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)

October 24, 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. ☐

Item 8.01. Other Events.

On October 24, 2017, Savara Inc. issued a press release regarding its product candidate Molgradex. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Savara Inc. dated October 24, 2017

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: October 24, 2017

SAVARA INC.
a Delaware corporation

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

Exhibit 99.1

SAVARA ANNOUNCES EXPANSION OF MOLGRADEX DEVELOPMENT TO INCLUDE TREATMENT OF NONTUBERCULOUS MYCOBACTERIAL (NTM) LUNG INFECTION

Company Anticipates Phase 2a Clinical Trial Will Begin in Early 2018

AUSTIN, TX – October 24, 2017 - Savara Inc. (NASDAQ: SVRA), an orphan lung disease company, today announced its indication expansion strategy of 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. Molgradex is currently being investigated in a pivotal Phase 3 clinical trial (IMPALA) for the treatment of autoimmune pulmonary alveolar proteinosis (PAP). Preparations are currently underway and the company plans to initiate a Phase 2a multi-center clinical trial in subjects with antibiotic-resistant NTM lung infection in early 2018.

"Our goal is to build Savara into a leading specialty pharmaceutical company in the field of orphan lung diseases and we are excited to announce the indication expansion of Molgradex for the treatment of NTM, a serious lung infection affecting tens of thousands of individuals in the United States," stated Rob Neville, Chief Executive Officer of Savara. "Resistance to antibiotics in general is an increasing problem globally, and we are thrilled to embark on this new project targeting NTM lung infection with a very novel approach that targets the lungs' immune cells and can avoid the problems of antibiotic resistance."

"Treatment of pulmonary NTM infection is difficult using multi-drug antibiotic regimens with significant burden, toxicity, and frequent failure of achieving eradication," stated Mark E. Wylam, M.D., Pulmonologist and Critical Care Specialist at Mayo Clinic, Rochester, MN. "In my review of the scientific literature on the role of GM-CSF on macrophage function, there is a strong rationale for the potential clinical utility of GM-CSF to enhance innate immunity against NTM infection. Based on the promising outcomes of the first clinical cases treated with inhaled GM-CSF, I believe Molgradex has the potential to help eradicate NTM lung infection, including *Mycobacterium abscessus*, with or without the concomitant use of antibiotics by stimulation of the innate immune system in the lungs."

Nontuberculous mycobacterial lung infections are a considerable therapeutic challenge due to the unique ability of these bacteria to evade the normal killing mechanisms of alveolar macrophages, a type of immune cells responsible for killing bacteria in the lungs. There is increasing scientific literature suggesting that GM-CSF plays an important role in enhancing the ability of macrophages to clear mycobacteria. For instance, GM-CSF knock out mice inoculated with *Mycobacterium abscessus* develop a chronic lung disease resembling human chronic infection, whereas wild type mice with intact GM-CSF production typically clear the bacteria quickly, and fail to develop chronic infection. In animal studies, GM-CSF has been shown to kill NTM with similar efficacy compared to commonly used NTM antibiotics, and the simultaneous use of GM-CSF with antibiotics can further improve the antibacterial effect of either GM-CSF or antibiotics given alone. In two thus far unpublished clinical case reports, inhaled GM-CSF was shown to eradicate or dramatically reduce the bacterial burden in patients with refractory *M. abscessus* lung infection, which suggests the promising animal data may be translatable to humans, and that the potential therapeutic role of GM-CSF in NTM lung infection warrants more intensive investigation. Among the various NTM species, *M. abscessus* is a particularly challenging clinical problem, being one of the most resistant organisms to antibiotics. Importantly, GM-CSF is not an antibiotic, but instead targets the human immune response, not the bacteria directly, thus avoiding the increasing problem of antibiotic resistance.

About the Phase 2 NTM Clinical Trial

The Phase 2a clinical trial, expected to begin in early 2018, will be conducted at multiple centers and will investigate the efficacy of Molgradex on NTM sputum culture conversion to negative, reduction of NTM bacterial load in sputum, exercise capacity as well as its effect on patient reported outcomes, and safety. Treatment in the Phase 2a clinical trial will consist of 24 weeks of treatment and a follow-up of 12 weeks after end of treatment. The primary endpoint will be sputum culture conversion during the treatment period defined as at least three consecutive negative sputum samples.

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 their environment and develop a slowly progressive and destructive lung disease. NTM lung infection is typically characterized by cough, fatigue, and weight loss. NTM infections often become chronic and require long courses of multiple antibiotics, and despite the 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. There are approximately 50,000 to 80,000 individuals affected by NTM lung infection in the U.S, the most common types involving *Mycobacterium avium* complex (MAC), and *Mycobacterium abscessus*. There have been few advancements in new systemic treatments for NTM lung infection. However, in a recent Phase 3 clinical trial by Insmed (NASDAQ: INSM), local delivery of an inhaled form of amikacin directly to the lung was shown to be effective in approximately one third of treatment refractory patients with pulmonary MAC infection, suggesting administration of high local concentrations of drug directly at the site of infection provides an attractive new avenue to improve clinical outcomes in this and other difficult to treat chronic lung infections.

About Molgradex

Molgradex, an inhaled formulation of recombinant human GM-CSF, is being developed for the treatment of autoimmune pulmonary alveolar proteinosis, or PAP, and Nontuberculous Mycobacterial, or NTM, lung infection**.** Molgradex is currently being investigated in a pivotal Phase 3 clinical trial, IMPALA, for the treatment of PAP and is in preparation for Phase 2a development for NTM. Molgradex has been granted Orphan Drug Designation for the treatment of PAP in the United States and the European Union.

About Savara

Savara Inc. is a clinical-stage specialty pharmaceutical company focused on the development and commercialization of novel therapies for the treatment of serious or life-threatening rare respiratory diseases. Savara's pipeline comprises: Molgradex, an inhaled granulocyte-macrophage colony-stimulating factor, or GM-CSF, in Phase 3 development for PAP and in preparation for Phase 2a development for NTM lung infection; AeroVanc, a Phase 3 stage inhaled vancomycin for treatment of MRSA infection in Cystic Fibrosis; and, Aironite, an inhaled sodium nitrite for HFpEF in Phase 2 development. 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. Savara's management team has significant experience in orphan drug development and pulmonary medicine, in 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)

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, our plans to initiate a Phase 2a multi-center clinical trial in subjects with antibiotic-resistant NTM infection in early 2018, our goal of building Savara into a leading specialty pharmaceutical company in the field of orphan lung diseases, being excited to announce the expansion of Molgradex for the treatment of NTM, that resistance to antibiotics in general is an increasing problem globally, that we are thrilled to embark on this new project

targeting NTM lung infection with a very novel approach that targets the lungs' immune cells and can avoid the problems of antibiotic resistances, that treatment of pulmonary NTM infection is difficult using multi-drug antibiotic regimens with significant burden, toxicity, and frequent failure of achieving eradication, that there is a strong rationale for the potential clinical utility of GM-CSF to enhance innate immunity against NTM infection, that GM-CSF plays an important role in enhancing the ability of macrophages to clear mycobacteria, the promising outcomes of the first clinical cases treated with inhaled GM-CSF, the belief that Molgradex has the potential to help eradicate NTM infection with or without the concomitant use of antibiotics and that administration of high local concentrations of drug directly at the site of infection provides an attractive new avenue to improve clinical outcomes in this and other difficult to treat chronic lung infections. 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. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such 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 clinical trials for our product candidates (including our planned Phase 2a clinical trial of Molgradex for the treatment of NTM), 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 our Phase 2a clinical trial of Molgradex for the treatment of NTM), the ability to obtain the necessary patient enrollment for our Molgradex Phase 2a clinical trial for the treatment of NTM and for our other product candidates and indications in a timely manner, the timing and ability of Savara to raise additional equity capital to fund continued operations; the ability to successfully develop our product candidates, and the risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates such as Molgradex, AeroVanc and Aironite that are safe and effective for use as human therapeutics. 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.
Ioana C. Hone (ir@savarapharma.com)
(512) 961-1891

The Trout Group
Kelly Mueller (kmueller@troutgroup.com)
(646) 378-2965

For Media:
LaVoieHealthScience
Andrew Mastrangelo
amastrangelo@lavoiehealthscience.com
(617) 374-8800, ext. 108

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