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 8, 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))

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 8, 2019, Savara Inc. issued a press release announcing its financial results for the quarter ended June 30, 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 August 8, 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: August 8, 2019

SAVARA INC.
a Delaware corporation

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

SAVARA REPORTS SECOND QUARTER 2019 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

Molgradex aPAP Program:

- *Continue with Regulatory Interactions, Expect FDA Written Responses to Type C Meeting in October*
- *Anticipate Filing for Breakthrough Designation*

AUSTIN, TX – August 8, 2019 – Savara Inc. (Nasdaq: SVRA), an orphan lung disease company, today reported financial results for the second quarter ending June 30, 2019 and provided a business update.

"Our highest corporate priority continues to be the Molgradex aPAP program," said Rob Neville, Chief Executive Officer, Savara. "While the IMPALA study did not achieve statistical significance on its pre-specified primary endpoint, the totality of the efficacy data are encouraging and reinforce the important role of Molgradex to improve oxygenation and reduce surfactant burden in these patients. Additionally, with adverse event frequencies similar to placebo, we believe this drug has a compelling risk-benefit profile. We are proceeding with regulatory interactions to determine the best path forward, while simultaneously preparing for an additional Phase 3 study should that be required."

Recent Developments and Upcoming Highlights

Molgradex for autoimmune pulmonary alveolar proteinosis (aPAP)

- Reported top line results from IMPALA, a pivotal Phase 3 clinical study.
- Granted a Type C meeting with the FDA, expect written responses from the agency in October 2019.
- Anticipate filing for Breakthrough Designation in the U.S.
- 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. 32 out of 35 eligible patients have enrolled in the extension study, with no whole lung lavages reported and no drop-outs to-date.

Molgradex for nontuberculous mycobacterial (NTM) lung infection

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

AeroVanc

- Revised enrollment completion guidance for AVAIL, a pivotal Phase 3 clinical study of AeroVanc for the treatment of persistent methicillin-resistant *Staphylococcus aureus* (MRSA) lung infection in CF.
  - — As of August 1, 2019, the study has enrolled 168 patients out of a target of 200. The approximate 50% screen failure rate with younger subjects has slowed enrollment. The screen failures are largely due to exacerbations between time of screening and randomization.
  - — Expect to complete patient enrollment in the first half of 2020 with top line results now expected in late 2020 or early 2021.

Exploratory Pipeline

- Deprioritized the amikacin/fosfomycin program in order to focus resources on the Company's later stage programs. Future development will be considered at a later time.

Second Quarter Financial Results (Unaudited)

Savara's net loss attributable to common stockholders for the three months ended June 30, 2019 was $21.9 million, or $(0.57) per share, compared with a net loss attributable to common stockholders of $11.6 million, or $(0.37) per share, for the three months ended June 30, 2018.

Research and development expenses were $10.5 million for the three months ended June 30, 2019, compared with $9.3 million for the three months ended June 30, 2018. The increase was primarily due to $2.2 million in increased development costs associated with the development of Molgradex and AeroVanc, which was partially offset by $1.0 million in expense in the form of common stock issued in connection with an asset purchase in the second quarter of 2018.

General and administrative expenses for the three months ended June 30, 2019 were $4.2 million, compared with $2.5 million for the three months ended June 30, 2018. The increase was primarily due to increased personnel costs and other legal, accounting, insurance, commercial strategy, business development, and operating activities.

During the three months ended June 30, 2019, we recognized a $7.4 million non-cash impairment charge to the carrying value of our goodwill following the results of our IMPALA study.

As of June 30, 2019, Savara had a carrying value of its debt of approximately $24.8 million and had cash, cash equivalents, and short-term investments of approximately $111.7 million. Under the current operating plan, the Company believes this is sufficient capital to fund planned operations into 2021.

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 August 15, 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 10133438.

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. 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 our highest corporate priority being the Molgradex aPAP program, that the totality of the IMPALA efficacy data are encouraging and reinforce the important role of Molgradex to improve oxygenation and reduce surfactant burden in aPAP patients, the belief that Molgradex has a compelling risk-benefit profile, that we are proceeding with regulatory interactions to determine the best path forward, while simultaneously preparing for an additional Phase 3 study should that be required, that we expect written responses from the FDA in October 2019, that we anticipate filing for Breakthrough Designation in the U.S., statements regarding the timing of top line results from our OPTIMA and AVAIL studies, statements regarding the enrollment of our AVAIL study, including the timing of completion of enrollment, that future development of the amikacin/fosfomycin program will be considered at a later time, the belief that Savara has sufficient capital to fund planned operations into 2021 under the current operating plan, 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, the outcome of our planned meeting with the FDA to discuss the IMPALA data and path forward, 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 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 June 30, (Unaudited)		Six months ended June 30, (Unaudited)	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 10,464	$ 9,268	$ 20,483	$ 17,807
General and administration	4,211	2,486	6,974	4,254
Impairment of acquired IPR&D	—	—	—	21,692
Impairment of goodwill	7,420	—	7,420	—
Depreciation and amortization	59	153	197	260
Total operating expenses	22,154	11,907	35,074	44,013
Loss from operations	$ (22,154)	$ (11,907)	$ (35,074)	$ (44,013)
Other income, net	215	313	1,023	1,016
Loss before income taxes	$ (21,939)	$ (11,594)	$ (34,051)	$ (42,997)
Income tax benefit	—	—	—	4,555
Net loss	$ (21,939)	$ (11,594)	$ (34,051)	$ (38,442)
Net loss per share - basic and diluted	$ (0.57)	$ (0.37)	$ (0.91)	$ (1.23)
Weighted average shares - basic and diluted	38,440,647	31,433,494	37,235,209	31,376,425
Other comprehensive income (expense):	211	(819)	12	(502)
Total comprehensive loss	$ (21,728)	$ (12,413)	$ (34,039)	$ (38,944)

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

	June 30, 2019	December 31, 2018
Cash, cash equivalents, and short-term investments	$ 111,732	$ 110,830
Working capital	105,116	106,090
Total assets	147,330	152,287
Total liabilities	34,531	44,068
Stockholders' equity	112,799	108,219

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