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 7, 2020

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) 614-1848
(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))

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, par value $0.001 per share	**SVRA**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company 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 7, 2020, Savara Inc. issued a press release announcing its financial results for the quarter ended March 31, 2020. 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 7, 2020

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 7, 2020

SAVARA INC.
a Delaware corporation

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

SAVARA REPORTS FIRST QUARTER 2020 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

Company Announces Expected Design for IMPALA 2, the Next Phase 3 Study of Molgradex in aPAP

AUSTIN, TX – May 7, 2020 – Savara Inc. (Nasdaq: SVRA), an orphan lung disease company, today reported financial results for the first quarter ending March 31, 2020 and provided a business update.

“With the recent clarity around the IMPALA 2 study design, along with the expansion of our pipeline with the Phase 3 Apulmiq development program, 2020 has kicked off with a strong start,” said Rob Neville, Chief Executive Officer, Savara. “We are now working diligently to get these two studies initiated as soon as possible.”

Recent Developments

Molgradex for autoimmune pulmonary alveolar proteinosis (aPAP)

- Based on discussions with the U.S. Food and Drug Administration (FDA), the Company believes the second Phase 3 study will be a randomized, double-blind, placebo-controlled study of Molgradex 300 µg administered once daily continuously compared to matching placebo over 48 weeks. The primary endpoint will be change from baseline to week 24 in diffusion capacity of the lungs (DLCO) percent predicted. Secondary endpoints will be change in baseline to week 24 in St. George’s Respiratory Questionnaire (SGRQ) Total Score, SGRQ Activity Component, and exercise capacity using a treadmill test.

Apulmiq for non-cystic fibrosis bronchiectasis (NCFB)

- Obtained the global rights to develop and commercialize Apulmiq (inhaled ciprofloxacin).
- The Company expects to work with the FDA to plan a confirmatory Phase 3 study that will be based on key learnings from previous studies of inhaled antibiotics for NCFB.

AeroVanc for methicillin-resistant *Staphylococcus aureus* (MRSA) lung infection

- Due to COVID-19 concerns, the Company closed enrollment in the Phase 3 AVAIL study. Total target enrollment was 200 patients. Enrollment in the adult population completed, with 55 patients out of a target of 50. One hundred and thirty-three patients were enrolled in the primary analysis population (younger patients between 6-21 years of age) out of a target of 150. Top line results are still expected in early 2021.

Molgradex for nontuberculous mycobacterial (NTM) lung infection

- Due to COVID-19 concerns, the Company closed enrollment in the Phase 2a ENCORE study. Fourteen patients out of a target of ~30 were enrolled. Despite closing enrollment early, data from the enrolled patients will provide useful information on the safety, and potential efficacy, of Molgradex in people living with cystic fibrosis who have NTM lung infection.

First Quarter Financial Results (Unaudited)

Savara’s net loss attributable to common stockholders for the three months ended March 31, 2020 was $15.4 million, or $(0.27) per share, compared with a net loss attributable to common stockholders of $12.1 million, or $(0.34) per share, for the three months ended March 31, 2019.

Research and development expenses were $13.2 million for the three months ended March 31, 2020, compared with $10.0 million for the three months ended March 31, 2019. The increase was primarily due to approximately $5.4 million equal to the aggregate of the fair value of Savara common stock to be issued and cash remunerated to the licensor under the development and commercialization licensing rights to Apulmiq. The upfront license payment expenses were offset by decreased development costs associated with the development of Molgradex and AeroVanc in the amount of $1.7 million and $0.5 million, respectively.

General and administrative expenses for the three months ended March 31, 2020 were $3.0 million, compared with $2.8 million for the three months ended March 31, 2019. The increase was primarily due to increased noncash stock-based compensation charges, personnel costs, and corporate insurance costs for the three months ended March 31, 2020.

As of March 31, 2020, Savara had debt of approximately $25.0 million and cash, cash equivalents, and short-term investments of approximately $105 million. Under the current operating plan, the Company believes this is sufficient capital to fund planned operations into 2022.

Conference Call/Webcast

Savara management will host a conference call/webcast today at 4:30 p.m. Eastern Time (ET) / 1:30 p.m. Pacific Time (PT). Shareholders and other interested parties may access the 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 requesting the “Savara Inc.” call. A live webcast of the call can be accessed on the Investors page of Savara’s website at https://www.savarapharma.com/investors/events-presentations/.

Approximately one hour after the call, a telephone replay will be available and will remain available through May 14, 2020 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 10143130. A webcast replay will be available on the Investors page of Savara’s website and will remain available for 30 days.

About Savara

Savara is an orphan lung disease company with a pipeline comprised of three investigational compounds, all of which use an inhaled delivery route. Our lead program, Molgradex, is an inhaled granulocyte-macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis (aPAP) and in Phase 2a development for nontuberculous mycobacterial (NTM) lung infection in both non-cystic fibrosis and cystic fibrosis-affected individuals. Apulmiq is an inhaled liposomal ciprofloxacin in Phase 3 development for non-cystic fibrosis bronchiectasis (NCFB). AeroVanc is an inhaled vancomycin in Phase 3 development for persistent methicillin-resistant *Staphylococcus aureus* (MRSA) lung infection in people living with cystic fibrosis. Savara’s strategy involves broadening its pipeline through indication expansion, strategic development partnerships and product acquisitions, with the goal of becoming a leading company in its field. Our 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 approval 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 initiation of IMPALA 2 and a study of Apulmiq in NCFB, our beliefs related to the design and endpoints of the IMPALA 2 study, that we expect to work with the FDA to plan a confirmatory Phase 3 study of Apulmiq in NCFB based on key learnings from previous studies of inhaled antibiotics for NCFB, that top line

results from AVAIL are still expected in early 2021, that data from the ENCORE study will provide useful information on the safety, and potential efficacy, of Molgradex in people living with cystic fibrosis who have NTM lung infection, our belief that there is sufficient capital to fund planned operations into 2022 under the current operating plan, and our 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, the risks and uncertainties relating to the impact of the COVID-19 pandemic on our business and operations, the outcome of our future interactions with regulatory authorities, 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 develop our product candidates, the risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates such as Molgradex, Apulmiq, and AeroVanc 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)	
	2020	**2019**
Operating expenses:		
Research and development	$ 13,200	$ 10,019
General and administration	2,982	2,763
Depreciation and amortization	58	138
Total operating expenses	16,240	12,920
Loss from operations	$ (16,240)	$ (12,920)
Other income, net	819	808
Loss before income taxes	$ (15,421)	$ (12,112)
Income tax benefit	—	—
Net loss attributable to common stockholders	$ (15,421)	$ (12,112)
Net loss per share—basic and diluted	$ (0.27)	$ (0.34)
Weighted average shares—basic and diluted	57,364,265	36,016,406
Other comprehensive expense	(111)	(199)
Total comprehensive loss	$ (15,532)	$ (12,311)

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

	March 31, 2020	December 31, 2019
Cash, cash equivalents, and short-term investments	$104,987	$ 121,761
Working capital	99,716	113,187
Total assets	119,975	136,203
Total liabilities	32,659	34,505
Stockholders' equity	87,316	101,698

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