
**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)

November 8, 2017

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.)

**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 2.02. Results of Operations and Financial Condition.

On November 8, 2017, Savara Inc. issued a press release announcing its financial results for the quarter ended September 30, 2017. 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 November 8, 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: November 8, 2017

SAVARA INC.
a Delaware corporation

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



SAVARA REPORTS THIRD QUARTER 2017 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

- **Anticipating complete enrollment in the Molgradex Phase 3 IMPALA study in Q1 2018**
- **Initiating Phase 2a study of Molgradex for the treatment of NTM in early 2018**
- **Expecting top-line results from the Aironite Phase 2 INDIE study in H1 2018**
- **Conference call scheduled for today at 5:30 p.m. E.T.**

AUSTIN, TX – November 8, 2017— [Savara Inc.](#) (NASDAQ: SVRA), an orphan lung disease company, today reported financial results for the quarter ended September 30, 2017 and provided a business update.

Recent Developments and Upcoming Milestones

- **Anticipating complete enrollment in the Molgradex Phase 3 IMPALA study in Q1 2018.** The IMPALA study is evaluating an inhaled formulation of granulocyte-macrophage colony-stimulating factor, or GM-CSF, for the treatment of pulmonary alveolar proteinosis, or PAP. More than 70% of the required 90 patients have been enrolled, with enrollment expected to be completed in Q1 2018 and top-line data anticipated by the end of 2018.
- **Initiate Phase 2a study of Molgradex for the treatment of NTM in early 2018.** Scientific literature suggests that GM-CSF plays an important role in enhancing the ability of macrophages to clear mycobacteria and that targeting the human immune response, not bacteria directly, provides a promising new treatment approach that can avoid the increasing problem of antibiotic resistance. The Phase 2a open-label clinical trial, expected to begin in early 2018, 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.
- **Expecting top-line results from the Aironite Phase 2 INDIE study in H1 2018.** The INDIE study is evaluating inhaled sodium nitrite in heart failure with preserved ejection fraction, or HFpEF. In October 2017, we announced that enrollment had been completed. The study is being conducted by the Heart Failure Clinical Trial Network with grant support from the NHLBI.
- **Our common stock was uplisted to the Nasdaq Global Select Market® which has the highest initial listing standards of any of the world's stock markets.**
- **Successfully closed a follow-on public offering with net proceeds to us of approximately \$50 million which will help to fund the indication expansion of Molgradex for the treatment of NTM, our ongoing programs and growth strategy.**

“It has been an incredibly productive third quarter for us on a number of fronts as we have executed on our key programs and our growth strategy on our journey to build Savara into a leading orphan lung disease company,” stated Rob Neville, Chief Executive Officer of Savara. “Importantly, our two lead programs, Molgradex and AeroVanc are now both in Phase 3 development. Following the closing of our most recent public offering, we believe that the company is sufficiently funded to execute our current business plan into 2020.”

Third Quarter Financial Results

Savara’s net loss attributable to common shareholders for the three months ended September 30, 2017 was \$6.8 million, or \$(.28) per share, compared with a net loss attributable to common shareholders of \$3.3 million, or \$(1.21) per share, for the third quarter of

2016, which represents the historical financial information of the private company Savara Inc., which completed its merger with Mast Therapeutics, Inc. on April 27, 2017.

Research and development expenses were \$5.0 million for the three-months ended September 30, 2017, compared with \$2.1 million for the third quarter of 2016. The increase was primarily due to the funding of the Molgradex Phase 3 study, which we acquired from Serendex A/S in July 2016 and the initiation of our AeroVanc Phase 3 study.

General and administrative expenses for the three-months ended September 30, 2017 were \$1.5 million, compared with \$1.0 million for the third quarter of 2016. The increase was primarily due to increased insurance, legal, and accounting costs associated with public company requirements and activities as well as increased personnel costs.

As of September 30, 2017, Savara had cash, cash equivalents and short-term investments of approximately \$53.3 million. The Company's operating expenses for the third quarter of 2017 were approximately \$6.5 million. Savara ended the third quarter of 2017 with approximately \$14.7 million in debt. Subsequent to third quarter end, in October 2017, Savara closed a public offering with net proceeds of approximately \$50 million (which includes the full exercise of the underwriters' option to purchase additional shares).

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 an overview and clinical 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 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 November 15th, 2017 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 10114091.

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 pulmonary alveolar proteinosis, or PAP, and in preparation for Phase 2a development for nontuberculous mycobacteria, or 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 heart failure with preserved ejection fraction, or 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](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 the timing of top-line data and completion of enrollment of our Molgradex Phase 3 IMPALA study, initiating our Phase 2a study of Molgradex for the treatment of NTM in early 2018, the timing of top-line results from the Aironite Phase 2 INDIE study in H1 2018, the offering proceeds helping to fund the indication expansion of Molgradex for the treatment of NTM, our ongoing programs and growth strategy, our journey to build Savara into a leading orphan lung disease company, our belief the company is sufficiently funded to execute our current business plan into 2020, 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, AeroVanc and Aironite 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 data)
(Unaudited)

	Three months ended September 30, (Unaudited)		Nine months ended September 30, (Unaudited)	
	2017	2016	2017	2016
Total net revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	4,966	2,142	12,076	4,694
General and administration	1,486	1,002	8,410	1,955
Depreciation and amortization	91	86	272	256
Total operating expenses	<u>6,543</u>	<u>3,230</u>	<u>20,758</u>	<u>6,905</u>
Loss from operations	\$ (6,543)	\$ (3,230)	\$ (20,758)	\$ (6,905)
Interest and other (expense)/income, net	<u>(391)</u>	<u>3</u>	<u>(3,359)</u>	<u>(50)</u>
Loss before income taxes	\$ (6,934)	\$ (3,227)	\$ (24,117)	\$ (6,955)
Income tax benefit	<u>117</u>	<u>—</u>	<u>824</u>	<u>—</u>
Net loss	\$ (6,817)	\$ (3,227)	\$ (23,293)	\$ (6,955)
Other expenses attributable to common shareholders	<u>—</u>	<u>(44)</u>	<u>(982)</u>	<u>(70)</u>
Net loss attributable to common shareholders	\$ (6,817)	\$ (3,271)	\$ (24,275)	\$ (7,025)
Net loss per share—basic and diluted	<u>\$ (0.28)</u>	<u>\$ (1.21)</u>	<u>\$ (1.76)</u>	<u>\$ (4.40)</u>
Weighted average shares—basic and diluted	<u>24,209,517</u>	<u>2,707,055</u>	<u>13,770,032</u>	<u>1,596,123</u>

Savara Inc. and Subsidiaries**Balance Sheet data**

(In Thousands)

(Unaudited)

	September 30, 2017	December 31, 2016
Cash, cash equivalents and short-term investments	\$ 53,286	\$ 13,373
Working capital	49,444	11,158
Total assets	118,888	28,934
Total liabilities	44,243	20,948
Redeemable convertible preferred stock	—	43,861
Stockholders equity (deficit)	74,645	(35,875)

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