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, 2019

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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	**SVRA**	**The Nasdaq Global Select Market**

Item 2.02. Results of Operations and Financial Condition.

On May 9, 2019, Savara Inc. issued a press release announcing its financial results for the quarter ended March 31, 2019. 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, 2019

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, 2019

SAVARA INC.
a Delaware corporation

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

SAVARA REPORTS FIRST QUARTER 2019 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

Top Line Results from Pivotal Phase 3 IMPALA Study Expected in June 2019

Molgradex Received Fast Track Designation by FDA for Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

Announce Indication for Proprietary Phase 2-Ready Combination Antibiotic

AUSTIN, TX – May 9, 2019 – Savara Inc. (Nasdaq: SVRA), an orphan lung disease company, today reported financial results for the first quarter ending March 31, 2019 and provided a business update.

"We are diligently preparing for the highly anticipated readout of our Phase 3 IMPALA study in June, which we expect to be followed by the submission of a Biologics License Application in the first half of 2020 and, if approved, a commercial launch of Molgradex later in 2020 or early 2021," said Rob Neville, Chief Executive Officer, Savara. "These pivotal results could be transformational for the Company and, more importantly, for patients with aPAP, a rare and progressive lung disease. Our commitment to improving the lives of people with orphan lung diseases, and accelerating the advancement of our innovative therapies, is unwavering. With multiple catalysts expected over the coming quarters, we are well positioned for sustained growth."

Recent Developments and Upcoming Highlights

Molgradex for aPAP

- Expect top line results from the IMPALA study in June 2019. IMPALA is a global, pivotal Phase 3 clinical study evaluating Molgradex, an inhaled formulation of granulocyte-macrophage colony-stimulating factor (GM-CSF) for the treatment of aPAP. Positive results would facilitate the submission of a Biologics License Application in the first half of 2020, with an anticipated commercial launch later in 2020 or early 2021.
- Continued strong enrollment in IMPALA-X, an open-label, multicenter extension study to determine the long-term safety and utilization of Molgradex in patients with aPAP. At the end of Q1 2019, 25 out of 26 eligible patients had enrolled in the extension study.
- Molgradex received Fast Track Designation by the FDA for the treatment of aPAP. A drug granted with this designation may be eligible for Priority and/or Rolling Review, if relevant criteria are met.

Molgradex for nontuberculous mycobacterial (NTM) lung infection

- Initiated ENCORE, a Phase 2a clinical study of Molgradex for the treatment of NTM in people living with cystic fibrosis (CF).
- Expect top line results from OPTIMA, a Phase 2a clinical study evaluating Molgradex for the treatment of NTM in non-CF patients in Q1 2020.

Molgradex manufacturing

- Entered into a new commercial manufacturing and supply agreement with GEMA Biotech, the company that has produced the drug substance for all Molgradex non-clinical and clinical studies. Under the terms of the agreement, GEMA Biotech will exclusively supply the Company with GM-CSF expressed from Savara's proprietary cell line.

AeroVanc

- Enrollment continues in AVAIL, a pivotal, global Phase 3 clinical study of AeroVanc, an inhaled vancomycin hydrochloride powder for the treatment of persistent methicillin-resistant *Staphylococcus aureus* (MRSA) lung infection in CF.
  - As of today, the study has enrolled 153 patients out of a target of 200. An approximate 50% screen failure rate with younger subjects (between 6-21 years of age) has slowed enrollment. The screen failures are largely due to exacerbations between time of screening and randomization.
  - Expect to complete patient enrollment in Q3 2019 with top line results in Q2 2020.

Exploratory Pipeline

- The initial indication for the Phase 2-ready aerosolized amikacin/fosfomycin combination antibiotic will focus on non-CF bronchiectasis patients with chronic lung infection and frequent exacerbations. A Phase 2 study is expected to start enrolling in bronchiectasis patients with recurrent exacerbations later in 2019 or early 2020 and will evaluate amikacin/fosfomycin and Molgradex separately, and in combination, to reduce bacterial infection load.

First Quarter Financial Results (Unaudited)

Savara's net loss attributable to common stockholders for the three months ended March 31, 2019 was $12.1 million, or $(0.34) per share, compared with a net loss attributable to common stockholders of $26.8 million, or $(0.86) per share, for the three months ended March 31, 2018.

Research and development expenses were $10.0 million for the three months ended March 31, 2019, compared with $8.5 million for the three months ended March 31, 2018. The increase was primarily due to $1.9 million in increased development costs associated with the development of Molgradex, partially offset by a slight decrease in other program costs for the three months ended March 31, 2019.

General and administrative expenses for the three months ended March 31, 2019 were $2.8 million, compared with $1.8 million for the three months ended March 31, 2018. The increase was primarily due to increased personnel costs and other legal, accounting, insurance and operating activities.

As noted in the first quarter 2018 10-Q, during the quarter ended March 31, 2018, the Company recognized a $21.7 million impairment charge to the carrying value of acquired IPR&D related to a drug candidate previously assumed by Savara. For the first quarter ended March 31, 2019, there were no costs associated with this activity as the Company was no longer supporting or pursuing the drug candidate**.**

Other income, net of other expense, increased by $0.1 million to $0.8 million for the three months ended March 31, 2019 from $0.7 million for the three months ended March 31, 2018 and was primarily related to a reduction of net interest expense.

Income tax benefit decreased by $4.5 million for the three months ended March 31, 2019 from the three months ended March 31, 2018 primarily due to the reversal of a deferred tax liability resulting from the impairment of certain acquired IPR&D during the first quarter of 2018.

As of March 31, 2019, Savara had a carrying value of its debt of approximately $24.7 million and had cash, cash equivalents, and short-term investments of approximately $105.2 million.

Conference Call and Webcast

Savara will host a conference call today at 4:30 p.m. Eastern Time (ET) / 1:30 p.m. Pacific Time (PT).
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 https://www.savarapharma.com/investors/events-presentations/.

Approximately one hour after the call, a replay of the webcast will be available on Savara's website for 30 days, and a telephone replay will be available through May 16, 2019 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 the replay access code 10130971.

About Savara

Savara is an orphan lung disease company. Savara's pipeline comprises Molgradex, an inhaled granulocyte-macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis (aPAP), in Phase 2a development for nontuberculous mycobacterial (NTM) lung infection in both non-cystic fibrosis (CF) and CF-affected individuals with chronic NTM lung infection; and AeroVanc, a Phase 3-stage inhaled vancomycin for treatment of persistent methicillin-resistant *Staphylococcus aureus* (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, LinkedIn: www.linkedin.com/company/savara-pharmaceuticals/)

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 the timing of top line results from our IMPALA, OPTIMA and AVAIL studies, statements regarding the expected timing of a Biologics License Application submission in the first half of 2020, statements regarding the anticipated timing of a commercial launch of Molgradex later in 2020 or early 2021, that pivotal results could be transformational for Savara and patients with aPAP, that with multiple catalysts expected over the coming quarters, we are well positioned for sustained growth, statements regarding the enrollment of our AVAIL study, including the timing of completion of enrollment, that a Phase 2 study is expected to start enrolling in bronchiectasis patients with recurrent exacerbations later in 2019 or early 2020 and will evaluate amikacin/fosfomycin and Molgradex separately, and in combination, to reduce bacterial infection load, and Savara's strategy. 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. 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 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 product acquisition 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 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.

Financial Information to Follow

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

	Three months ended March 31, (Unaudited)	
	2019	**2018**
Operating expenses:		
Research and development	$ 10,019	$ 8,539
General and administration	2,763	1,769
Impairment of acquired IPR&D	—	21,692
Depreciation and amortization	138	107
Total operating expenses	12,920	32,107
Loss from operations	$ (12,920)	$ (32,107)
Other income, net	808	703
Loss before income taxes	$ (12,112)	$ (31,404)
Income tax benefit	—	4,555
Net loss	$ (12,112)	$ (26,849)
Net loss per share – basic and diluted	$ (0.34)	$ (0.86)
Weighted average shares – basic and diluted	36,016,406	31,318,746
Other comprehensive income (expense):	(199)	317
Total comprehensive loss	$ (12,311)	$ (26,532)

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

	March 31, 2019	December 31, 2018
Cash, cash equivalents, and short-term investments	$105,179	$ 110,830
Working capital	98,598	106,090
Total assets	148,263	152,287
Total liabilities	46,459	44,068
Stockholders' equity	101,804	108,219

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