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 6, 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 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 6, 2020, Savara Inc. issued a press release announcing its financial results for the quarter ended June 30, 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 August 6, 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: August 6, 2020

SAVARA INC.
a Delaware corporation

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

SAVARA REPORTS SECOND QUARTER 2020 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

Announces Final Clinical Study Design for IMPALA 2, the Next Phase 3 Study of Molgradex in Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

Study Expected to Start in Q1 2021

AUSTIN, TX – August 6, 2020 – Savara Inc. (Nasdaq: SVRA), an orphan lung disease company, today reported financial results for the second quarter ending June 30, 2020 and provided a business update.

"With a final design for IMPALA 2, we are working diligently on study preparations and expect it to start in the first quarter of next year," said Rob Neville, Chief Executive Officer, Savara. "Building on the learnings from the first IMPALA study, and following constructive discussions with the regulatory agencies, we are confident in the study design and believe IMPALA 2 will effectively measure the potential efficacy and safety of Molgradex to treat aPAP."

Recent Developments

Molgradex for aPAP

- The Phase 3 IMPALA 2 study, which incorporates feedback from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), will be a randomized, double-blind, placebo-controlled study evaluating Molgradex for the treatment of aPAP. A total of 160 patients will be enrolled at approximately 50 sites across the U.S., Canada, Japan, South Korea, and select countries in Europe. Patients will be randomized in one of two arms: Molgradex 300 µg administered once-daily continuously or matching placebo. 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. While efficacy endpoints will be assessed at week 24 for primary analyses, the placebo-controlled period will be 48 weeks to better assess the durability of treatment effect, as well as long-term safety of the drug, which is intended to be administered chronically. At the end of the 48-week double-blind period, both treatment arms will rollover into a 48-week open-label follow-on period in which all patients will receive Molgradex 300 µg administered once-daily.
- The study is expected to start in the first quarter of 2021.

Apulmiq for non-cystic fibrosis bronchiectasis (NCFB)

- The Company is further analyzing data from the previous Apulmiq development program and is also working on the design of a future program, with inputs from external bronchiectasis experts, for future discussion with the FDA.

AeroVanc for methicillin-resistant *Staphylococcus aureus* (MRSA) lung infection in cystic fibrosis (CF)

- In March 2020, the Phase 3 AVAIL study stopped enrolling new patients due to COVID-19 concerns. 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 from AVAIL are still expected in early 2021.

Molgradex for nontuberculous mycobacterial (NTM) lung infection

- In March 2020, the exploratory ENCORE study stopped enrolling new patients due to COVID-19 concerns. Fourteen patients out of a target of ~30 were enrolled. Despite closing enrollment early, data from the enrolled patients will provide useful information on Molgradex in people living with CF who have NTM lung infection.

Second Quarter Financial Results (Unaudited)

The Company's net loss attributable to common stockholders for the three months ended June 30, 2020 was $9.4 million, or $(0.16) per share, compared with a net loss attributable to common stockholders of $21.9 million, or $(0.57) per share, for the three months ended June 30, 2019.

Research and development expenses decreased by $4.4 million, or 41.9%, to $6.1 million for the three months ended June 30, 2020 from $10.5 million for the three months ended June 30, 2019. The decrease was primarily related to ~$2.8 million in lower AVAIL clinical study costs due to the close of enrollment in the study, the transition to processing the last patient out and database management and lock, and a reduction in CMC and clinical operations activities. Additionally, there was a decrease of ~$1.6 million in costs associated with the Molgradex aPAP program as study activities associated with IMPALA have concluded and preparations for a second Molgradex Phase 3 study (IMPALA 2) are underway.

General and administrative expenses decreased by $1.1 million, or 26.0%, to $3.1 million for the three months ended June 30, 2020 from $4.2 million for the three months ended June 30, 2019. The decrease was primarily due to reduced commercial activities for the three months ended June 30, 2020.

As of June 30, 2020, the Company had a carrying value of its debt of ~$24.9 million and had cash, cash equivalents, and short-term investments of ~$100 million. The Company anticipates an additional ~$46.0 million in gross proceeds from the second tranche of the December 2019 financing.

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 August 13, 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 10146176. 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 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 expected timing of the start of the IMPALA 2 study; the planned study design for IMPALA 2; that we are confident in the IMPALA 2 study design and believe the study will effectively measure the potential efficacy and safety of Molgradex to treat aPAP; our plans for the design of the Apulmiq development program, including discussions with the FDA; that top line results from AVAIL are expected in early 2021; our expectations for the data from the ENCORE study; and that we anticipate an additional ~$46.0 million in gross proceeds from the second tranche of the December 2019 financing. 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 closing of the second tranche of funding from the December 2019 financing, 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 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 June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 6,079	$ 10,464	$ 19,279	$ 20,483
General and administration	3,117	4,211	6,099	6,974
Impairment of goodwill	—	7,420	—	7,420
Depreciation and amortization	68	59	126	197
Total operating expenses	9,264	22,154	25,504	35,074
Loss from operations	$ (9,264)	$ (22,154)	$ (25,504)	$ (35,074)
Other income (expense), net	(125)	215	693	1,023
Net loss attributable to common stockholders	$ (9,389)	$ (21,939)	$ (24,811)	$ (34,051)
Net loss per share - basic and diluted	$ (0.16)	$ (0.57)	$ (0.43)	$ (0.91)
Weighted average shares - basic and diluted	58,858,216	38,440,647	58,111,225	37,235,209
Other comprehensive income	247	211	136	12
Total comprehensive loss	$ (9,142)	$ (21,728)	$ (24,675)	$ (34,039)

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

	June 30, 2020	December 31, 2019
Cash, cash equivalents, and short-term investments	$ 99,609	$ 121,761
Working capital	96,109	113,187
Total assets	115,146	136,203
Total liabilities	31,348	34,505
Stockholders' equity	83,798	101,698

Contacts:
Savara Inc. IR & PR
Anne Erickson (anne.erickson@savarapharma.com)
(512) 851-1366

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