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) August 9, 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 2.02. Results of Operations and Financial Condition.

On August 9, 2018, Savara Inc. issued a press release announcing its financial results for the quarter ended June 30, 2018. A copy of the press release is furnished as Exhibit 99.1 to this report.

The information pursuant to Item 2.02 in this report on Form 8-K is being furnished as contemplated by General Instruction B(2) to Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Savara Inc. dated August 9, 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: August 9, 2018

SAVARA INC.
a Delaware corporation

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

SAVARA REPORTS SECOND QUARTER 2018 FINANCIAL RESULTS AND PROVIDES POSITIVE BUSINESS UPDATE

- **Molgradex Phase 3 IMPALA study enrollment on track for completion in Q3 2018**
- **AeroVanc Phase 3 AVAIL study enrollment on track for completion in Q1 2019**
- **Molgradex Phase 2a OPTIMA study enrollment on track for completion in Q3 2018; Interim results expected in Q4 2018**
- **Molgradex commercialization preparations underway**
- **Launched exploratory product pipeline**
- **Conference call scheduled for today at 5:30 p.m. E.T.**

AUSTIN, TX – August 9, 2018—Savara Inc. (NASDAQ: SVRA), an orphan lung disease company, today reported financial results for the second quarter ended June 30, 2018 and provided a business update.

"We have had an incredibly eventful and productive quarter," said Rob Neville, chief executive officer of Savara. "With two product candidates approaching pivotal data reads and our exploratory NTM program well underway, we believe we are heading into the most exciting twelve months in Savara's history. Furthermore, the recent acquisition of the assets of Cardeas Pharma Corporation underlines our commitment to our vision to build a prominent orphan lung disease company. With the closing of our recent public offering, we have initiated preparations for Molgradex commercial launch for aPAP, as well as for a new clinical study in CF-affected individuals with chronic NTM infection, and will support our exploratory pipeline."

Upcoming Milestones and Recent Developments

- **Anticipating completion of enrollment in the Molgradex Phase 3 IMPALA study in Q3 2018.** The IMPALA study is evaluating our inhaled formulation of granulocyte-macrophage colony-stimulating factor, or GM-CSF, for the treatment of autoimmune pulmonary alveolar proteinosis, or aPAP. At the end of Q2, enrollment was at 106 patients out of a total target of 135 patients, with completion of enrollment currently on track for Q3 2018 and topline data anticipated in Q2 2019.

- **Encouraging patient enrollment in the Molgradex IMPALA-X safety extension study**. The IMPALA-X study is an open-label, multicenter study designed to determine the long-term safety and utilization of Molgradex in patients with aPAP. IMPALA-X offers patients the opportunity to continue treatment with Molgradex for up to three years after completion of the pivotal Phase 3 IMPALA study. Of the 14 subjects eligible to enroll into IMPALA-X at the end of Q2, 12 have enrolled to date, while the remaining 2 subjects are expected to enroll shortly.

- **Anticipating completion of enrollment in the Molgradex Phase 2a OPTIMA study in Q3 2018.** The OPTIMA study is evaluating our inhaled GM-CSF for the treatment of nontuberculous mycobacterial (NTM) lung infection. At the end of Q2, enrollment was at 17 patients out of a total target of 30 patients, and completion of enrollment remains on track for Q3 2018. Interim results are anticipated in Q4 2018, and topline data anticipated in Q2 2019.

- **Anticipating completion of enrollment in the AeroVanc Phase 3 AVAIL study in Q1 2019.** The AVAIL study is evaluating our vancomycin hydrochloride inhalation powder for the treatment of persistent methicillin-resistant *Staphylococcus aureus* (MRSA) lung infection in individuals affected by cystic fibrosis. At the end of Q2, enrollment was at 107 patients out of a total target of 200 patients, with completion of enrollment currently on track for Q1 2019 and topline data anticipated in H2 2019.

- **Provided positive update on the development and commercialization of Molgradex.** Savara has received positive investigator feedback on treatment with Molgradex in the open label portion of the IMPALA study, as well as a high interest in participation in the IMPALA-X study. The Company believes the high enrollment rates into the IMPALA-X study gives important insight into the level of satisfaction with Molgradex. Driven by its confidence in the outcome of the IMPALA study, Savara will expedite its preparation for potential commercial launch with investments into core commercial leadership and staff, as well as external activities required for a successful launch. Assuming robust results from the IMPALA study and subsequent breakthrough and/or fast track designation, submission of the Molgradex Biologic License Application, or BLA, is anticipated in the first half of 2020, with a resultant commercial launch in late 2020 or early 2021.

- **Announced expansion of the Molgradex program, with a Phase 2a clinical study in the U.S. in CF-affected individuals with chronic NTM lung infection expected to begin in Q1 2019**. Savara is preparing to initiate a new open-label study in the U.S., which will enroll 30 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. The primary endpoint in the study will be NTM sputum culture conversion to negative.

- **Launched exploratory product pipeline, announced the acquisition of the assets of Cardeas Pharma Corporation and the appointment of A. Bruce Montgomery, M.D., as strategic advisor.** As part of Savara's commitment to growth through innovation and acquisition, the Company launched its exploratory pipeline, focused on pre-proof-of-concept, high-potential programs in difficult-to-treat lung diseases, and announced the acquisition of Cardeas Pharma's Phase 2 ready aerosolized amikacin/fosfomycin, a proprietary combination antibiotic. In connection with the acquisition, Savara appointed Dr. A. Bruce Montgomery, a leading pioneer in the field of inhaled antibiotics and other orphan lung disease products, as strategic advisor.

- **Successfully closed a public offering with gross proceeds of approximately $48.9 million.** The offering was led largely by existing shareholders along with new institutional healthcare investors. The proceeds of the offering will be used for working capital and general corporate purposes, including helping to fund commercial preparatory efforts for Molgradex in aPAP, launching a new clinical study in CF-affected individuals with chronic NTM infection, and supporting Savara's exploratory pipeline.

Second Quarter Financial Results

Savara's net loss attributable to common shareholders for the three months ended June 30, 2018 was $11.6 million, or $(0.38) per share, compared with a net loss attributable to common shareholders of $12.5 million, or $(0.90) per share, for the three months ended June 30, 2017.

Research and development expenses were $9.3 million for the three months ended June 30, 2018, compared with $4.2 million for the three months ended June 30, 2017. This increase was due to several factors, including $2.3 million in additional expenses associated with the AeroVanc Phase 3 study activities; $1.8 million in development costs of Molgradex, including the expansion of the aPAP study in the U.S. and costs associated with the Phase 2 NTM study; and $1 million in expense related to the acquisition of assets from Cardeas.

General and administrative expenses for the three months ended June 30, 2018 were $2.5 million, compared with $5.1 million for the three months ended June 30, 2017. For the three months ended June 30, 2017, the Company recorded a $1.9 million change in fair value of the contingent consideration associated with its acquisition of Serendex compared to only $0.1 million for the three months ended June 30, 2018. In the second quarter of 2017, the Company incurred $1.7 million in expense associated with its merger transaction with Mast Therapeutics, Inc. (the "Merger") in April 2017, none of which was incurred in the second quarter of 2018. In the second quarter of 2018, Savara incurred approximately $0.9 million in additional costs related to personnel and other expenditures associated with public company requirements and activities. Other expense decreased by $2.7 million for the three months ended June 30, 2018 as compared to the same period in 2017. This decrease was primarily due to the second quarter of 2017 having $1.8 million of expense associated with the extinguishment of certain pre-Merger convertible promissory notes.

As of June 30, 2018, Savara had a debt balance of approximately $15.0 million and had cash, cash equivalents and short-term investments of approximately $74.8 million.

Conference Call and Webcast
Savara will hold a conference call today beginning at 5:30pm Eastern Time / 4:30pm Central Time to provide a business update. Shareholders and other interested parties may access the conference call by dialing (855) 239-3120 from the U.S., (855) 669-9657 from Canada, and (412) 542-4127 from elsewhere outside the U.S. and request the Savara Inc. call. A live webcast of the conference call will be available online in the Investors section of Savara's website at http://www.savarapharma.com/investors/events/. Replays of the webcast will be available on Savara's website for 30 days and a telephone replay will be available through August 16, 2018 by dialing (877) 344-7529 from the U.S., (855) 669-9658 from Canada, and (412) 317-0088 from elsewhere outside the U.S. and entering replay access code 10122221.

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 mycobacteria, 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)

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 our two product candidates approaching pivotal data reads and our exploratory NTM program being well underway, our belief that we are heading into the most exciting twelve months in Savara's history, that the recent acquisition of the assets of Cardeas Pharma Corporation underlines our commitment to our vision to build a prominent orphan lung disease company, that we will support our exploratory pipeline, the timing of topline data or interim results and completion of enrollment of our Molgradex Phase 3 IMPALA, Molgradex IMPALA-X safety extension, Molgradex Phase 2a OPTIMA, and AeroVanc Phase 3 AVAIL studies, that the remaining 2 subjects are expected to enroll shortly in the IMPALA-X safety extension study, statements relating to 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, statements related to Savara's confidence in the outcome of the IMPALA study, that we will expedite preparation for potential commercial launch with investments into core commercial leadership and staff, as well as external activities required for a successful launch, our belief that, assuming robust results in the IMPALA study and subsequent breakthrough and/or fast track designation, submission of the Molgradex BLA is anticipated in the first half of 2020 with a resultant commercial launch in late 2020 or early 2021, that Savara is preparing to initiate a new open-label study in the U.S., which will enroll 30 subjects with chronic *Mycobacterium abscessus (M. abscessus)* or *Mycobacterium avium* complex (MAC) infection, statements related to the use of proceeds of the public offering, and our strategy and goals. 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, 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 identify exploratory product pipeline 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 if 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

Tables to follow

Savara Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
Research and development	9,268	4,164	17,807	7,111
General and administration	2,486	5,088	4,254	6,924
Impairment of acquired IPR&D	—	—	21,692	—
Depreciation	153	91	260	181
Total operating expenses	11,907	9,343	44,013	14,216
Loss from operations	$ (11,907)	$ (9,343)	$ (44,013)	$ (14,216)
Interest and other (expense)/income, net	36	(2,631)	(185)	(2,968)
Loss before income taxes	$ (11,871)	$ (11,974)	$ (44,198)	$ (17,184)
Income tax benefit	277	470	5,756	707
Net loss	$ (11,594)	$ (11,504)	$ (38,442)	$ (16,477)
Other expenses attributable to common shareholders	—	(958)	—	(982)
Net loss attributable to common shareholders	$ (11,594)	$ (12,462)	$ (38,442)	$ (17,459)
Net loss per share – basic and diluted	$ (0.38)	$ (0.90)	$ (1.26)	$ (2.06)
Weighted average common shares – basic and diluted	30,658,494	13,807,861	30,601,425	8,465,053

Savara Inc. and Subsidiaries
Condensed Consolidated Balance Sheet data
(In thousands)
(Unaudited)

	June 30, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	$ 74,755	$ 94,313
Working capital	69,915	91,849
Total assets	117,941	159,628
Total liabilities	35,232	40,319
Stockholders' equity	82,709	119,309

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