of the balance sheet date. Accordingly, any gains or losses resulting from variances between this exchange rate at the contract inception date were recognized as "Other income (net)" in the consolidated statements of operations and comprehensive loss. As of December 31, 2020, there were no unsettled forward exchange contracts to purchase foreign currency nor a corresponding liability.

11. Stockholders' Equity

Private Placement

On December 24, 2019, the Company completed a private placement in a public entity (the "Private Placement" or "PIPE") under a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional and accredited investors (the "Investors"), pursuant to which we issued and sold to the Investors 9,569,430 shares of our common stock at a price of $1.745 per share and pre-funded warrants ("Pre-Funded PIPE Warrants") to purchase an aggregate of 5,780,537 shares of common stock at $1.744 per share (or $1.745 minus par value of $.001). The net proceeds after deducting placement fees and offering expenses were approximately $25.2 million. We also issued accompanying warrants (the "Milestone Warrants"), with an exercise price of $1.48 per share, to purchase an aggregate of up to 32,577,209 additional shares of common stock and may receive up to approximately $48.2 million from the exercise of the Milestone Warrants prior to their expiration, totaling potential aggregate gross proceeds of up to approximately $75.0 million from the PIPE before deducting placement agent fees and estimated offering expenses. The Milestone Warrants are exercisable at any time prior to the earlier of thirty days following the achievement of a defined clinical milestone or two years after the closing date of the Private Placement. The Pre-Funded PIPE Warrants are exercisable at any time after their original issuance and will not expire.

We intend to use the net proceeds from the Private Placement to fund a new clinical trial of molgramostim for the treatment of aPAP and for other general corporate purposes.

In connection with the Private Placement and the Purchase Agreement, the Company filed a Form S-3 on April 17, 2020 to register for resale the shares of common stock sold in the Private Placement and the shares of common stock underlying the Milestone Warrants and Pre-Funded PIPE Warrants described above.

The Company determined that the securities issued in the PIPE were free-standing and that the Pre-Funded PIPE Warrants and Milestone Warrants did not contain any settlement obligations that would result in liability classification under ASC 480 "Distinguishing Liability from Equity." Since the settlement of the Pre-Funded PIPE Warrants and Milestone Warrants were initially permitted in unregistered shares, indexed to the Company's stock, and satisfy the other criteria under ASC 815 "Derivatives and Hedging," the Pre-Funded PIPE Warrants and Milestone Warrants qualify for equity classification and were valued using the Black-Scholes option pricing model with the following assumptions: volatility of 90.39%, expected term of two years, risk-free interest rate of 1.63%, and a zero-dividend yield. The net proceeds from the Private Placement were allocated among the instruments based upon their relative fair values at December 24, 2019 resulting in carry values of the respective instruments as follows (in thousands):

Financial instruments:	**Relative Fair Value Allocation**
Common Stock and Pre-Funded PIPE Warrants	$ 11,713
Milestone Warrants	13,534
Total Net Proceeds from Private Placement	**$ 25,247**

Common Stock Sales Agreement

On April 28, 2017, the Company entered into a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC ("Wainwright"), as sales agent, which was amended by Amendment No. 1 to the Common Stock Agreement (the "Amendment") on June 29, 2018 (the "Sales Agreement"), pursuant to which the Company may offer and sell, from time to time, through Wainwright, shares of Savara's common stock, par value $0.001 per share (the "Shares"), having an aggregate offering price of not more than $60.0 million, in addition to the $2.3 million in shares sold prior to the Amendment. The Amendment was effective on July 13, 2018, the date the Company's shelf registration statement on Form S-3, as filed with the Securities and Exchange Commission on June 29, 2018, was declared effective ("New Registration Statement") by the Securities and Exchange Commission. The Shares will be offered and sold pursuant to the New Registration Statement. Subject to the terms and conditions of the Sales Agreement, Wainwright will use its commercially reasonable efforts to sell the Shares from time to time, based upon the Company's instructions. The Company has provided Wainwright with customary indemnification rights, and Wainwright will be entitled to a commission at a fixed commission rate equal to 3.0% of the gross proceeds per Share sold. Sales of the Shares, if any, under the Sales Agreement may be made in transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act of 1933, as amended. The Company has no obligation to sell any of the Shares and may at any time suspend sales under the Sales Agreement or terminate the Sales Agreement.

During the years ended December 31, 2020 and 2019, the Company sold 942,825 and 4,769,726 shares of common stock under the Sales Agreement for net proceeds of approximately $2.3 million and $29.6 million, respectively.

Common Stock

The Company's amended and restated certificate of incorporation, as amended in June 2018, authorizes the Company to issue 201 million shares of capital stock, consisting of 200 million shares of common stock with $0.001 par value per share and one million 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, 2020 and 2019:

	December 31	
	2020	2019
Common stock authorized	200,000,000	200,000,000
Common stock outstanding	54,152,955	50,790,441

The Company's shares of common stock reserved for issuance as of December 31, 2020 and 2019 were as follows:

	December 31,	
	2020	2019
Warrants acquired in merger	403,927	403,927
Warrants converted in connection with merger	72,869	72,869
April 2017 Warrants	24,725	24,725
June 2017 Warrants	41,736	41,736
December 2018 Warrants	11,332	11,332
2017 Pre-Funded Warrants	775,000	775,000
Pre-Funded PIPE Warrants	5,780,537	5,780,537
Milestone Warrants	31,274,121	32,577,209
Stock options outstanding	6,240,342	4,541,432
Issued and nonvested RSUs	509,397	315,625
Total shares reserved	**45,133,986**	**44,544,392**

Warrants

The following table summarizes the outstanding warrants for the Company's common stock as of December 31, 2020:

Shares Underlying Outstanding Warrants		Exercise Price	Expiration Date
403,927	$	29.40	February 2021
72,869	$	8.98	June 2021
775,000	$	0.01	October 2024
24,725	$	2.87	April 2027
41,736	$	2.87	June 2027
11,332	$	2.87	December 2028
5,780,537	$	0.001	None
31,274,121	$	1.48	December 2021 or 30 days after clinical milestone
38,384,247			

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):

(in thousands)	Foreign Exchange Translation Adjustment	Unrealized Gain (Loss) on ST Investments	Total Accumulated Other Comprehensive Income (Loss)
December 31, 2018	**$ 231**	**$ (31)**	**$ 200**
Change	(296)	79	(217)
Balance, December 31, 2019	**(65)**	**48**	**(17)**
Change	1,006	(47)	959
Balance, December 31, 2020	**$ 941**	**$ 1**	**$ 942**

12. Commitments

Operating Leases

We are obligated under operating leases and subleases for office space. On November 29, 2017, we entered into a sublease agreement for office space for our corporate headquarters in Austin, Texas. The term of the sublease commenced on January 1, 2018 and will continue until July 31, 2021, with annual rental payments of approximately $0.2 million, paid over monthly installments, subject to increases of approximately 2% annually on the anniversary of the commencement date of the sublease term. We lease office space in Copenhagen, Denmark under a lease with an effective date of November 1, 2018 and that expires on September 30, 2022. The lease in Copenhagen can be terminated by the lessee and lessor no earlier than March 31, 2022 for vacating the premises by September 30, 2022 and contains an option to extend the lease term to remain in force until it is terminated in writing by either the lessee or lessor with a six-month notice period from the first day of the month following September 30, 2022. As of December 31, 2020, it is not reasonably certain the Company will exercise the extension options inherent in the lease. Our annual rent is approximately $0.1 million, paid over monthly installments, subject to annual increases equal to the Danish consumer price index, or approximately 2% annually. 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, 2020 (in thousands):

Year ending December 31,		
2021	$	194
2022		67
Total future minimum lease payments		**261**
Less imputed interest		(8)
Total	**$**	**253**

Operating cash outflows from operating leases	$	476
Weighted-average remaining lease term (in months) - operating leases		15.5
Weighted-average discount rate - operating leases		8.5%

As of December 31, 2020, the carrying value of the right-of-use assets for the operating leases was $0.2 million, which is reflected in “Other non-current assets,” and the carrying value of the lease liabilities for operating leases was $0.3 million, of which approximately $0.2 million related to the current portion of the lease liabilities is recorded in “Accrued expenses and other current liabilities,” and $0.1 million related to the non-current portion of the lease liabilities is recorded in “Other long-term liabilities.”

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 CEO whereby the CEO is entitled to payments and benefits upon certain events. Upon termination (i) without cause or as a result of the CEO’s disability, (ii) termination due to the CEO’s death, or (iii) the CEO’s resignation for good reason, the CEO is entitled to receive (i) continued monthly payment of base salary for 12 months from the date of termination, (ii) a lump sum payment equal to 100% of his target bonus, (iii) a pro-rated portion of the unpaid target bonus, (iv) reimbursement for continued coverage under medical benefit plans for 12 months or until covered under a separate plan from another employer, and (v) the immediate and full vesting of outstanding nonvested Company equity awards. Additionally, all of the CEO’s outstanding stock options will be exercisable through the earlier of (x) the 12-month anniversary of the termination date or (y) the original expiration date.

Upon a termination other than for cause, death or disability or resignation for good reason within three 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, plus one-hundred percent of the unpaid target bonus, plus a pro-rated portion of any unpaid bonus earned during the relevant performance period, (ii) reimbursement for continued coverage under medical benefit plans for 24 months or until covered under a separate plan from another employer, and (iii) the immediate and full vesting of outstanding nonvested 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 Officer ("CFO") and Chief Medical Officer ("CMO") is entitled to payments and benefits if the CFO or CMO, respectively, is terminated without cause or resigns for good reason. Upon termination without cause, and not as a result of death or disability or resignation for good reason, the CFO or CMO is entitled to receive a payment of base salary for 12 months and a pro-rated portion of the unpaid bonus, and is entitled to reimbursement for continued coverage under medical benefit plans for six months or until covered under a separate plan from another employer. Upon a termination other than for cause or resignation for good reason within 12 months following a change in control, the CFO or CMO is entitled to receive a payment of base salary for 18 months and one-hundred percent of the unpaid bonus and be entitled to a payment equal to the amount required to continue coverage under medical benefit plans for 12 months and will also be entitled to full acceleration of outstanding nonvested options at the time of such termination.

13. Related Parties

Pursuant to the Private Placement on December 24, 2019 (Note 11), Bain Capital Life Science Investors, LLC and affiliates ("Bain"), acquired 4,571,139 shares of the Company's common stock, 3,615,498 Pre-Funded PIPE Warrants, and 17,374,517 Milestone Warrants and has a right to designate a member of the Company's board of directors. As an investor with the right to designate a member of the Company's board of directors, Bain has significant influence over the Company and is thereby considered a related party as of December 31, 2020.

14. Stock-Based Compensation

A. Equity Incentive Plans

2008 Stock Option Plan

The Company adopted the Savara Inc. Stock Option Plan (the "2008 Plan"), pursuant to which the Company had reserved shares for issuance to employees, directors, and consultants. The 2008 Plan includes (i) the option grant program providing for both incentive and non-qualified stock options, as defined by the Internal Revenue Code, and (ii) the stock issuance program providing for the issuance of awards that are valued based upon common stock, including restricted stock, dividend equivalents, stock appreciation rights, phantom stock, and performance units. The 2008 Plan also allows eligible persons to purchase shares of common stock at an amount determined by the plan administrator. Upon a participant's termination, the Company retains the right to repurchase nonvested shares issued in conjunction with the stock issuance program at the fair market value per share as of the date of termination.

The Company had previously issued incentive and non-qualified options and restricted stock to employees and non-employees under the 2008 Plan. The terms of the stock options, including the exercise price per share and vesting provisions, were determined by the board of directors. Stock options were granted at exercise prices not less than the estimated fair market value of the Company's common stock at the date of grant based upon objective and subjective factors including: third-party valuations, preferred stock transactions with third parties, current operating and financial performance, management estimates and future expectations.

The Company no longer issues stock-based awards under the 2008 Plan.

2015 Omnibus Incentive Option Plan

The Company operates the 2015 Omnibus Incentive Plan (the "2015 Plan"), as amended and restated with approval by our stockholders in June 2018 and May 2020. The 2015 Plan provides for the grant of incentive and non-statutory stock options, as well as share appreciation rights, restricted shares, restricted stock units, performance units, shares and other stock-based awards. Share-based awards are subject to terms and conditions established by our board of directors or the compensation committee of our board of directors. As of December 31, 2020, the number of shares of our common stock available for grant under the 2015 Plan was 1,677,046 shares.

Shares of common stock that are subject to awards granted under the 2015 Plan shall be counted against the shares available for issuance under this plan as one share for each share subject to a stock option or stock appreciation right and as 1.34 shares for each share subject to an award other than a stock option or a stock appreciation right such as a restricted stock unit ("RSU"). If any shares of common stock subject to an award granted under any of our stockholder-approved, equity-based incentive plans are forfeited, or an award expires or is settled for cash pursuant to the terms of an award, the shares subject to the award may be used again for awards under the 2015 Plan to the extent of the forfeiture, expiration or cash settlement. The shares of common stock will be added back as one share for every share of common stock if the shares were subject to a stock option or stock appreciation right, and as 1.34 shares for every share of common stock if the shares were subject to an award other than a stock option or stock appreciation right.

Under the 2015 Plan, the purchase price of shares of common stock covered by a stock option cannot be less than 100% of the fair market value of the common stock on the date the stock option is granted. Fair market value of the common stock is generally equal to the closing price for the common stock on the principal securities exchange on which the common stock is traded on the date the stock option is granted (or if there was no closing price on that date, on the last preceding date on which a closing price was reported).

Inducement Awards

The Company has granted equity awards under inducement grants filed in accordance with Nasdaq Listing Rule 5635(c)(4) exclusively to the Company's CMO as an inducement for the CMO to enter into employment with the Company.

Under both the 2008 Plan and 2015 Plan, stock option and restricted stock unit grants typically vest quarterly over three to four years and expire ten years from the grant date, and restricted stock grants vest on a quarterly basis over four years and expire ten years from the grant date.

B. Stock Options and Restricted Stock Units

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. Stock option awards generally have ten-year contractual terms and vest over four years for issuances to employees based on continuous service; however, the 2015 Plan allows for other vesting periods.

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

C. Fair Value Assumptions for 2015 Plan

The following table summarizes the assumptions used for estimating the fair value of stock options granted to employees for the years ended December 31, 2020 and 2019:

	2020	2019
Risk-free interest rate	.36% - .66%	1.39% - 2.60%
Expected term (years)	6.08 - 6.24	6.19 - 7.05
Expected volatility	78.9% - 96.4%	79.9% - 91.3%
Dividend yield	0%	0%

The following table summarizes the assumptions used for estimating the fair value of stock options granted to non-employees for the years ended December 31, 2020 and 2019:

	2020	2019
Risk-free interest rate	—	1.62% - 1.92%
Expected term (years)	—	6.16 - 9.96
Expected volatility	—	83.9% - 91.3%
Dividend yield	—	0%

D. Stock-Based Award Activity

The following tables provide a summary for the 2008 Plan and 2015 Plan of stock option activity for employees and non-employees, and RSU activity for the year ended December 31, 2020:

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, 2019	**4,541,432**	**$ 5.29**	**8.25**	**$ 461**
Granted	2,938,639	1.28	6.19	
Exercised	(67,477)	1.30		66
Expired/cancelled/forfeited	(1,172,252)	9.46		
Outstanding at December 31, 2020	**6,240,342**	**2.66**	**7.52**	**190**
Options exercisable at December 31, 2020	**2,367,880**	**3.58**	**4.21**	**133**
Vested and expected to vest at December 31, 2020	**6,240,342**	**2.66**	**7.52**	**190**

RSUs:

	Shares Underlying Option Awards	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2019	**315,625**	**$ 3.45**
Granted	252,272	1.30
Vested	(49,125)	8.21
Expired/cancelled/forfeited	(9,375)	11.33
Outstanding at December 31, 2020	**509,397**	**$ 1.78**

The weighted-average grant date fair values for the Company's stock options granted during the years ended December 31, 2020 and 2019 were $0.95 per share and $2.30 per share, respectively. The total compensation cost related to nonvested stock options not yet recognized as of December 31, 2020 was $6.5 million, which will be recognized over a weighted-average period of approximately 2.3 years.

The total compensation cost related to unvested RSUs not yet recognized as of December 31, 2020 was $0.7 million, which will be recognized over a weighted-average period of 1.2 years.

During the years ended December 31, 2020 and 2019, the Company granted options to purchase a total of 0 and 60,000 shares of common stock to non-employees, respectively, under the 2015 Plan.

The Company recorded a minimal amount of stock-based compensation expense for options issued to non-employees for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, options to purchase 39,376 shares were held by non-employees and were vested and outstanding.

E. Stock-Based Compensation and Stock Option Modification

Effective September 11, 2020, the Company's Chief Executive Officer ("CEO") who also served as Chairman of the Board of Directors ("Chairman") as well as the Chief Business Officer (together, the "Former Executives") resigned, and Matthew Pauls was appointed as the Company's Interim Chief Executive Officer ("Interim CEO") and Chairman and subsequently confirmed as CEO. As part of the termination of employment of the Former Executives, certain supplementary modifications to the Former Executives' vested and nonvested stock option awards including additional acceleration of nonvested shares, voluntary forfeiture of certain stock option awards, and the extension of the post-termination exercise period of certain stock option awards. During the year ended December 31, 2020, the Company recorded a one-time, noncash incremental compensation expense net of the required reversal of previously recognized compensation attributed to nonvested shares in the amount of $0.8 million which is included in "General and administrative expenses" related to these stock option award modifications. The Company accounted for the resulting net incremental stock option award modification compensation under ASC Topic 718, Compensation – "Stock Compensation."

Stock-based compensation expense is included in the following line items in the accompanying statements of operations and comprehensive loss for the years ended December 31, 2020 and 2019 (in thousands):

	Year ended December 31, 2020	2019
Research and development	$ 1,626	$ 2,123
General and administrative	3,481	2,318
Total stock-based compensation	**$ 5,107**	**$ 4,441**

15. Income Taxes

The components of loss before income taxes for the years ended December 31, 2020 and 2019 are as follows (in thousands):

	December 31, 2020	2019
Domestic	$ (30,396)	$ (52,440)
Foreign	(19,219)	(25,733)
Total	**$ (49,615)**	**$ (78,173)**

The Company did not record a federal tax benefit or expense for the year ended December 31, 2020. The Company recorded no state provision for income taxes for the years ended December 31, 2020 and 2019 due to revenues below the minimum tax threshold. The components of the benefit for income taxes are as follows for the years ended December 31, 2020 and 2019 (in thousands):

	December 31, 2020	2019
Current:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total current	—	—
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred	—	—
Total income tax expense (benefit)	**$ —**	**$ —**

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 years ended December 31, 2020 and 2019 (in thousands):

	December 31, 2020	2019
Income tax benefit computed at federal statutory tax rate	$ (10,419)	$ (16,416)
Change in valuation allowance	14,311	12,780
Orphan drug & research credits generated	(1,904)	(2,855)
Orphan drug & research credit expense disallowance	68	278
Impact of foreign operations	(847)	(312)
Goodwill impairment	—	5,671
Other permanent differences	(1,209)	854
Total	**$ —**	**$ —**

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, 2020 and 2019, the valuation allowance increased by $14.3 million and $12.8 million, respectively.

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

	December 31, 2020	2019
Deferred tax liabilities:		
Prepaid assets	$ —	$ —
Intangible assets	—	2,143
Other	524	516
Total deferred tax liabilities	524	2,659
Deferred tax assets:		
Net operating loss carryforwards	38,256	30,953
Intangible assets	230	—
Amortization	1,332	97
Credit carryforwards	17,620	15,654
Accrued liabilities & other	1,806	365
Total deferred tax assets	59,244	47,069
Subtotal	58,720	44,410
Valuation allowance	(58,720)	(44,410)
Net deferred taxes	**$ —**	**$ —**

As of December 31, 2020 and 2019, the Company had foreign net operating loss ("NOL") carryforwards of approximately $54.8 million and $40.3 million, respectively, which have an indefinite carryforward period. As of December 31, 2020 and 2019, the Company had NOL's for federal income tax purposes of approximately $123.9 million and $103.8 million, respectively. The federal NOL carryforwards begin to expire in 2027, with $70.7 million not having an expiration date. As of December 31, 2020 and 2019, the Company also had available research and orphan drug tax credit carryforwards for federal income tax purposes of approximately $17.2 million and $15.3 million, respectively. If not utilized, these carryforwards expire at various dates beginning in 2028. As of December 31, 2020 and 2019, the Company had state research and development tax credit carryforwards of approximately $0.5 million and $0.4 million, respectively, which will begin to expire in 2034 if not utilized.

Utilization of the NOL and tax credit carryforwards may be subject to an annual limitation due to ownership change limitations that have occurred previously or that could occur in the future, as provided by Section 382 of the Internal Revenue Code of 1986 ("Section 382"), as well as similar state provisions. Ownership changes may limit the amount of NOL carryforwards and tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. 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. The Company has initiated a study to determine whether any ownership change has occurred since the Company's formation, and expects to complete the study in the first half of 2021. However, the Company believes that it has experienced at least two ownership changes in the past and that it may experience additional ownership changes as a result of subsequent shifts in its stock ownership. Should there be an ownership change that has occurred or will occur, the Company's ability to utilize existing carryforwards could be substantially restricted and may result in the expiration of such carryforwards prior to utilization.

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, 2020 and 2019, the Company had no unrecognized tax benefits. During the years ended December 31, 2020 and 2019, 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, 2020, the statute of limitations for assessment by the Internal Revenue Service ("IRS") is open for the 2017 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 2016 and subsequent tax years remain open and subject to examination by the state taxing authorities. The 2017 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.

16. 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, 2020 and 2019, potentially dilutive securities include:

	Year ended December 31,	
	2020	2019
Awards under equity incentive plan	6,240,342	4,541,432
Nonvested restricted shares and restricted stock units	509,397	315,625
Warrants to purchase common stock	31,828,710	33,131,798
Total	**38,578,449**	**37,988,855**

The following table calculates basic earnings per share of common stock and diluted earnings per share of common stock for the years ended December 31, 2020 and 2019 (in thousands, except share and per share amounts):

	Year ended December 31, 2020	2019
Net loss	$ (49,615)	$ (78,173)
Net loss attributable to common stockholders	$ (49,615)	$ (78,173)
Undistributed earnings and net loss attributable to common stockholders, basic and diluted	$ (49,615)	$ (78,173)
Weighted-average common shares outstanding, basic and diluted	59,309,090	40,027,758
Basic and diluted EPS	**$ (0.84)**	**$ (1.95)**

17. Subsequent Events

Termination of Manufacturing Agreement

On December 10, 2020, the Company announced that the Phase 3 trial of vancomycin hydrochloride inhalation powder in people living with cystic fibrosis who have MRSA lung infection did not meet the primary endpoint. Subsequently, on January 7, 2021 the Company issued a termination notice to GlaxoSmithKline Trading Services Limited (“GSK”), who manufactures the drug product from bulk vancomycin powder. On January 26, 2021, the Company and GSK entered a change order for termination costs associated with the closeout and winddown of vancomycin activities. Termination costs were less than $1 million.

Loan Agreement with Silicon Valley Bank

On February 25, 2021, SVB agreed to delay the existing requirement for the Company to have an ongoing (first patient dosed) Phase 3 clinical trial for molgramostim for the treatment of aPAP from March 31, 2021 to June 30, 2021. If the first patient dosed does not occur by June 30, 2021, then (i) a payment equal to three months of principal that was deferred between April 1, 2021 and June 1, 2021 will be collected on July 1, 2021 (calculated based on a 24-month amortization) and (ii) the remaining balance will begin amortizing July 1, 2021 over the remaining 21 months of the loan. As part of this accommodation, the end of term charge of the Loan Agreement increased from 6.0% to 6.2%.

Parexel Agreement

On March 5, 2021, the Company entered into a Master Services Agreement (“MSA”) and executed a work order with Parexel International (IRL) Limited (“Parexel”) pursuant to which Parexel will provide contract research services related to support IMPALA 2 clinical trial development activities. The MSA has an initial term of five years. Under the work order, the Company will pay Parexel service fees and pass-through expenses estimated to be approximately $31 million over the course of the IMPALA 2 clinical trial.

Exhibit 10.9

Savara Inc. 2015 Omnibus Incentive Plan

Incentive Stock Option Grant Agreement – Exempt Employees

THIS INCENTIVE STOCK OPTION GRANT AGREEMENT (this "Agreement"), effective as of [●] (the "Grant Date"), is entered into by and between Savara Inc., a Delaware corporation (the "Company"), and [●] (the "Participant").

1. Grant of Option. The Company hereby grants to the Participant [NUMBER] stock options (the "Options"). Each Option entitles the Participant to purchase one (1) Common Stock of the Company, par value $0.001 per share (the "Shares"), at the exercise price of $[●] per Share (the "Exercise Price") pursuant to the Savara Inc. 2015 Omnibus Incentive Plan (the "Plan").

Participant should consult with Participant's own tax advisor regarding the tax effects of this Option

2. Subject to the Plan. This Agreement is subject to the provisions of the Plan, and, unless the context requires otherwise, terms used herein shall have the same meaning as in the Plan. In the event of a conflict between the provisions of the Plan and this Agreement, the Plan shall control. All questions of interpretation concerning this Agreement and the Plan shall be determined by the Committee or its designee. All such determinations shall be final or conclusive, and binding upon all persons having an interest in the Option as provided in the Plan.

3. Term of Option. Unless the Option terminates earlier pursuant to the provisions of this Agreement, the Option shall expire ten years from the Grant Date, except as provided in paragraph (6) of Section 6.

4. Vesting. The Options shall become vested with respect to 1/16th on each three-month anniversary of **[Enter Vesting Commencement Date]** until all of the Options have vested; provided, however, that the Participant is providing Services on each such vesting date.

5. Exercise of Option

(a) Manner of Exercise. To the extent vested, the Option may be exercised, in whole or in part, by delivering notice to the Company in accordance with paragraph (g) of Section 9 in such form as the Company may require from time to time (the "Exercise Notice"). Such Exercise Notice shall specify the number of Options being exercised, and shall be accompanied by full payment of the Exercise Price of such Shares in a manner permitted under the terms of Section 5.5 of the Plan, except that payment with previously acquired Shares may only be made with the consent of the Committee.

(b) Issuance of Shares. Upon exercise of the Option and payment of the Exercise Price for the Shares as to which the Option is exercised, the Company shall issue to the Participant the applicable number of Shares in the form of fully paid and non-assessable Shares.

(c) Capitalization Adjustments. The number of Shares subject to the Option and the Exercise Price shall be equitably and appropriately adjusted, if applicable, as provided in Section 12.2 of the Plan.

(d) Withholding. No Shares will be issued on exercise of the Option unless and until the Participant pays to the Company, or makes satisfactory arrangements with the Company for payment of, any federal, state or local taxes required by law to be withheld in respect of the exercise of the Option. The Participant hereby agrees that the Company may withhold from the Participant's wages or other remuneration the applicable taxes. At the discretion of the Company, the applicable taxes may be withheld in kind from the Shares otherwise deliverable to the Participant on exercise of the Option, up to the Participant's minimum required withholding rate or such other rate that will not trigger a negative accounting impact.

(e) Notice of Disposition. Participant agrees to notify the Company in writing within fifteen (15) days after the date of any disposition of any of the Shares issued upon exercise of the Option that occurs within the later of two (2) years after the Grant Date or within one (1) year after such Shares are transferred to the Participant.

6. Termination of Option

(a) Termination of Employment or Service Relationship Other Than Due to Retirement, Death, Disability or Cause. Unless the Option has earlier terminated, the Option shall terminate in its entirety, regardless of whether the Option is vested, ninety (90) days after the date the Participant ceases to provide Services for any reason other than, as applicable, the Participant's Retirement, death, Disability or termination for Cause. Except as provided in paragraphs (b), (c) or (d) of this Section, any portion of the Option that is not vested at the time the Participant ceases to provide Services shall immediately terminate.

(b) Retirement. Upon the Retirement of the Participant, unless the Option has earlier terminated, the Option shall continue in effect (and, for purposes of vesting pursuant to Section 4, the Participant shall be deemed to continue to be providing Services) until the earlier of (i) two (2) years after the Participant's Retirement (or, if later, the fifth anniversary of the Grant Date), and (ii) the expiration of the Option's term pursuant to Section 3. For purposes of this Agreement, "Retirement" shall mean termination of the Participant's employment with the Company and its Affiliates, or a successor company (or a subsidiary or parent thereof) and their respective subsidiaries, other than for Cause (a) if (i) the Participant is then at least age 60 and (ii) the sum of the Participant's age and years of continuous Service with the Company and its Affiliates is then equal to at least 70 or (b) if the Committee characterizes such termination as a "Retirement" for purposes of this

Agreement. For clarity, this Section 6(b) shall apply only to Participants who are Employees at the time of termination.

(c) Death. Upon the Participant's death, unless the Option has earlier terminated, the Participant's executor or personal representative, the person to whom the Option shall have been transferred by will or the laws of descent and distribution, or such other permitted transferee, as the case may be, may exercise the Option in accordance with paragraph (a) of Section 5, to the extent vested, provided such exercise occurs within twelve (12) months after the date of the Participant's death or the end of the term of the Option pursuant to Section 3, whichever is earlier.

(d) Disability. In the event that the Participant ceases to provide Services by reason of Disability, unless the Option has earlier terminated, the Option may be exercised, in accordance with paragraph (a) of Section 5, to the extent vested, provided such exercise occurs within six (6) months after the date of Disability or the end of the term of the Option pursuant to Section 3, whichever is earlier. For purposes of this Agreement, "Disability" shall mean the Participant's becoming disabled within the meaning of Section 22(e)(3) of the Code, or as otherwise determined by the Committee in its discretion. The Committee may require such proof of Disability as the Committee in its sole and absolute discretion deems appropriate and the Committee's determination as to whether the Participant has incurred a Disability shall be final and binding on all parties concerned.

(e) Termination for Cause. Upon termination by the Company or an Affiliate or a successor company (or a subsidiary or parent thereof) of the Participant's Service for Cause, unless the Option has earlier terminated, the Option shall immediately terminate in its entirety and shall thereafter not be exercisable to any extent whatsoever. For purposes of this Agreement, except as otherwise provided in a written employment or severance agreement between the Participant and the Company or a severance plan of the Company covering the Participant (including a change in control severance agreement or plan), "Cause" shall mean: the commission of any act of fraud, embezzlement or dishonesty by Participant, any unauthorized use or disclosure by such person of confidential information or trade secrets of the Company or an Affiliate or a successor company (or a subsidiary or parent thereof), or any other intentional misconduct by such person adversely affecting the business affairs of the Company or an Affiliate or a successor company (or a subsidiary or parent thereof) in a material manner.

(f) Automatic Extension of Exercise Period. Notwithstanding any provisions of Section 3 or paragraphs (a), (b), (c) or (d) of this Section to the contrary, if on the last business day of the term of the Option under Section 3 or if following termination of Service and during any part of the time period set forth in the applicable paragraph of this Section (i) exercise of the Option is prohibited by applicable law or (ii) the Participant may not purchase or sell Shares due to a "black-out period" of a Company insider trading policy, the term of the Option under Section 3 or the time period to exercise the Option under Section 3 or paragraphs (a), (b), (c) or (d) of this Section, as applicable, shall be extended until the later of (x) thirty (30) days after the end of the applicable legal prohibition or

black-out period or (y) the end of the time period set forth in the applicable paragraph of this Section.

7. Good Leaver Following a Change in Control.

(a) Effect on Options. If the Option is to be assumed by the successor corporation (or the parent thereof) in connection with a Change in Control (as defined in the Plan) or is otherwise to be continued in full force and effect pursuant to the terms of the Change in Control transaction, then none of the Options shall vest on an accelerated basis upon the occurrence of that Change in Control, and the Participant shall accordingly continue to vest the Options in one or more installments in accordance with the provisions of this Agreement. However, upon a termination of Participant's employment due to reasons covered by sub-section (a) under section 6 (1), by section 6 (2) or by section 6 (4) of "Termination of Employment" in this Agreement within twelve (12) months following such Change in Control, all the Options shall automatically vest in full on an accelerated basis so that such Option shall immediately become exercisable and may be exercised for any or all of those option shares as vested shares. The Option shall remain so exercisable until the Expiration Date.

8. Taxation according to Special Rules: By signing this Agreement, the Participant and Savara ApS (the "Danish Employer") agrees that the Options covered by this Agreement, to the extent that Options are exercised, should be covered by Article 7P in the Danish Assessment Act, provided that the conditions to use Article 7P in the Danish Assessment Act are fulfilled.

Tax implications of the Participant are of no concern to the Danish Employer or the Company.

9. Miscellaneous.

(a) No Rights of Stockholder. The Participant shall not have any of the rights of a stockholder with respect to the Shares subject to this Option until such Shares have been issued upon the due exercise of the Option.

(b) No Registration Rights; No Right to Settle in Cash. The Company has no obligation to register with any governmental body or organization (including, without limitation, the U.S. Securities and Exchange Commission ("SEC")) any of (a) the offer or issuance of any Award (including this Option), (b) any Shares issuable upon the exercise of this Option, or (c) the sale of any Shares issued upon exercise of this Option, regardless of whether the Company in fact undertakes to register any of the foregoing. In particular, in the event that any of (x) any offer or issuance of this Option, (y) any Shares issuable upon exercise of this Option, or (z) the sale of any Shares issued upon exercise of this Option are not registered with any governmental body or organization (including, without limitation, the SEC), the Company will not under any circumstance be required to settle its obligations, if any, under this Plan in cash.

(c) Nontransferability of Option. The Option shall be nontransferable otherwise than by will or the laws of descent and distribution, and during the lifetime of the Participant, the Option may be exercised only by the Participant or, during the period the Participant is under a legal disability, by the Participant's guardian or legal representative. Notwithstanding the foregoing, the Participant may, by delivering written notice to the Company, in a form provided by or otherwise satisfactory to the Company, designate a third party who, in the event of the Participant's death, shall thereafter be entitled to exercise the Option.

(d) Severability. If any provision of this Agreement shall be held unlawful or otherwise invalid or unenforceable in whole or in part by a court of competent jurisdiction, such provision shall (i) be deemed limited to the extent that such court of competent jurisdiction deems it lawful, valid and/or enforceable and as so limited shall remain in full force and effect, and (ii) not affect any other provision of this Agreement or part thereof, each of which shall remain in full force and effect.

(e) Governing Law. This Agreement shall be governed by, and interpreted in accordance with, the laws of the State of California, other than its conflict of laws principles.

(f) Headings. The headings in this Agreement are for reference purposes only and shall not affect the meaning or interpretation of this Agreement.

(g) Notices. Any document relating to participation in the Plan or any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given (except to the extent that this Agreement provides for effectiveness only upon actual receipt of such notice) upon personal delivery, electronic delivery at the e-mail address, if any, provided for Participant by the Company (or, if applicable the Affiliate for whom Participant provides Services), or upon deposit in the U.S. Post Office or foreign postal service, by registered or certified mail, or with a nationally recognized overnight courier service, with postage and fees prepaid, addressed to the other party at the address of such party set forth or at such other address as such party may designate in writing from time to time to the other party. Notice by mail shall be deemed delivered on the date on which it is postmarked.

Mailed notices to the Company should be addressed to:

Savara Inc.
6836 Bee Cave Road
Building III, Suite 200
Austin, TX 78746
Attention: Chief Financial Officer

Mailed notice to the Participant should be addressed to the Participant at the Participant's address as it appears on the records of the Company or the Affiliate for whom Participant is providing Services or a successor company (or a subsidiary or parent thereof). The

Company or the Participant may by writing to the other party, designate a different address for notices.

The Plan documents, which may include but do not necessarily include: the Plan, this Agreement, the Plan Prospectus, and any reports of the Company provided generally to the Company's stockholders, may be delivered to Participant electronically. In addition, if permitted by the Company, Participant may deliver electronically the Exercise Notice called for by paragraph (a) of Section 5 to the Company or to such third party involved in administering the Plan as the Company may designate from time to time. Such means of electronic delivery may include but do not necessarily include the delivery of a link to a Company intranet or the internet site of a third party involved in administering the Plan, the delivery of the document via e-mail or such other means of electronic delivery specified by the Company.

Participant acknowledges that Participant has read this paragraph (g) of Section 8 and consents to the electronic delivery of the Plan documents and, if permitted by the Company, the delivery of the Exercise Notice, as described above. Participant acknowledges that he or she may receive from the Company a paper copy of any documents delivered electronically at no cost to Participant by contacting the Company by telephone or in writing. Participant further acknowledges that the Participant will be provided with a paper copy of any documents if the attempted electronic delivery of such documents fails. Similarly, Participant understands that Participant must provide the Company or any designated third party administrator with a paper copy of any documents if the attempted electronic delivery of such documents fails. Participant may revoke his or her consent to the electronic delivery of documents described above or may change the electronic mail address to which such documents are to be delivered (if Participant has provided an electronic mail address) at any time by notifying the Company of such revoked consent or revised e-mail address by telephone, postal service or electronic mail. Finally, Participant understands that he or she is not required to consent to electronic delivery of documents.

(h) Agreement Not a Contract. This Agreement (and the grant of the Option) is not an employment or service contract, and nothing in the Option shall be deemed to create in any way whatsoever any obligation on Participant's part to continue as an employee or director of or consultant to the Company or any Affiliate or a successor company (or a subsidiary or parent thereof), or of the Company or any Affiliate or a successor company (or a subsidiary or parent thereof) to continue Participant's Service as such an employee, director or consultant.

(i) Entire Agreement; Modification. This Agreement and the Plan contain the entire agreement between the parties with respect to the subject matter contained herein and may not be modified, except as provided in the Plan or in a written document signed by each of the parties hereto, and may be rescinded only by a written agreement signed by both parties.

IN WITNESS WHEREOF, the parties have executed this Agreement effective as of the Grant Date.

SAVARA INC.

By: _____

Title: _____

Participant

_____
Signature

_____
Name

SAVARA ApS:

By: _____

Title: _____

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements (No. 333-225994 and 333-237734) on Form S-3 and (No. 333-126551, 333-151903, 333-174940, 333-190376, 333-198046, 333-206330, 333-217894, 333-225998 and 333-237735) on Form S-8 of Savara Inc. of our report dated March 10, 2020, relating to the consolidated financial statements, appearing in this Annual Report on Form 10-K of Savara Inc. for the year ended December 31, 2020.

/s/ RSM US LLP
Austin, Texas
March 10, 2021

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Matthew Pauls, certify that:

1. I have reviewed this report on Form 10-K of Savara Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2021

By: /s/ Matthew Pauls
Matthew Pauls
Chief Executive Officer and Chairman
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Lowrance, certify that:

1. I have reviewed this report on Form 10-K of Savara Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2021

By: /s/ David Lowrance
David Lowrance
Chief Financial Officer
(Principal Financial and Accounting Officer

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Savara Inc. (the "Company") on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Matthew Pauls, principal executive officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 10, 2021

/s/ Matthew Pauls
Matthew Pauls
Chief Executive Officer and Chairman
(Principal Executive Officer)

In connection with the Annual Report of Savara Inc. (the "Company") on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Lowrance, principal financial and accounting officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 10, 2021

/s/ David Lowrance
David Lowrance
Chief Financial Officer
(Principal Financial and Accounting Officer)