UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)
June 1, 2017

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

Delaware	001-32157	84-1318182
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

900 South Capital of Texas Highway, Las Cimas IV, Suite 150
Austin, TX
(Address of principal executive offices, including zip code)

(512) 961-1891
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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. ☐

Explanatory Note

On April 27, 2017, Savara Inc., a Delaware corporation formerly known as Mast Therapeutics, Inc. ("Savara"), completed its business combination with Aravas Inc., a Delaware corporation formerly known as Savara Inc. ("Aravas"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of January 6, 2017, by and among Savara, Victoria Merger Corp. ("Merger Sub"), and Aravas, pursuant to which the Merger Sub merged with and into Aravas, with Aravas surviving as a wholly owned subsidiary of Savara (the "Merger").

Savara is filing this Current Report on Form 8-K to provide updated pro forma financial information related to the Merger and certain other information that it is providing to investors in connection with the proposed offering of common stock announced on June 1, 2017.

Item 8.01 Other Events.

Clinical Development of Molgradex

Phase 3

Savara is currently conducting a Phase 3 clinical study on Molgradex in Europe and Japan in autoimmune pulmonary alveolar proteinosis, or PAP, patients. Based on guidance received from the U.S. Food and Drug Administration, or FDA, as well as scientific advice received from the European Medicines Agency, or EMA, Savara believes the study has the potential to be accepted as the sole pivotal study in support of a BLA submission in the United States, and a marketing authorization application in the European Union. The aim of this randomized, double-blind, placebo-controlled study is to compare efficacy and safety of Molgradex with placebo in up to 90 PAP patients. Enrollment of the study is expected to be completed by the first quarter of 2018, with top line data readout expected in the fourth quarter of 2018.

The Phase 3 clinical study on Molgradex is enrolling patients diagnosed with autoimmune PAP and fulfilling all other entry criteria. These patients are randomized to receive double-blind treatment for up to 24 weeks in one of three treatment arms: 1) Molgradex 300 µg administered once daily, 2) Molgradex 300 µg and matching placebo administered daily in 7-day intermittent cycles of each, or 3) inhaled placebo administered once daily. The placebo-controlled period is followed by an open label follow-up period of 24-48 weeks. The study is being conducted at multiple sites in the European Union, Russia, Israel and Japan, with plans to open new study sites in certain other countries, including the United States. The primary endpoint of the study is the absolute change from baseline of arterial-alveolar oxygen gradient ((A-a)DO2) after 24 weeks of treatment. This endpoint is a measure of the patient's oxygenation status, and the endpoint value is expected to decrease as the physical obstacle of gas exchange is reduced by clearance of excess surfactant from the lungs. In addition, based on FDA guidance recently received by Savara, the FDA will focus its review on three key secondary endpoints that will be assessed for improvement in clinical symptoms and function, including six-minute walk distance (6MWD), St. George's respiratory questionnaire (SGRQ), and the time to whole lung lavage.

Based on the sample size calculation for the study, 42 evaluable patients (14 in each treatment group) are required to be randomized to have 90% power to detect a difference of 10 mmHg in (A-a)DO_2 between the two active arms combined and placebo, using a significance level of 0.01. To account for the FDA's review of the key secondary endpoints, a sample size of 30 patients per treatment group will be enrolled to achieve approximately 90% power to detect a difference of 50 meters in the 6MWD between each active arm and placebo, and a difference of ten points in the SGRQ between each active arm and placebo, each active arm analyzed sequentially using a significance level of approximately 0.02, after correction for multiplicity with an appropriate method for correlated endpoints.

A data safety monitoring board, or DSMB, provides safety oversight in the Phase 3 study. Following its first two meetings, no concerning safety issues were identified, and the DSMB has endorsed continuation of the study as planned.

Clinical Development of AeroVanc

Phase 3

Savara intends to initiate a Phase 3 clinical study designed to demonstrate the safety and efficacy of AeroVanc in cystic fibrosis, or CF, patients with persistent methicillin-resistant *Staphylococcus aurens*, or MRSA, lung infection. The plan is to initiate this trial in the third quarter of 2017. The study is planned to be conducted primarily in the United States and Canada.

Savara has received detailed guidance from the FDA on the design of the study, and believes that the planned study is in accordance with the FDA's requirements for a sole pivotal study to be used in an NDA submission. The study has also been planned in consultation with the Cystic Fibrosis Foundation's Therapeutic Development Network. The Phase 3 study is designed to detect whether the administration of AeroVanc results in a significant improvement in lung function. The study will assess a 32 mg dose administered twice a day for three on/off cycles of 28 days. The planned primary efficacy endpoint is absolute change from baseline in FEV_1 percent predicted at Week 4 and Week 20, a commonly used measure of lung function. Secondary efficacy endpoints include the time to use of other antibiotics for pulmonary infection, FEV_1 improvement (relative change, number of response cycles) and a respiratory symptoms diary.

The planned Phase 3 study is a randomized (1:1), double-blind, placebo-controlled study of AeroVanc in approximately 200 CF patients with persistent MRSA lung infection. The plan is to enrich the study with younger patients, by enrolling 75% of the subjects between the ages of 6 and 21 years. This was the population most responsive to treatment in the Phase 2 study, and will form the primary analysis population of the study. The duration of the study drug (AeroVanc or placebo) administration will be three cycles of 28 days on drug and 28 days off drug, during which time the primary efficacy endpoint will be measured and assessed. Following the efficacy study period, subjects will transition into another three cycles (28 days on treatment, 28 days off treatment per cycle) of open label AeroVanc use to provide more information on long-term safety.

The planned primary efficacy endpoint of the study is the mean absolute change from baseline in FEV_1 percent predicted. In accordance with guidance from the FDA, the endpoint will be analyzed sequentially at Week 4 (first treatment cycle), and at Week 20 (third treatment cycle). Both time points will be tested at a statistical significance level of $p = 0.05$ due to the sequential nature of the analysis. Savara believes that a statistically significant improvement at Week 20 would provide support for a chronic treatment label, whereas improvement at Week 4 only may result in a more restricted label. Approval in any form is subject to the positive evaluation of the clinical meaningfulness of the treatment effect, judged by the review of all data, including safety data, and the outcome of key secondary endpoints, such as time to use of other antibiotics.

In the single-cycle Phase 2 study, with missing data imputed using conservative rules adopted by the FDA, a difference in the mean absolute change in FEV1 percent predicted of 4.3% was observed between the treatment arms in subjects below 21 years of age. Based on the observed treatment effect size and variability, a sample size of 45 subjects per arm would provide 90% power to detect a statistically significant difference at an alpha level of 0.05. To account for a potential loss of power caused by premature discontinuations in a three-cycle study, a sample size of 100 subjects per arm will be enrolled.

Selection of the dose for the study was made based on the Phase 2 study in CF patients. In that study, administration of the 32 mg bid dose resulted in sputum trough vancomycin concentrations that were on average more than 100-fold above the observed minimum inhibitory concentration (MIC90) value, suggesting that the concentrations reached after repeated administration of the 32 mg bid dose are likely to be sufficient for effective management of MRSA infection. In terms of safety and tolerability, the 32 mg AeroVanc dose did not appear significantly different from placebo, and produced encouraging trends of efficacy in all key endpoints in subjects below 21 years of age. In contrast, the higher AeroVanc dose of 64 mg bid was not as well tolerated in the older subjects (above 21 years of age), resulting in an increased number of premature discontinuations of the study drug treatment in this subgroup.

After the completion of the Phase 3 study, Savara intends to submit an NDA under the 505(b)(2) regulatory pathway. In addition to being designated an Orphan Drug Product and QIDP, AeroVanc has been designated a Fast Track development program by the FDA.

Clinical Development of Aironite We have supported, or currently are supporting, four investigator-sponsored Phase 2 clinical studies of Aironite (also known as AIR001) in patients with heart failure with preserved ejection fraction (HFpEF) being conducted at prominent research institutions in the United States.

Phase 2 INDIE-HFpEF Study

In 2016, Aironite was selected by the Heart Failure Clinical Research Network, or HFN, for evaluation in a multicenter, randomized, double-blind, placebo-controlled crossover Phase 2 study in approximately 100 patients with HFpEF known as the Inorganic Nitrite Delivery to Improve Exercise Capacity in HFpEF study, or the INDIE-HFpEF study. The study began in the third quarter of 2016 and patient enrollment is ongoing. Results are expected in the first half of 2018. The study is being conducted with significant support from a grant awarded by the National Heart, Lung, and Blood Institute, part of the National Institutes of Health. We are providing test materials (Aironite and placebo), drug delivery devices (nebulizers), regulatory and technical support, and some additional financial support.

The study is a randomized, double-blind, placebo-controlled crossover study to evaluate the effect of AIR001 on peak exercise capacity as assessed by cardiopulmonary exercise testing, or CPET. Approximately 100 patients with a diagnosis of HFpEF will be enrolled across approximately 20 clinical centers in the United States that are part of the HFN. The primary efficacy endpoint is the peak oxygen consumption (VO2) after four weeks of treatment with Aironite or placebo as assessed by CPET performed at peak drug levels. Secondary objectives include (i) submaximal activity tolerance chronically, (ii) quality of life, (iii) chronic filling pressures as assessed by echocardiography and natriuretic peptide levels, and/or (iv) ventilator efficiency or submaximal exercise capacity at peak drug levels, and evaluation of the safety and tolerability of Aironite.

Phase 2 INABLE-TRAINING Study

Enrollment is ongoing in a Phase 2 clinical study of Aironite in patients with HFpEF known as the Inorganic Nitrite to Amplify the Benefits and Tolerability of Exercise Training study, or the INABLE-TRAINING study. This randomized, blinded, placebo-controlled, two-arm, parallel-group study in approximately 68 patients with HFpEF is evaluating Aironite's potential to improve the clinical responses to and tolerability of exercise training, or ET, in individuals with HFpEF. The primary endpoint of the study is the change in exercise capacity as measured by peak oxygen consumption (baseline to 12 weeks).

All study subjects will undergo 12 weeks of ET. Subjects will be randomized to receive Aironite three times daily or nebulized inhaled placebo (sodium chloride) three times daily during the study period and will wear accelerometry devices to track daily physical activity at home. After 12 weeks of ET as part of standard cardiac rehabilitation, study subjects will repeat the assessment of cardiovascular function and exercise capacity as performed at study entry to assess efficacy at a final visit.

The INABLE-TRAINING study has 2 aims. First, to determine whether treatment with Aironite in addition to ET for 12 weeks improves exercise capacity and hemodynamic reserve in HFpEF. Expired gas analysis, inert gas (C2H2) rebreathe, and echocardiography will be performed during rest and exercise to measure oxygen consumption (VO2), CO, and hemodynamics before and after completion of 12 weeks of ET with inhaled NO2- vs ET with inhaled placebo. Second, to determine whether treatment with Aironite in addition to ET for 12 weeks increases daily activity levels and quality of life, or QOL, and reduces symptoms of effort intolerance during ET. Tolerability of ET will be assessed by Borg perceived effort and dyspnea scores. Large and small vessel endothelial function (brachial and digital arteries) and QOL will also be assessed. Secondary endpoints include cardiac output reserve, peak exercise workload, rest and exercise hemodynamics assessed by echocardiography, Borg dyspnea and fatigue scores recorded during ET, endothelial function assessed by tonometry and brachial artery flow mediated dilation, and QOL assessed by the Kansas City Cardiomyopathy Questionnaire

Phase 1/2 Aironite Study in Cystic Fibrosis Patients

An investigator-sponsored open-label Phase 1/2 study of Aironite in adults with CF and airway infection with *Pseudomonas aeruginosa* (*P. aeruginosa*) was initiated in January 2017 and is being conducted at a prestigious research institution with funding from a grant award from a non-profit organization. The study will assess safety of Aironite administered in a dose escalation manner. The study also aims to explore the effects of Aironite on measures of lung function, exhaled airway nitric oxide, and reduction in bacterial burden. Sodium nitrite has demonstrated *in vitro* antimicrobial activity against *P. aeruginosa* and other airway pathogens, as well as the ability to disperse biofilms. If supportive, we believe data from this Phase 1/2 study would facilitate the design of a potential Phase 2 program to establish Aironite's utility as an antimicrobial agent for *P. aeruginosa* and sensitizer to standard antibiotic therapies in CF patients.

Government Regulation

We believe our AeroVanc product candidate will be regulated by the FDA as a drug and will require the submission and approval of a New Drug Application, or NDA, and our Molgradex product candidate will be regulated by the FDA as a biologic and will require the submission and approval of a Biologic License Application, or BLA.

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 biologics and drugs, such as those Savara is developing. Savara, 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 it wishes to conduct studies or seek approval or licensure of its 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.

BLA/NDA Approval Process

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

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or 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, or 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 Biologic License Application, or BLA or New Drug Application, or NDA, after completion of all required clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA or NDA 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 current Good Manufacturing Practices, or cGMP, 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, or cGCPs; and
- FDA review and approval of the BLA or NDA to permit commercial marketing of the product for particular indications for use in the United States, which must be updated annually and when significant changes are made.

The testing and approval process requires substantial time, effort and financial resources, and Savara cannot be certain that any approvals for its product candidates will be granted on a timely basis, if at all. Prior to beginning the first clinical trial with a product candidate, Savara 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 studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; 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 study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, 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 Institutional Review Board, or 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 study 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 studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study 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 studies and clinical study results to public registries.

Clinical trials typically are conducted in three or four sequential phases, but the phases my overlap or be combined.

- *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. These so-called Phase 4 studies may be required as a condition to approval of the BLA or NDA.

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. 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 or NDA requesting approval to market the product for one or more indications. The BLA or NDA 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 studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. The submission of a BLA or NDA requires payment of a substantial User Fee to FDA, and the sponsor of an approved NDA 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 the BLA or NDA to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA or NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA or NDA must be resubmitted with the additional information. Once a BLA or NDA 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 or NDA 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 or NDA, 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 or NDA, 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 Savara may encounter difficulties or unanticipated costs in its efforts to secure necessary governmental approvals, which could delay or preclude us from marketing its products. After the FDA evaluates a BLA or NDA and conducts inspections of manufacturing facilities where the investigational product and/or its 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 or NDA 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 or NDA with a Risk Evaluation and Mitigation Strategy, or REMS, plan 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-market studies 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 studies. 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 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 or NDA 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 or

NDA 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 or NDA 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 studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's or drug's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the Food and Drug Administration Safety and Innovation Act, or FDASIA, 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 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 biologic or 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 or NDA for review on a rolling basis. Savara may seek designation as a breakthrough therapy for some or all of its product candidates.

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

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 United States, or more than 200,000 individuals in the United States 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 United States. Orphan drug designation must be requested before submitting a BLA or NDA. 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 biologic or 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 exclusivity, which means that the FDA may not approve any other applications, including a full BLA or NDA, 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 FDA finds that the holder of the orphan 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 biologic or drug was designated. Orphan exclusivity does not prevent the FDA from approving a different biologic or drug for the same disease or condition, or the same biologic or drug for a different disease or condition. Among the other benefits of orphan designation are tax credits for certain research and a waiver of the BLA or NDA application user fee.

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

As in the United States, designation as an orphan product for the treatment of a specific indication in the European Union, must be made before the application for marketing authorization is made. Orphan products 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 biologics or drugs to assure the availability of sufficient quantities of their orphan biologic or drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the orphan biologic or drug.

GAIN Exclusivity for Antibiotics

In 2012, Congress passed legislation known as the Generating Antibiotic Incentives Now Act, or GAIN Act. This legislation is designed to encourage the development of antibacterial and antifungal drug products that treat pathogens that cause serious and life-threatening infections. To that end, the new law grants an additional five years of exclusivity upon the approval of an NDA for a drug product designated by FDA as a QIDP. Thus, for a QIDP with Orphan Designation, the periods of five-year exclusivity and seven-year orphan drug exclusivity, would become 12 years.

A QIDP is defined in the GAIN Act to mean "an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by (1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens" or (2) certain "qualifying pathogens." A "qualifying pathogen" is a pathogen that has the potential to pose a serious threat to public health (such as resistant Gram-positive pathogens, multi-drug resistant Gram-negative bacteria, multi-drug resistant tuberculosis, and C. difficile) and that is included in a list established and maintained by FDA. A drug sponsor may request the FDA to designate its product as a QIDP any time before the submission of an NDA. The FDA must make a QIDP determination within 60 days of the designation request. A product designated as a QIDP will be granted priority review by the FDA and can qualify for "fast track" status.

The additional five years of exclusivity under the GAIN Act for drug products designated by the FDA as QIDPs applies only to a drug that is first approved on or after July 9, 2012. Additionally, the five year exclusivity extension does not apply to: a supplement to an application under FDCA Section 505(b) for any QIDP for which an extension is in effect or has expired; a subsequent application filed with respect to a product approved by the FDA for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength; or a product that does not meet the definition of a QIDP under Section 505(g) based upon its approved uses.

Abbreviated Licensure Pathway for Biological Products as Biosimilar or Interchangeable

The Patient Protection and Affordable Care Act, or the ACA, signed into law in March, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which amended the Public Health Services Act and created an abbreviated approval pathway for biological products shown to be highly similar to an FDA-licensed reference biological product. The BPCIA attempts to minimize duplicative testing, and thereby lower development costs and increase patient access to affordable treatments.

The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the branded product is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving any products that are biosimilar to the branded product. The FDA cannot approve a biosimilar application for twelve years from the date of first licensure of the reference product. Additionally, a biosimilar product sponsor may not submit an biosimilar application for four years from the date of first

licensure of the reference product. A reference product may also be entitled to exclusivity under other statutory provisions. For example, a reference product designated for a rare disease or condition (an "orphan drug") may be entitled to seven years of exclusivity, in which case no product that is biosimilar to the reference product may be approved until either the end of the twelve-year period provided under the BPCIA or the end of the seven-year orphan exclusivity period, whichever occurs later. In addition, the FDA may under certain circumstances extend the exclusivity period for the reference product by an additional six months if the FDA requests, and the manufacturer undertakes, studies on the effect of its product in children, a so-called pediatric extension.

The first biological product determined to be interchangeable with a branded product for any condition of use is also entitled to a period of exclusivity, during which time the FDA may not determine that another product is interchangeable with the reference product for any condition of use. This exclusivity period extends until the earlier of: (1) on year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued.

505(b)(2) New Drug Application

The provisions of section 505(b)(2) of the Food, Drug, and Cosmetic Act, or the FDCA, were created, in part, to help avoid unnecessary duplication of studies already performed on a previously approved ("reference" or "listed") drug; the section gives the FDA express permission to rely on data not developed by the NDA applicant. An NDA filed under section 505(b)(2) is one for which one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. We are pursuing a section 505(b)(2) regulatory strategy for AeroVanc.

The owner of an NDA for a branded drug product may list with the FDA certain patents whose claims allegedly cover the applicant's branded product. Each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files a 505(b)(2) NDA application referencing a drug listed in the Orange Book must certify to the FDA that: (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA, referred to as a Paragraph I Certification; (2) such patent has expired, referred to as a Paragraph II Certification; (3) the date on which such patent expires, referred to ad a Paragraph III Certification; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted, referred to as a Paragraph IV Certification. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain, or carves out, any language regarding the patented method-of use rather than certify to a listed method-of-use patent. An applicant submitting a Paragraph IV Certification must provide notice to each owner of the patent that is the subject of the certification and to the holder of the approved branded drug to which the 505(b)(2) application refers. If the reference branded drug holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the Paragraph IV Certification notice, the FDA is prohibited from approving the 505(b)(2) application until the earlier of 30 months from the receipt of the Paragraph IV Certification, expiration for the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant.

Additionally, a 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the NDA branded reference drug has expired as described in further detail below. Market and data exclusivity provisions under the FDCA can delay the submission or the approval of certain applications for competing products. In addition to patent exclusivities, the holder of the NDA for a reference listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve another drug application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological

or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any application for the same active moiety and that relies on the FDA's findings regarding that drug; the FDA may accept an application for filing after four years if the follow-on applicant makes a Paragraph IV Certification. A drug may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials, other than bioavailability or bioequivalence studies, was essential to the approval of the application and was conducted or sponsored by the applicant. Should this occur, the FDA would be precluded from approving any Abbreviated New Drug Application, or ANDA, that references such product until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the entire exclusivity period.

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 GMP, which impose certain procedural and documentation requirements upon Savara and its 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 Savara 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. Savara cannot be certain that it or its present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements. If Savara's present or future suppliers are not able to comply with these requirements, the FDA may, among other things, halt its clinical trials, require them to recall a product from distribution, or withdraw approval of the NDA.

Future FDA and state inspections may identify compliance issues at Savara's facilities or at the facilities of its 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 NDA, 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 an NDA if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies 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 studies;
- 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 Savara 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

Savara's products 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 with 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. Savara believes its 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, or CDER, which will have primary jurisdiction over premarket development and approval. FDA's Center for Devices and Radiological Health, or CDRH, will provide support and review of the inhaler component of the product candidate.

Other Healthcare Laws and Compliance Requirements

Savara's 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 United States in addition to FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services and state and local governments. Savara's promotional and scientific/educational programs and interactions with healthcare professionals must comply with the federal Anti-Kickback Statute, the civil False Claims Act, 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 False Claims Act. 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 federal civil False Claims Act, or FCA, imposes 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, or 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 Savara's products, once commercialized, are sold in a foreign country, Savara 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 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 $150,000 per year (or up to an aggregate of $1 million 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. 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.

Savara may also be subject to data privacy and security regulation by both the federal government and the states in which it conducts its business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or 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 Savara's operations are found to be in violation of any of such laws or any other governmental regulations that apply to them, Savara may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of its 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 its ability to operate its business and its financial results.

In addition to the foregoing health care laws, Savara is also subject to the U.S. Foreign Corrupt Practices Act 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. Savara has plans to adopt an anti-corruption policy, which will become effective upon the completion of this offering, and expect to prepare and implement procedures to ensure compliance with such policy. The anti-corruption policy mandates compliance with the FCPA and similar anti-bribery laws applicable to its business throughout the world. However, Savara cannot assure you that such a policy or procedures implemented to enforce such a policy will protect them from intentional, reckless or negligent acts committed by its 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 its 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 Savara currently believes that third-party payers will provide coverage and reimbursement for its product candidates, if approved, Savara 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 further limit Savara's net revenue and results. Savara may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of its products. The product candidates that Savara develops may not be considered cost-effective and thus may not be covered or sufficiently reimbursed. It is time consuming and expensive for them to seek coverage and reimbursement from third-party payers, as each payer will make its own determination as to whether to cover a product and at what level of 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 them to sell its products on a competitive and profitable basis.

Healthcare Reform

The United States 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 Savara's ability to sell its products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

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 Savara's 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 2024 unless additional Congressional action is taken. In January 2013, 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, increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for Savara's product candidates, if approved, and, accordingly, its financial operations.

Savara expects that healthcare reform measures that may be adopted in the future, including the possible repeal and replacement of the Affordable Care Act which the Trump administration has stated is a priority, are unpredictable, and the potential impact on Savara's operations and financial position are uncertain, but may result in more rigorous coverage criteria and lower reimbursement, and place additional downward pressure on the price that it receives for any approved product. 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 Savara from being able to generate revenue, attain profitability or commercialize their drugs.

Foreign Regulation

In addition to regulations in the United States, Savara will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of its products to the extent Savara chooses to develop or sell any products outside of the United States. 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.

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

Pharmaceutical products generally are subject to rigorous nonclinical testing and clinical studies 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.

Savara is preparing AeroVanc for a Phase 3 trial, the success of which will be needed for FDA approval to market AeroVanc in the United States to treat persistent MRSA lung infection in cystic fibrosis patients. While significant communication with the FDA on the Phase 3 study design has occurred, even if the Phase 3 clinical study meets all of its statistical goals and protocol end points, the FDA may not view the results as robust and convincing. They may require additional clinical studies and/or other costly studies, which could require Savara to expend substantial additional resources and could significantly extend the timeline for clinical development prior to market approval. Additionally, Savara is required by the FDA to conduct a two-year nonclinical carcinogenicity study on the AeroVanc powder. The results of this study will not be known until a short time prior to potential submission of an NDA for AeroVanc. If the carcinogenicity study cannot be completed for technical or other reasons, or provides results that the FDA determine to be concerning, this may cause a delay or failure in obtaining approval for AeroVanc.

Molgradex is currently undergoing a Phase 3 clinical study in Europe and Japan. Concurrently, Savara plans to explore formulation changes to Molgradex that could simplify the composition of the drug product by eliminating one or more potentially unnecessary or harmful excipients. While this change is expected by Savara to improve the product quality and possibly reduce other documentation requirements, the regulatory agencies may require additional clinical or nonclinical studies prior to approval of such formulation changes. Savara currently plans not to make any formulation changes prior to submitting applications to regulatory authorities for regulatory approvals of Molgradex, but instead, to qualify the excipients in its nonclinical and clinical studies. However, regulatory agencies may request Savara to attempt to make the aforementioned formulation changes prior to approval of the product, and therefore, even if current clinical studies are deemed successful, such formulation changes could require Savara to expend substantial additional resources, including conducting an additional Phase 3 clinical study that would significantly extend the timeline for clinical development of Molgradex in PAP.

Savara has recently received guidance from the FDA on the requirements to initiate clinical studies in the United States and on the clinical study requirements to achieve BLA approval for Molgradex. Based on the guidance, Savara plans to amend its ongoing Phase 3 clinical study to include more patients, and to amend its endpoint hierarchy and statistical analyses to be used for U.S. approval purposes prior to submission of a U.S. IND. However, no agreement has yet been reached on the specific details of the statistical analysis plan, which Savara plans to submit for FDA review prior to the data analysis. Furthermore, even if the clinical study meets all of its statistical goals and protocol end points, the FDA may not view the results to provide persuasive evidence of efficacy across multiple clinical endpoints. Instead, they may require additional clinical studies and/or other costly studies, including an additional Phase 3 study, which would require Savara to expend substantial additional resources and would significantly extend the timeline for clinical development prior to market approval, or in failure to complete the clinical development of Molgradex.

Significant uncertainty exists with respect to the regulatory approval process for any investigational new drug, including AeroVanc and Molgradex. 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 an NDA or BLA or the equivalent foreign regulatory approval submission for filing or, if accepted, approve an NDA or BLA. There are many components to an NDA or BLA or marketing authorization application submission in addition to clinical study 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 an NDA for review or before approving the NDA or BLA, the FDA or foreign regulatory agencies may request that Savara provide additional information that may require significant resources and time to generate and there is no guarantee that its product candidates will be approved for any indication for which Savara may apply. The FDA or foreign regulatory agencies may choose not to approve an NDA or BLA for any of 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 studies 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 studies adequate scientific support for a conclusion of effectiveness and/or safety and may require one or more additional Phase 3 or other studies prior to granting marketing approval. If this were to occur, the overall development cost for the product candidate would be substantially greater and its competitors may bring products to market before Savara, which could impair its ability to generate revenues from the product candidates, or even seek approval, if blocked by a competitor's Orphan Drug exclusivity, which would have a material adverse effect on Savara's business, financial condition and results of operations.

Further, development of Savara's product candidates and/or regulatory approval may be delayed for reasons beyond its control. For example, U.S. federal government shut-down or budget sequestration, such as one that occurred during 2013, 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 Savara's ability to progress development of its product candidates or obtain regulatory approval for its product candidates.

Even if the FDA or foreign regulatory agencies grant approvals for Savara's product candidates, the conditions or scope of the approval(s) may limit successful commercialization of the product candidates and impair Savara's ability to generate substantial sales revenue. For example, the FDA may approve label claims for AeroVanc with age restrictions and/or treatment duration limitations, or Molgradex with restrictions for use only by patients unresponsive to the current standard of care. They may limit the label of AeroVanc or Molgradex to a subset of patients based on a review of which patient groups had the greatest efficacious response in clinical studies. 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 its 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 current good manufacturing processes, or cGMP, good clinical practices, international conference on harmonization regulations and good laboratory practices, which are regulations and guidelines that are enforced by the FDA or foreign regulatory agencies for all of its clinical development and for any clinical studies that Savara conducts

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 its products. These actions could result from, among other things, safety concerns, including unexpected side effects or drug-drug interaction problems, or concerns over misuse of a product. If any of these actions were to occur following approval, Savara may have to discontinue commercialization of the product, limit its 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 its 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 Savara's products.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements, other than statements of historical fact, included herein regarding the development of our products, financial position, strategy, regulatory status, clinical and nonclinical studies, collaborations, commercial prospects, internal growth, competition, intellectual property, regulatory reforms, products and objectives are forward-looking statements. Forward-looking statements may include, but are not limited to, statements about:

- the anticipated timing, structure and results of the clinical trials for our product candidates;
- the anticipated timing and outcome of the regulatory review process for our product candidates;
- any statements of the plans, strategies and objectives for our future operations;
- any statements concerning proposed new products, services or developments;
- any statements regarding future economic conditions or performance;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- our estimates regarding the sufficiency of our cash resources and our need for additional funding.

The words "believe," "anticipate," "estimate," "plan," "expect," "intend," "may," "could," "should," "potential," "likely," "projects," "continue," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements reflect our current views with respect to future events, are based on assumptions and are subject to risks and uncertainties. We cannot guarantee that we actually will achieve the plans, intentions or expectations expressed in our forward-looking statements and you should not place undue reliance on these statements. There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by our forward-looking statements. These important factors include those discussed herein and the risks and uncertainties described in Savara's filings with the SEC including the Form 8-K filed on April 27, 2017, other filings on Form 8-K, the Annual Report on Form 10-K for the fiscal year ended December 31, 2016, the Form 10-Q for the quarter ended March 31, 2017 and the Registration Statement on Form S-4, as amended, related to the Mast/Savara merger. These factors and the other cautionary statements made herein and therein should be read as being applicable to all related forward-looking statements whenever they appear. Except as required by law, we do not assume any obligation to update any forward-looking statement. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(b) Pro Forma Financial Information

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

The following unaudited pro forma condensed combined financial statements give effect to the merger between Savara Inc. (formerly known as Mast Therapeutics, Inc.) and Aravas Inc. (formerly known as Savara Inc.) and Aravas's previously consummated acquisition of Serendex A/S ("Serendex") as discussed below. The merger was structured as a reverse merger and Aravas was determined to be the accounting acquirer based upon the terms of the merger and other factors including: (i) Aravas security holders owned approximately 77% of the combined company immediately following the closing of the merger, (ii) Aravas directors hold the majority (5 out of 7) of board seats in the combined company, and (iii) Aravas management holds all key positions in the management of the combined company. The transaction will be accounted for under the acquisition method of accounting under accounting principles generally accepted in the United States (US GAAP). Under the acquisition method of accounting for the purpose of these unaudited pro forma condensed combined financial statements, management of Savara and Aravas have determined a preliminary estimated purchase price, calculated as described in Note 2 to these unaudited pro forma condensed combined financial statements. The net tangible and intangible assets acquired and liabilities assumed in connection with the transaction are recorded at their estimated acquisition date fair values. Any excess of purchase price over fair value of identified assets acquired and liabilities assumed will be recognized as goodwill. A final determination of these estimated fair values will be based on the actual net tangible and intangible assets of Savara that exist as of the date of completion of the transaction.

Previously Consummated Serendex Acquisition

On July 15, 2016, Aravas completed its acquisition of Serendex for total purchase consideration of $12.4 million. The purchase consideration consisted primarily of $2.9 million in common stock and $9.5 of contingent consideration. The acquisition of Serendex is reflected in Aravas's historical consolidated balance sheet at March 31, 2017.

Pro Forma Information

The unaudited pro forma condensed combined balance sheet as of March 31, 2017 and the unaudited pro forma condensed combined statements of operations for the three months ended March 31, 2017 and for the year ended December 31, 2016 are based on (i) the historical consolidated results of operations of Aravas and its subsidiary (which include the results of Serendex subsequent to Aravas's July 15, 2016 acquisition of Serendex); (ii) the historical consolidated results of operations of Savara; (iii) and the historical results of operations of Serendex for the period January 1, 2016 to July 14, 2016.

The unaudited pro forma condensed combined balance sheet as of March 31, 2017 assumes that the merger took place on March 31, 2017 and combines the historical balance sheets of Savara and Aravas as of March 31, 2017. The unaudited pro forma condensed combined statements of operations for the three months ended March 31, 2017 and for the year ended December 31, 2016 assumes that both the merger and the acquisition of Serendex took place as of January 1, 2016, and combines the historical results of Savara and Aravas and the pre-acquisition historical results of Serendex. The historical financial statements of Savara, Aravas and Serendex (for the interim period through June 30, 2016), have been adjusted to give pro forma effect to events that are (i) directly attributable to the mergers, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results.

The unaudited pro forma condensed combined financial statements are based on the assumptions and adjustments that are described in the accompanying notes. The unaudited pro forma condensed combined financial statements and pro forma adjustments have been prepared based on preliminary estimates of fair value of assets acquired and liabilities assumed. Differences between these preliminary estimates and the final acquisition accounting will occur and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial statements and the combined company's future results of operations and financial position.

The unaudited pro forma condensed combined financial statements do not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the acquisition. The unaudited pro forma condensed combined financial statements have been prepared for illustrative purposes only and are not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had Savara, Aravas and Serendex been a combined company during the specified periods. The unaudited pro forma condensed combined financial statements, including the notes thereto, should be read in conjunction with the Savara, Aravas and Serendex historical audited financial statements for the year ended December 31, 2016 and the unaudited condensed financial statements of Savara and Aravas for the three months ended March 31, 2017, and Serendex for the six months ended June 30, 2016.

Unaudited Pro Forma Condensed Combined Balance Sheet
March 31, 2017
(in thousands)

	Savara	Aravas	Pro Forma Merger Adjustments		Pro Forma Combined
Assets					
Current assets:					
Cash and cash equivalents	$ 7,771	$ 10,464	$ 3,987	K	$ 22,222
Investment securities	—	—	—		—
Grant and awards receivable	—	—	—		—
Prepaid expenses and other assets	388	1,038	—		1,426
Total current assets	8,159	11,502	3,987		23,648
Property, plant, and equipment, net	88	762	—		850
In-process research and development	2,500	10,609	18,803	G	31,912
Goodwill	3,007	3,089	18,394	H	24,490
Deposits and other non-current assets	131	—	—		131
Total assets	$ 13,885	$ 25,962	$ 41,184		$ 81,031
Liabilities, redeemable convertible preferred stock and stockholders' deficit					
Current liabilities:					
Accounts payable	$ 502	$ 696	$ —		$ 1,198
Accrued expenses and other liabilities	2,241	3,672	356	D	8,119
			1,850	E	
Accrued compensation and payroll taxes	2,270	—	—		2,270
Debt facility	1,580	—	(1,580)	K	—
Capital lease obligation, current portion	—	442	—		442
Total current liabilities	6,593	4,810	626		12,029
Noncurrent liabilities:					
Accrued interest on convertible promissory notes	—	238	(238)	F	—
Debt facility, net of current portion	1,933	—	5,567	K	7,500
Deferred income tax liability	995	2,334	7,526	I	10,855
Convertible promissory notes	—	3,597	(3,597)	F	—
Put option liability	—	1,055	(1,055)	F	—
Contingent consideration	—	9,808	—		9,808
Capital lease obligation, net of current portion	14	579	—		593
Other long-term liabilities	—	305	—		305
Total liabilities	9,535	22,726	8,829		41,090
Redeemable convertible preferred stock:					
Convertible preferred stock	—	43,885	(43,885)	C	—
Stockholders' equity:					
Common stock	255	5	3	B	271
			7	C	
			1	F	
Additional paid-in-capital	321,037	3,174	(287,271)	A	86,684
			(3)	B	
			43,878	C	
			5,869	F	
Accumulated other comprehensive income/(loss)	—	(448)	—		(448)
Accumulated earnings/(deficit)	(316,942)	(43,380)	316,942	A	(46,566)
			(356)	D	
			(1,850)	E	
			(980)	F	
Total stockholders' equity/(deficit)	4,350	(40,649)	76,240		39,941
Total liabilities and stockholders' equity	$ 13,885	$ 25,962	$ 41,184		$ 81,031

See accompanying notes to the unaudited pro forma condensed combined financial statements.

Unaudited Pro Forma Condensed Combined Statement of Operations
(in thousands, except share and per share data)

For the Three Months Ended March 31, 2017

	Savara	Aravas	Pro Forma Merger Adjustment		Pro Forma Combined
Grant revenue	$ 94	$ —	$ —		$ 94
Operating expenses:					
Product development	1,443	2,948	—		4,391
General and administrative	1,585	744	—		2,329
Impairment of IPR&D	—	—	—		—
Depreciation and amortization	11	90	—		101
Transaction related costs	2,752	992	(3,744)	J	—
Total operating expenses	5,791	4,774	(3,744)		6,821
Loss from operations	(5,697)	(4,774)	3,744		(6,727)
Interest and other income (expense), net	(172)	(437)	21	K	(588)
Loss before income taxes	(5,869)	(5,211)	3,765		(7,315)
Income taxes	—	237	—		237
Net loss	$ (5,869)	$ (4,974)	$ 3,765		$ (7,078)
Accretion of redeemable convertible preferred stock	—	(24)	—		(24)
Net loss attributable to common stockholders	$ (5,869)	$ (4,998)	$ 3,765		$ (7,102)
Basic and diluted net loss per share	$ (1.61)	$ (0.97)	$ —		$ (0.46)
Weighted average common share outstanding- basic and diluted	3,639,242	5,169,323	6,571,593	B	15,380,158

See accompanying notes to the unaudited pro forma condensed combined financial statements.

Unaudited Pro Forma Condensed Combined Statement of Operations

(in thousands, except share and per share data)

For the Year Ended December 31, 2016

	Savara	Aravas	Serendex (see note 4)	Pro Forma Merger Adjustment		Pro Forma Combined
Grant revenue	$ 128	$ 400	$ —	$ —		$ 528
Operating expenses:						
Product development	20,793	8,182	4,102	—		33,077
General and administrative	9,342	2,503	2,665	—		14,510
Impairment of IPR&D	6,049	—	—	—		6,049
Depreciation and amortization	99	346	—	—		445
Transaction related costs	301	317	—	(618)	J	—
Total operating expenses	36,584	11,348	6,767	(618)		54,081
Loss from operations	(36,456)	(10,948)	(6,767)	618		(53,553)
Interest and other income (expense), net	(2,053)	(332)	(58)	1,424	K	(1,019)
Loss before income taxes	(38,509)	(11,280)	(6,825)	2,042		(54,572)
Income taxes	2,409	357	—	—		2,766
Net loss	$ (36,100)	$ (10,923)	$ (6,825)	$ 2,042		$ (51,806)
Accretion of redeemable convertible preferred stock	—	(94)	—	—		(94)
Net loss attributable to common stockholders	$ (36,100)	$ (11,017)	$ (6,825)	$ 2,042		$ (51,900)
Basic and diluted net loss per share	$ (12.12)	$ (3.29)	$ —	$ —		$ (4.12)
Weighted average common share outstanding- basic and diluted	2,978,348	3,348,647	—	6,260,093	B	12,587,088

See accompanying notes to the unaudited pro forma condensed combined financial statements.

NOTES TO THE UNAUDITED PRO FORMA

CONDENSED COMBINED FINANCIAL INFORMATION

1. Description of Transaction and Basis of Presentation

Description of Transaction

On January 6, 2017, Aravas entered into the Merger Agreement with Savara, pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, that a wholly-owned subsidiary of Savara will merge with and into Aravas, with Aravas becoming a wholly-owned subsidiary of Savara and the surviving corporation of the merger. At the closing of the merger, each outstanding share of Aravas's common stock was converted into the right to receive approximately .5860 of a share of common stock of Savara, as well as the payment of cash in lieu of fractional shares. Immediately following the effective time of the merger, Savara equity holders owned approximately 23% of the outstanding capital stock of the combined company, with Aravas's preexisting equity holders owning approximately 77%.

Basis of Presentation

The unaudited pro forma condensed combined financial statements were prepared in accordance with the regulations of the Securities and Exchange Commission (SEC). The unaudited pro forma condensed combined balance sheet as of March 31, 2017 is presented as if the merger had been completed on March 31, 2017. The unaudited pro forma condensed combined statement of operations for the three months ended March 31, 2017 and for the year ended December 31, 2016 assumes that both the merger and Aravas's acquisition of Serendex took place as of January 1, 2016, and combines the historical results of Mast and Savara and the pre-acquisition historical results of Serendex.

Based on the terms of the merger, Aravas is deemed to be the acquiring company for accounting purposes and the merger will be accounted for under the acquisition method of accounting in accordance with the provisions of Accounting Standards Codification 805, Business Combinations. Accordingly, assets and liabilities of Aravas will be recorded as of the merger closing date at their respective carrying value and assets and liabilities of Savara will be recorded as of the merger closing date at their respective fair values. Under the acquisition method of accounting for the purpose of these unaudited pro forma financial statements, management of Aravas and Savara have determined a preliminary estimated purchase price, calculated as described in Note 2 to these unaudited pro forma condensed combined financial statements. The net tangible assets acquired and liabilities assumed in connection with the transaction are at their estimated acquisition date fair values. A final determination of these estimated fair values will be based on the actual net tangible assets of Savara that exist as of the date of completion of the transaction.

To the extent there are significant changes to the business following completion of the merger, the assumptions and estimates set forth in the unaudited pro forma condensed combined financial statements could change significantly. Accordingly, the pro forma purchase price adjustments are subject to further adjustments as additional information becomes available and as additional analyses are conducted following the completion of the merger. There can be no assurances that these additional analyses will not result in material changes to the estimates of fair value.

2. Preliminary Purchase Price

The preliminary estimated purchase price of the merger is $34.0 million using Savara's share price for its common stock and its common shares outstanding as of the close of business on April 27, 2017. Note that in a reverse merger, the purchase consideration determined under US GAAP will be based on the market capitalization of Savara on the date of the merger. The estimated fair value of the net assets acquired, excluding goodwill is $12.6 million.

Management of Aravas has preliminarily concluded the proposed merger is a business combination and will apply the acquisition method of accounting. Under the acquisition method of accounting, the total purchase price is allocated to the acquired tangible and intangible assets and assumed liabilities of Savara based on their estimated fair values as of the proposed merger closing date. The excess of the purchase price over the fair value of assets acquired and liabilities assumed, if any, is allocated to goodwill. To the extent the actual purchase price varies from the estimated purchase price used in these unaudited pro forma condensed combined financial information, the impact will be an increase or decrease in goodwill.

The preliminary allocation of the estimated total purchase price of the proposed merger is as follows (in thousands):

Fair value of Savara net assets to carry over to merged company	$12,634
Goodwill	21,401
Total purchase consideration	$34,035

The preliminary estimated fair values of the acquired assets and assumed liabilities of Savara as of March 31, 2017 is as follows (in thousands):

Net tangible assets (liabilities)	$ (148)
In-process research and development intangible asset, net of deferred tax liability	12,782
Estimated fair value of net assets acquired	$12,634

The allocation of the estimated purchase price is preliminary. The purchase price allocation will remain preliminary until Aravas's management determines the fair values of assets acquired and liabilities assumed. The final determination of the purchase price allocation is anticipated to be completed as soon as practicable and will be based on the fair values of the assets acquired and liabilities assumed as of the merger closing date. The final amounts allocated to assets acquired and liabilities assumed could differ significantly from the amounts presented in the unaudited pro forma condensed combined financial statements.

3. Pro Forma Adjustments

Pro forma adjustments are necessary to reflect the acquisition consideration exchanged and to adjust amounts related to the tangible assets and liabilities of Savara to reflect the preliminary estimate of their fair values, and to reflect the impact on the statements of operations of the merger as if the companies had been combined during the periods presented therein. The pro forma adjustments included in the unaudited pro forma condensed combined financial statements are as follows:

A. To reflect the elimination of Savara's historical stockholders' equity balances, including accumulated deficit, and to reflect the adjustments to the fair value of Savara's net assets recorded in the preliminary allocation of the estimated total purchase price, at the close of the merger referred to in Note 2 above.

Elimination of Savara's accumulated deficit	$(316,942)
Fair value adjustment to intangible assets (see G below)	18,803
Fair value adjustment to goodwill (see H below)	18,394
Adjustment to deferred tax liability (see I below)	(7,526)
Total	$(287,271)

B. To reflect the reclassification Aravas's par value of common stock and additional paid-in capital in connection with the exchange of Aravas's common stock for Savara's common stock.

C. To reflect the conversion of Aravas's redeemable convertible preferred stock to Aravas common stock and then into shares of Savara common stock.

D. To record $.4 million of estimated transaction costs that were not incurred as of March 31, 2017.

E. To record $1.9 million of severance liabilities in relation to termination of employees of Savara upon consummation of the merger.

F. To reflect the conversion of $4.3 million in aggregate principal of, and accrued interest on, Aravas's convertible notes into approximately 1.1 million shares of Aravas common stock and then into shares of Savara common stock and to reflect the elimination of the put option (redemption feature) on Aravas's convertible notes.

G. To record intangible assets acquired in the merger and eliminate Savara's historical intangible assets.

To record intangible assets acquired in the merger	$21,303
To eliminate historical Savara intangible assets	(2,500)
Total	$18,803

H. To record goodwill as a result of the merger and eliminate Savara's historical goodwill.

To record goodwill acquired in the merger	$21,401
To eliminate historical Savara goodwill	(3,007)
Total	$18,394

I. To eliminate Savara's deferred tax liability related to prior acquisitions that arose from amortizing, for tax purposes, intangible assets from business combination transactions prior to this merger and record deferred tax liability related to the merger (assumes a 40% tax rate applied to intangible assets acquired).

To record net deferred tax liability related to the merger	$8,521
To eliminate deferred tax liabilities related to Savara's intangible assets from prior acquisitions	(995)
Total	$7,526

J. To eliminate nonrecurring transaction costs of $3.7 million and $0.6 million incurred during the three months ended March 31, 2017 and the year ended December 31, 2016, respectively, that are directly related to the merger.

K. The net increase to debt reflects the new debt of $7.5 million incurred to finance the acquisition of Savara, less the effects of extinguishing Savara's outstanding debt of $3.5 million upon consummation of the acquisition.

To record the decrease for extinguishment of existing Savara debt	$(3,513)
To record the increase for issuance of new debt	7,500
Total	$ 3,987

Represents the net increase to interest expense resulting from interest on the new debt to finance the merger and extinguish its existing debt as follows:

	Three months ended March 31, 2017	Year ended December 31, 2016
To eliminate interest expense and amortization of debt issuance costs on outstanding Savara debt	$ (178)	$ (2,053)
To record the interest expense on new WSJ prime + 4.25% debt	157	629
Total	$ (21)	$ (1,424)

4. Serendex's Historical Financial Statements

Schedule 1

Serendex
Statements of Operations
For the Period from January 1, 2016 to July 14, 2016

	January 1, 2016 to June 30, 2016 (1) (2)	July 1, 2016 to July 14, 2016 (1)	US GAAP Adjustments		As Converted to US GAAP	
	DKK	DKK	DKK		DKK	USD
Grant revenue	704	—	(704)	(a)	—	$ —
Operating expenses						
Product development	6,034	3,336	18,014	(a) (b)	27,384	4,102
General and administrative	12,954	4,834	—		17,788	2,665
Total operating expenses	18,988	8,170	18,014		45,172	6,767
Loss from operations	(18,284)	(8,170)	(18,718)		(45,172)	(6,767)
Interest and other income (expense), net	(328)	(59)	—		(387)	(58)
Net loss	(18,612)	(8,229)	(18,718)		(45,559)	$(6,825)

(1) Amounts derived from Serendex's accounting records in accordance with the IFRS as issued by the IASB and have been reclassified to be consistent with the manner in which items are classified in Aravas consolidated statement of operations and comprehensive loss.
(2) Amounts derived from Serendex's historical unaudited condensed financial statements for the six months ended June 30, 2016.

US GAAP Adjustments to Serendex's Historical Financial Statements

On July 15, 2016, Aravas completed the acquisition of Serendex through its wholly-owned subsidiary, Savara ApS. Serendex prepared its financial statements in accordance with the IFRS as issued by the IASB. Included in Schedule 1 above are the US GAAP adjustments to Serendex's historical financial statements for the period from January 1, 2016 to July 14, 2016.

(a) Revenue recognition

i. In accordance with the IFRS as issued by the IASB, revenue generated from sales of active pharmaceutical ingredient (API) to vendors associated with clinical trial studies is recognized as net revenue on the financial statements.

ii. Under US GAAP, revenue generated from sales of API to vendors associated with clinical trial studies would be considered contra-R&D expenses as those revenues were not generated due to commercialized sales to customers.

(b) Research and development costs- capitalization

i. In accordance with the IFRS as issued by the IASB, research and development costs directly and indirectly attributable to development of new products are capitalized as in-process R&D.

ii. Under US GAAP, research and development costs are expensed as incurred.

Translation of Serendex's Historical Financial Statements to US Dollars

The unaudited pro forma condensed combined financial information is presented in US dollars unless otherwise stated, and accordingly, the financial information of Serendex used to prepare the unaudited pro forma condensed combined financial information was translated from Danish Krone to US dollars (Schedule 1) using the following exchange rates, which correspond with the exchange rates for the periods being presented:

Statement of operations for the period from January 1, 2016 to July 14, 2016 (pre -acquisition period): Average for Period 1 = US$.1498

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SAVARA INC.

By: /s/ Dave Lowrance
Dave Lowrance
Chief Financial Officer

Date: June 1, 2017