
**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) May 9, 2018

SAVARA INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-32157
(Commission
File Number)

84-1318182
(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 May 9, 2018, Savara Inc. issued a press release announcing its financial results for the quarter ended March 31, 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 May 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: May 9, 2018

SAVARA INC.
a Delaware corporation

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



**SAVARA REPORTS FIRST QUARTER 2018 FINANCIAL RESULTS
AND PROVIDES 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**
 - **First patient enrolled in Molgradex IMPALA-X safety extension study**
 - **Conference call scheduled for today at 5:30 p.m. E.T.**

AUSTIN, TX – May 9, 2018 - [Savara Inc.](#) (NASDAQ: SVRA), an orphan lung disease company, today reported financial results for the first quarter ended March 31, 2018 and provided a business update.

“It has been an incredibly productive quarter, including the launch of two new clinical studies, [OPTIMA](#) and [IMPALA-X](#), with our lead product candidate Molgradex,” stated Rob Neville, chief executive officer of Savara. “With a total of four ongoing clinical studies, our focus for the remainder of the year will continue to be the advancement of our core programs, while actively exploring the further expansion of our 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 Q1, enrollment was at 96 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.
- **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 living with cystic fibrosis. At the end of Q1, enrollment was at 62 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.
- **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. The study was initiated in mid-March 2018 and is expected to be completed in Q3 2018. As OPTIMA is an open-label study, depending on enrollment and other factors, interim results from the study may be provided during 2018.
- **Announcing first patient enrolled 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. Savara plans to initiate the IMPALA-X study in a rolling fashion in 12 of the countries participating in the IMPALA study by the end of 2018.

First Quarter Financial Results

Savara’s net loss attributable to common shareholders for the three months ended March 31, 2018 was \$26.8 million, or \$(0.88) per share, compared with a net loss attributable to common shareholders of \$5.0 million, or \$(1.65) per share, for the first quarter of 2017, which represents the historical financial information of the private company Savara Inc., which completed its merger transaction with Mast Therapeutics, Inc. on April 27, 2017 (the “Merger”).

Research and development expenses were \$8.5 million for the three months ended March 31, 2018, compared with \$2.9 million for the first quarter of 2017. The increase was primarily due to \$2.7 million in increased expenses associated with the development of Molgradex, including the expansion of the IMPALA study in the U.S. and other countries and the commencement of the Molgradex NTM study, an increase of \$2.2 million in AeroVanc study costs related to Phase 3 activities, and \$0.7 million related to non-recurring milestone payments relating to the Aironite study acquired in the Merger, which was not a part of our product pipeline in the first quarter of 2017.

General and administrative expenses for the three months ended March 31, 2018 were \$1.8 million, compared with \$1.7 million for the first quarter of 2017.

Also, during the three months ended March 31, 2018, we recognized a one-time noncash impairment charge of \$21.7 million to the carrying value of IPR&D related to the Aironite product candidate assumed in the Merger due to the unfavorable results from a Phase 2 study in which Aironite failed to meet the endpoints of the study and showed limited effectiveness in patients. We do not intend to further support or pursue the development of Aironite.

We reported a \$4.6 million tax benefit for the first quarter of 2018 related to the reversal of a deferred tax liability resulting from the impairment of IPR&D acquired in the Merger.

As of March 31, 2018, Savara had cash, cash equivalents and short-term investments of approximately \$85.0 million. The company's operating expenses for the first quarter of 2018 were approximately \$32.1 million which included the one-time noncash impairment charge of \$21.7 million to the carrying value of IPR&D acquired in the Merger. Savara ended the first quarter of 2018 with approximately \$14.9 million in debt.

Conference Call and Webcast

Savara will hold a conference call today beginning at 5:30 p.m. Eastern Time / 4:30 p.m. 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 should request the Savara Inc. call. A live webcast of the conference call will be available online from 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 May 16th, 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. by entering replay access code 10119917.

About Savara

Savara Inc. 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 aPAP, and in Phase 2a development for NTM lung infection; and AeroVanc, a Phase 3 stage inhaled vancomycin for treatment of MRSA infection in cystic fibrosis. 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](https://twitter.com/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 relating to our focus for the remainder of the year being on the continued advancement of our core programs and actively exploring further expansion of our pipeline, the timing of topline data or interim results and completion of enrollment of our Molgradex Phase 3 IMPALA, AeroVanc Phase 3 AVAIL and Molgradex Phase 2a OPTIMA studies, our plans to initiate the IMPALA-X study in 12 of the countries participating in the IMPALA study by the end of 2018, and our strategy and our 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 develop our product candidates, the risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates such as Molgradex and AeroVanc 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.

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Tables to follow

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

	Three months ended March 31, (Unaudited)	
	2018	2017
Operating expenses:		
Research and development	8,539	2,948
General and administration	1,769	1,736
Impairment of acquired IPR&D	21,692	—
Depreciation	107	90
Total operating expenses	<u>32,107</u>	<u>4,774</u>
Loss from operations	\$ (32,107)	\$ (4,774)
Interest and other (expense)/income, net	(221)	(437)
Loss before income taxes	\$ (32,328)	\$ (5,211)
Income tax benefit	5,479	237
Net loss	\$ (26,849)	\$ (4,974)
Other expenses attributable to common shareholders	—	(24)
Net loss attributable to common shareholders	<u>\$ (26,849)</u>	<u>\$ (4,998)</u>
Net loss per share - basic and diluted	<u>\$ (0.88)</u>	<u>\$ (1.65)</u>
Weighted average common shares - basic and diluted	<u>30,543,746</u>	<u>3,029,223</u>

Savara Inc. and Subsidiaries

Balance Sheet data

(In thousands)

(Unaudited)

	March 31, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	\$ 84,984	\$ 94,313
Working capital	82,184	91,849
Total assets	128,872	159,628
Total liabilities	35,169	40,319
Stockholders' equity	93,703	119,309

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