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)

December 19, 2018

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.)**

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

Item 7.01. Regulation FD Disclosure.

On December 19, 2018, Savara Inc. issued a press release announcing interim results from OPTIMA, a Phase 2a clinical study evaluating its lead product candidate Molgradex for the treatment of nontuberculous mycobacterial (NTM) lung infection. A copy of the press release is filed herewith as Exhibit 99.1.

The information in Item 7.01 and in Exhibit 99.1 furnished herewith shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Savara Inc. dated December 19, 2018

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.

Date: December 19, 2018

SAVARA INC.
a Delaware corporation

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

Exhibit 99.1

SAVARA ANNOUNCES INTERIM RESULTS FOR OPTIMA CLINICAL STUDY OF MOLGRADEX FOR THE TREATMENT OF NTM

AUSTIN, TX – December 19, 2018 – Savara Inc. (Nasdaq: SVRA), an orphan lung disease company, today announced interim results from OPTIMA, a Phase 2a clinical study evaluating its lead product candidate Molgradex, an inhaled formulation of recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of nontuberculous mycobacterial (NTM) lung infection. The ongoing study is evaluating treatment of both *Mycobacterium avium* complex (MAC) infection, and the more difficult-to-treat *Mycobacterium abscessus* (MABSC) infection. Savara believes microbiological data from this early analysis demonstrate an encouraging efficacy signal, with a favorable safety profile.

The interim analysis focused on efficacy, as assessed by microbiological results, in 14 patients who completed the 24-week treatment period and had culture results available up to at least the 16-week timepoint. Ten of the evaluable patients have MAC infection and four have MABSC infection. Of the patients with MAC infection, eight are in treatment Group 1 (on anti-mycobacterial treatment) and two are in treatment Group 2 (not on anti-mycobacterial treatment). The four evaluable MABSC patients are evenly split between both treatment groups. Safety and tolerability was assessed for all 32 patients enrolled in the study.

Summary of Microbiological Data

The data show that among the 10 patients with MAC infection, four experienced a consistent sputum smear conversion to negative by week 24, and three experienced a negative sputum culture at weeks 16 and 20, with culture results pending for the week 24 timepoint. Sputum smear or sputum culture conversions were not observed in the four patients with MABSC infection. Due to the generally slow growth of nontuberculous mycobacteria on culture media, a sputum sample can be determined negative only after eight weeks of observation, causing a corresponding lag time in the assessment of the culture data.

“These early signals of potential efficacy are encouraging, as is the good tolerability and safety profile of Molgradex in patients with refractory NTM lung infection,” said study investigator Rachel Thomson, MBBS PhD., Associate Professor, University of Queensland, Australia. “Importantly, the microbiological responses seem to be associated with improvements in clinical signs and symptoms, and I am keen to see if these responses can be sustained over a longer period of time, and if we will see more of them. Antibiotics currently used with these patients are often poorly tolerated, frequently fail to eradicate the infection and are associated with a high recurrence rate. Based on this interim data review, I am optimistic that Molgradex may help combat NTM infection in a unique way by stimulating the innate immune system in the lungs.”

Summary of Safety Information

Safety was assessed in the total study population. Among the 32 patients, six (19%) experienced serious adverse events (SAEs), including one patient who died by suicide. The death was considered unrelated to treatment. The majority of SAEs consisted of hospitalizations due to pulmonary exacerbations or worsening of NTM infection, of which one was considered possibly treatment-related. GM-CSF was generally well tolerated, with nine patients (28%) reporting mostly mild, potentially treatment-related respiratory adverse events. Respiratory adverse events were defined as shortness of breath, chest tightness or wheeze. A total of three patients (9%) discontinued treatment due to adverse events.

Consistent with the systemic pharmacological effect of GM-CSF on white blood cells, 17 patients (53%) experienced increased levels of blood eosinophils. The increase generally peaked at the week 4 timepoint, and levels decreased or plateaued at subsequent visits.

Based on the microbiological data and safety profile, which provides the basis to continue treating patients for a longer period of time, the duration of the OPTIMA study is extended from 24 to 48 weeks. This increases the ability to observe a more robust anti-infective effect, including culture conversions. Final results from OPTIMA are now expected by the first quarter of 2020.

About the OPTIMA Clinical Study

OPTIMA is an open-label, non-controlled, multi-center, Phase 2a clinical study of Molgradex in 32 subjects (□18 years of age) with persistent pulmonary NTM lung infection. OPTIMA enrolled subjects with chronic *Mycobacterium avium* complex (MAC) infection or *Mycobacterium abscessus* (MABSC) infection, with all patients having either antibiotic refractory infection or intolerance to standard NTM antibiotics. Patients with cystic fibrosis were not enrolled. The study comprises a 48-week treatment period and a 12-week follow up period. Two groups of subjects were recruited into the OPTIMA study. Group 1 consists of patients who remained sputum culture positive while currently on a multidrug NTM guideline-based anti-mycobacterial regimen, which had been ongoing for at least six months prior to the baseline visit. Group 2 consists of patients who remained sputum culture positive, but either stopped a multidrug NTM guideline-based anti-mycobacterial regimen at least 28 days prior to screening due to lack of response or intolerance, or never started such treatment.

The primary endpoint in the study is sputum culture conversion, defined as at least three consecutive sputum samples without growth of nontuberculous mycobacteria. Secondary endpoints include: (i) the number of patients with sputum smear conversion to negative, defined as at least three consecutive negative acid-fast bacilli (AFB) stained sputum smears on microscopy among patients who were smear positive at baseline, (ii) the number of patients with durable sputum culture conversion, defined as sputum culture conversion at or before week 48 and culture still negative for growth of nontuberculous mycobacteria at 12-week follow up, (iii) the number of patients with durable sputum smear conversion, defined as sputum smear conversion at or before week 48 and AFB stained smear still negative for nontuberculous mycobacteria at 12-week follow up among patients who were smear positive at baseline, and (iv) other microbiological indicators, exercise capacities and patient reported outcomes.

About NTM Lung Infection

NTM lung infection is a rare and serious lung disorder associated with increased rates of morbidity and mortality. Nontuberculous mycobacteria are naturally-occurring organisms and NTM lung infection can occur when an individual inhales the organism from the environment and develops a slowly progressive and destructive lung disease. NTM lung infection is typically characterized by cough, fatigue and weight loss. NTM infection often becomes chronic, requires long courses of multiple antibiotics and, despite aggressive treatment regimens, treatment failure rates are high, and recurrence of infection common. Chronic NTM lung infection can have a significant impact on quality of life.

About Savara

Savara is an orphan lung disease company. Savara's pipeline comprises Molgradex, an inhaled granulocyte-macrophage colony-stimulating factor, or GM-CSF, in Phase 3 development for autoimmune pulmonary alveolar proteinosis, or aPAP, in Phase 2a development for nontuberculous mycobacterial, or NTM, lung infection, and in preparation for Phase 2a development in cystic fibrosis, or CF, affected individuals with chronic NTM lung infection; and AeroVanc, a Phase 3 stage inhaled vancomycin for treatment of persistent methicillin resistant staphylococcus aureus, or MRSA, lung infection in CF. Savara's strategy involves expanding its pipeline of potentially best-in-class products through indication expansion, strategic development partnerships and product acquisitions, with the goal of becoming a leading company in its field. The most recent acquisition is aerosolized amikacin/fosfomycin, a Phase 2-ready, proprietary combination antibiotic, which has demonstrated potent and broad-spectrum antibacterial activity against highly drug resistant pathogens. Savara's management team has significant experience in orphan drug development and pulmonary medicine, identifying unmet needs, developing and acquiring new product candidates, and effectively advancing them to approvals and commercialization.

More information can be found at www.savarapharma.com. (Twitter: @SavaraPharma, LinkedIn: www.linkedin.com/company/savara-pharmaceuticals/)

Forward-Looking Statements

Savara cautions you that statements in this press release that are not a description of historical fact are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of words referencing future events or circumstances such as “expect,” “intend,” “plan,” “anticipate,” “believe,” and “will,” among others. Such statements include, but are not limited to, statements regarding Savara’s belief that microbiological data from this early analysis demonstrate an encouraging efficacy signal with a favorable safety profile, that the early signals of potential efficacy are encouraging, as is the good tolerability and safety profile of Molgradex in patients with refractory NTM lung infection, that the microbiological responses seem to be associated with improvements in clinical signs and symptoms, statements regarding the interest in seeing if these responses can be sustained over a longer period of time and if we will see more of them, statements regarding optimism that based on this interim data review Molgradex may help combat NTM infection in a unique way by stimulating the innate immune system in the lungs, that the microbiological data and safety profile provides a basis to continue treating patients for a longer period of time, statements regarding the duration of the OPTIMA study, that the increase in the duration of the OPTIMA study increases the ability to observe a more robust anti-infective effect, including culture conversions, statements regarding the timing of final results from the OPTIMA study, and Savara’s strategy. Savara may not actually achieve any of the matters referred to in such forward-looking statements, and you should not place undue reliance on these forward-looking statements. These forward-looking statements are based upon Savara’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with the outcome of our ongoing and planned clinical trials for our product candidates (including the OPTIMA clinical study), the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the availability of sufficient resources for Savara’s operations and to conduct or continue planned clinical development programs (including the OPTIMA clinical study), the ability to obtain the necessary patient enrollment for our product candidates in a timely manner, the ability to successfully identify product acquisition candidates, the ability to successfully develop our product candidates, the risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates such as Molgradex, AeroVanc and amikacin/fosfomycin that are safe and effective for use as human therapeutics and the timing and ability of Savara to raise additional equity capital as needed to fund continued operations. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. For a detailed description of our risks and uncertainties, you are encouraged to review our documents filed with the SEC including our recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Savara undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as may be required by law.

Contacts:

Savara, Inc. IR:
Ioana C. Hone (ir@savarapharma.com)
(512) 961-1891

Savara, Inc. PR and Media:
Anne Erickson (anne.erickson@savarapharma.com)
(512) 851-1366

For IR: Solebury Trout
Gitanjali Jain Ogawa (Gogawa@troutgroup.com)
(646) 378-2949

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