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)

July 25, 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 8.01. Other Events.

On July 25, 2018, Savara Inc. issued a press release providing an update on the clinical development and commercial preparatory efforts for its lead product candidate Molgradex, an inhaled formulation of recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF). A copy of the press release is filed herewith as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Savara Inc. dated July 25, 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: July 25, 2018

SAVARA INC.
a Delaware corporation

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

Exhibit 99.1

SAVARA PROVIDES POSITIVE UPDATE ON DEVELOPMENT AND COMMERCIAL PREPARATIONS OF MOLGRADEX, INCLUDING EXPANSION INTO NTM IN CF

Acquires assets of Cardeas and Announces Appointment of A. Bruce Montgomery, M.D., As Strategic Advisor

AUSTIN, TX – July 25, 2018 – Savara Inc. (Nasdaq: SVRA), an orphan lung disease company, today provided an update on the clinical development and commercial preparatory efforts for its lead product candidate Molgradex, an inhaled formulation of recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF). In addition, Savara is expanding its Molgradex nontuberculous mycobacteria (NTM) program with a new study in the U.S. in cystic fibrosis (CF) affected individuals with chronic NTM lung infection. The Company also announced its acquisition of the assets of Cardeas Pharma Corporation as part of its launch of an exploratory product pipeline comprising pre-proof-of-concept, high-potential programs focused on difficult-to-treat lung diseases, and the appointment of Dr. A. Bruce Montgomery as a strategic advisor.

Molgradex Program Update

IMPALA and IMPALA-X Clinical Studies

Savara's pivotal Phase 3 IMPALA study is evaluating Molgradex for the treatment of autoimmune pulmonary alveolar proteinosis, or aPAP. Completion of patient enrollment remains on track for the third quarter of 2018 and topline data are anticipated in the second quarter of 2019. The IMPALA study includes a six-month placebo-controlled period with 2:1 randomization on Molgradex or placebo, followed by a six-month open-label period with all subjects receiving Molgradex. Earlier this year, the Company launched the IMPALA-X study, an open-label, multicenter study designed to evaluate the long-term use of Molgradex in patients with aPAP. The IMPALA-X study offers patients completing the IMPALA study the opportunity to continue treatment with Molgradex for up to three additional years.

Savara is encouraged by positive investigator feedback on treatment with Molgradex in the IMPALA study as well as the high interest in participation in the IMPALA-X study. The Company believes high enrollment into the IMPALA-X study gives important insight into the level of satisfaction with Molgradex. Of the 14 subjects eligible to enroll in the IMPALA-X study by the end of the second quarter of 2018, ten subjects have enrolled to date, while the remaining four subjects are expected to be enrolled upon delivery of the study drug to their clinical sites.

Driven by its confidence in the outcome of the IMPALA study, the Company will expedite its preparation for potential commercial launch by starting investments into core commercial staff and external activities required for timely launch, subject to product approval by the FDA. The Company believes that robust results in the IMPALA study would make Molgradex eligible for designation as a breakthrough therapy and facilitate the submission of the Molgradex Biologic License Application, or BLA, in the first half of 2020, with an anticipated commercial launch in late 2020 or early 2021.

"This business update on Molgradex emphasizes the gradual inclusion of a strong commercial focus within Savara in addition to our activities in product development, and it represents an important step in our evolution towards a fully integrated pharmaceutical company with our own product revenues," stated Rob Neville, Chief Executive Officer of Savara.

Phase 2a Open-Label Clinical Study in Cystic Fibrosis Affected Individuals With NTM

Savara is currently conducting a Phase 2a open-label clinical study, OPTIMA, evaluating Molgradex for the treatment of NTM lung infection. The OPTIMA study excludes CF affected individuals. Interim results are expected in the fourth quarter of 2018 with top line results expected in the second quarter of 2019.

The Company is now preparing to initiate a new study in the U.S. in CF affected individuals with chronic NTM infection. This Phase 2a open-label study will enroll 30 subjects with CF and chronic NTM lung infection, and is planned to begin in the first quarter of 2019. The study will enroll subjects with chronic *Mycobacterium abscessus (M. abscessus)* or *Mycobacterium avium* complex (MAC) infection. The study will comprise a 48-week treatment period and a 24-week follow-up period, and three subgroups of subjects will be recruited into the study. Group 1 will consist of subjects who have been on antimycobacterial treatment for at least six months prior to the baseline visit. Group 2 will consist of subjects who have stopped antimycobacterial treatment due to intolerance or lack of effect prior to the baseline visit. Group 3 will consist of subjects who have not been treated with antimycobacterial treatment but are clinically stable prior to the baseline visit.

The primary endpoint in the study will be NTM sputum culture conversion to negative (3 negative samples 4 weeks apart). Secondary endpoints include: (i) consistent NTM sputum culture conversion until end of treatment; (ii) sputum smear conversion/reduction in count of acid-fast bacilli (AFB); (iii) durable conversion (culture/smear) after end of treatment; (iv) change in pulmonary function; (v) change in respiratory symptom score; (vi) change in body mass index.

Exploratory Product Pipeline

As part of its growth strategy, Savara has launched an exploratory product pipeline comprising pre-proof-of-concept, high-potential programs focused on difficult-to-treat lung diseases. As the first new product in the exploratory pipeline, Savara acquired the rights to amikacin/fosfomycin inhalation solution, a Phase 2 ready product candidate that had been in development by Cardeas Pharma Corporation for the treatment of ventilator associated pneumonia.

Following the acquisition, Savara appointed A. Bruce Montgomery, M.D., a leading pioneer in the field of inhaled antibiotics and other orphan lung disease products, as a strategic advisor to support Savara's ongoing development programs as well as the growth of its exploratory pipeline. The Company anticipates investing initially up to $5 million to $10 million per year in its exploratory pipeline, which pipeline could eventually prove to be transformational to the Company's future growth.

"I am excited to become an advisor to Savara at such an important time in the Company's development," said Dr. Montgomery. "I believe the results of the planned and underway clinical trials in multiple rare lung diseases will go far to meet Savara's vision of becoming "The Orphan Lung Disease Company". I have provided input on the development of Molgradex and AeroVanc for many years and look forward to assisting Savara's team with these programs that address unmet medical needs. In addition, I look forward to assisting the Company in identifying and evaluating new impactful products to help fuel the Company's growth."

Aerosolized amikacin/fosfomycin is a proprietary combination antibiotic that has demonstrated potent and broad-spectrum antibacterial activity in highly drug resistant pathogens, with promising applications in the intensive care unit (ICU) setting. In particular, multi-drug resistant Gram-negative infections in the ICU continue to be associated with significant mortality and require new innovative treatments. In this context, the potential to combine locally administered antibiotics with Molgradex's localized stimulation of the innate immune system—an anti-infective immunotherapy—is a new approach that could represent the beginning of a paradigm shift in the treatment of refractory lung infection.

"The expansion of our NTM program, and the launch of our exploratory pipeline underline our commitment to growth through innovation and acquisition," said Dr. Taneli Jouhikainen, President and COO of Savara. "We are delighted to have Dr. Montgomery—one of the most accomplished entrepreneurs in our field—join us on this exciting journey. Dr. Montgomery is a leading innovator in inhaled antibiotics and orphan lung diseases in general, and we are proud to welcome him to assist our team."

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 and in Phase 2a development for nontuberculous mycobacteria, or NTM lung infection; and AeroVanc, a Phase 3 stage inhaled vancomycin for treatment of persistent methicillin resistant staphylococcus aureus, or MRSA, lung infection in cystic fibrosis, or 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. 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)

About A. Bruce Montgomery

Dr. Montgomery is a board-certified internist and pulmonologist with more than 35 years of drug development and general management experience in the pharmaceutical industry, including positions at Genentech, Inc., PathoGenesis Corporation, Corus Pharma and Gilead Sciences, Inc. Prior to founding Cardeas, Dr. Montgomery served five years as senior vice president of Gilead and six years as chief executive officer of Corus Pharma, a specialized biotechnology company that he founded to develop Cayston, an inhaled antibiotic treatment for individuals affected by CF. Corus Pharma was subsequently acquired by Gilead, where Dr. Montgomery successfully completed the development and commercial launch of Cayston. Dr. Montgomery also served as executive vice president of Research and Development at PathoGenesis Corporation until its acquisition by Chiron Corporation in 2000. At PathoGenesis, Dr. Montgomery led the development of the first ever FDA approved inhaled antibiotic, TOBI, which has since then become the cornerstone of chronic antibiotic treatment in individuals with CF. In the 1980s, Dr. Montgomery co-invented aerosolized pentamidine, a prophylaxis for Pneumocystis carinii pneumonia (PCP), then the most common cause of death in patients with acquired immunodeficiency syndrome (AIDS) and is the inventor of 28 U.S. patents. He has served as a board member for ZymoGenetics, Inc. and is currently on the Board of Alder Biopharmaceuticals and Xencor, Inc.

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 relating to being encouraged by positive investigator feedback for treatment with Molgradex in the IMPALA study as well as the high interest in participation in the IMPALA-X study, our belief that high enrollment into the IMPALA-X study gives important insight into the level of satisfaction with Molgradex, that the remaining four subjects are expected to be enrolled upon delivery of the study drug to their clinical sites, our confidence in the outcome of the IMPALA study, that we will expedite our preparation for potential commercial launch, our belief that robust results in the IMPALA study would make Molgradex eligible for designation as a breakthrough therapy, and facilitate the submission of the Molgradex BLA, in the first half of 2020 with an anticipated commercial launch in late 2020 or early 2021, that this business update on Molgradex emphasizes the gradual inclusion of a strong commercial focus within Savara and represents an important step in our evolution towards a fully integrated pharmaceutical company with our own product revenues, that the Phase 2a open-label study will enroll 30 subjects with CF and chronic NTM lung infection, and is planned to begin in the first quarter of 2019, that interim results are expected in the fourth quarter of 2018 with top line results in the second quarter of 2019, anticipating investing initially up to $5 million to $10 million per year in an exploratory pipeline, that such pipeline could eventually prove to be transformational to the Company's future growth, belief that the results of the planned and underway proof of concept clinical trials in multiple rare lung diseases will go far to meet Savara's vision of becoming "The Orphan Lung Disease Company," look forward to assisting Savara's team with these programs and identifying and

evaluating new impactful products to help fuel the company's growth. 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 and planned clinical trials for our product candidates, , the ability to successfully identify exploratory product pipeline candidates, the ability to successfully execute our strategy for amikacin/fosfomycin, 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, the ability to obtain the necessary patient enrollment for our product candidates in a timely manner, 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:
Ioana C. Hone (ir@savarapharma.com)
(512) 961-1891

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

For Media: Neon Interactive
Patrick Wallace (patrick@neoninteractive.com)
(619) 200-7856

###