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 7, 2018

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. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 7, 2018, Savara Inc. issued a press release announcing its financial results for the quarter ended September 30, 2018. 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 7, 2018

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 7, 2018

SAVARA INC.
a Delaware corporation

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

Exhibit 99.1

SAVARA REPORTS THIRD QUARTER 2018 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

- Completed Enrollment in Two Clinical Studies of Molgradex: IMPALA, a Pivotal Phase 3 Study and OPTIMA, a Phase 2a Study
- IMPALA Top Line Results Expected Q2 2019
- OPTIMA Interim Results Expected Q4 2018

AUSTIN, TX – Nov. 7, 2018 – Savara Inc. (Nasdaq: SVRA), an orphan lung disease company, today reported financial results for the third quarter ending September 30, 2018 and provided a business update.

"We are creating a differentiated orphan lung disease company through a portfolio of investigational programs addressing significant unmet need in rare respiratory diseases," said Rob Neville, Chief Executive Officer, Savara. "This past quarter's achievements demonstrate considerable progress with our lead candidate, Molgradex, and in the coming year we look forward to numerous important data read-outs from our three clinical studies, two of which are pivotal. Additionally, we expect Savara's pipeline, buoyed by indication expansion and product acquisitions, to facilitate sustainable growth now and in the future."

Recent Developments and Upcoming Highlights

Molgradex for autoimmune pulmonary alveolar proteinosis (aPAP)

- Completed enrollment of 139 patients in the IMPALA study, a global, pivotal Phase 3 clinical study evaluating Molgradex, an inhaled formulation of granulocyte-macrophage colony-stimulating factory (GM-CSF) for the treatment of aPAP.
- Expect top line results from the IMPALA study in Q2 2019. Positive results would facilitate the submission of a Biologic License Application in the first half of 2020, with an anticipated commercial launch in the U.S. and EU in 2020 or early 2021.
- Continue active enrollment in IMPALA-X, an open-label, multicenter extension study to determine the long-term safety and utilization of Molgradex in patients with aPAP.
- Announced a partnership with the PAP Foundation to support their efforts to unite, educate and assist the PAP patient community, including work to further expand the PAP patient registry.

Molgradex for nontuberculous mycobacterial (NTM) lung infection

- Completed enrollment of 32 patients in the OPTIMA study, a Phase 2a clinical study evaluating Molgradex for the treatment of NTM lung infection.
- Expect interim results from the OPTIMA study in Q4 2018.
- Anticipate top line results from the OPTIMA study in Q2 2019.
- The Investigational New Drug application for Molgradex in cystic fibrosis (CF)-affected individuals with chronic NTM lung infection has been accepted by the U.S. Food and Drug Administration. Savara expects to initiate a Phase 2a study of Molgradex in CF subjects with NTM lung infection in Q1 2019.
- Completed license agreement with Mayo Clinic, enabling inclusion of Mayo clinical data in Savara's patent applications related to NTM.

AeroVanc

- Continue patient enrollment in the AVAIL study, a pivotal, global Phase 3 clinical study of AeroVanc, an inhaled vancomycin hydrochloride powder for the treatment of persistent methicillin resistant staphylococcus aureus, or MRSA, lung infection in CF. At the end of Q3, patient enrollment was at 126 out of a target of 200.
- Continue to target completion of patient enrollment in the AVAIL study in Q1 2019, with top line data in H2 2019.

Exploratory Pipeline

- Expect to announce the initial indication for the Phase 2-ready aerosolized amikacin/fosfomycin proprietary combination antibiotic early in 2019, with an anticipated study-start later in 2019.

Financials

- Successfully closed a public offering at the end of July with net proceeds to Savara of approximately $45.8 million.

Third Quarter Financial Results

Savara's net loss attributable to common stockholders for the three months ended September 30, 2018 was $12.6 million, or $(0.37) per share, compared with a net loss attributable to common stockholders of $6.8 million, or $(0.28) per share, for the three months ended September 30, 2017.

Research and development expenses were $9.5 million for the three months ended September 30, 2018, compared with $5.0 million for the three months ended September 30, 2017. This increase was primarily due $2.5 million in additional expenses associated with AeroVanc Phase 3 study activities and $2.5 million in development costs of Molgradex, including the expansion of the aPAP study in the U.S. and costs associated with the Phase 2 NTM study. Conversely, the total research and development costs for the three months ended September 30, 2017 included approximately $0.4 million related to the Aironite program, which was assumed in the merger with Mast Therapeutics, Inc. in April 2017 and subsequently terminated in the first quarter of 2018.

General and administrative expenses for the three months ended September 30, 2018 were $3.1 million, compared with $1.5 million for the three months ended September 30, 2017. This increase was primarily due to $1.5 million additional costs related to personnel. The remaining increase in expense was associated with continued legal and accounting requirements for a public company.

Other income of $0.1 million was recognized for the three months ended September 30, 2018 as compared to other expense of $0.4 million for the three months ended September 30, 2017. The change was primarily due to additional interest income attributable to an increased balance maintained in our short-term investments for the three months ended September 30, 2018, as compared to that for the three months ended September 30, 2017.

As of September 30, 2018, Savara had a debt balance of approximately $15.0 million and had cash, cash equivalents and short-term investments of approximately $112.0 million.

Conference Call and Webcast

Savara will hold a conference call today beginning at 5:30 PM Eastern Time/4:30 PM Central Time to provide a business 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 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/. A replay of the webcast will be available on Savara's website for 30 days, and a telephone replay will be available through November 12, 2018 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 10125683.

About Savara

Savara is an orphan lung disease company. Savara's pipeline comprises Molgradex, an inhaled granulocyte-macrophage colony-stimulating factor, or GM-CSF, in Phase 3 development for autoimmune pulmonary alveolar proteinosis, or aPAP, in Phase 2a development for nontuberculous mycobacteria, or NTM, lung infection, and in preparation for Phase 2a development in cystic fibrosis, or CF, affected individuals with chronic NTM lung infection; and AeroVanc, a Phase 3-stage inhaled vancomycin for treatment of persistent methicillin resistant staphylococcus aureus, or 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 Statement

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 Savara creating a differentiated orphan lung disease company through a portfolio of investigational programs addressing significant unmet need in rare respiratory diseases, that this past quarter's achievements demonstrate considerable progress with our lead candidate, Molgradex, that in the coming year we look forward to numerous important data read-outs from our three clinical studies, our expectation that Savara's pipeline, buoyed by indication expansion and product acquisitions, will facilitate sustainable growth now and in the future, statements regarding the timing of top line data or interim results from our OPTIMA and IMPALA studies, that positive results in the IMPALA study would facilitate the submission of a Biologic License Application in the first half of 2020, with an anticipated commercial launch in the U.S. and EU in 2020 or early 2021, that we continue active enrollment in our IMPALA-X study, that Savara expects to initiate a Phase 2a study of Molgradex in CF subjects with NTM lung infection in Q1 2019, statements regarding the enrollment of our AVAIL study, including the timing of completion of enrollment, that we expect to announce the initial indication for the Phase 2-ready aerosolized amikacin/fosfomycin proprietary combination antibiotic early in 2019, with an anticipated study-start later in 2019, and our strategy and 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 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 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.

Financial Information to Follow

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

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	9,509	4,966	27,316	12,076
General and administration	3,148	1,486	7,402	8,410
Impairment of acquired IPR&D	—	—	21,692	—
Depreciation	127	91	387	272
Total operating expenses	12,784	6,543	56,797	20,758
Loss from operations	$ (12,784)	$ (6,543)	$ (56,797)	$ (20,758)
Interest and other (expense)/income, net	114	(391)	(71)	(3,359)
Loss before income taxes	$ (12,670)	$ (6,934)	$ (56,868)	$ (24,117)
Income tax benefit	110	117	5,866	824
Net loss	$ (12,560)	$ (6,817)	$ (51,002)	$ (23,293)
Other expenses attributable to common stockholders	—	—	—	(982)
Net loss attributable to common stockholders	$ (12,560)	$ (6,817)	$ (51,002)	$ (24,275)
Net loss per share - basic and diluted	$ (0.37)	$ (0.28)	$ (1.61)	$ (1.76)
Weighted average common shares - basic and diluted	33,708,563	24,209,517	31,648,510	13,770,032

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

	September 30, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	$ 112,048	$ 94,313
Working capital	103,525	91,849
Total assets	155,124	159,628
Total liabilities	37,270	40,319
Stockholders' equity	117,854	119,309

Contacts:

Savara Inc. IR:
Ioana C. Hone (ir@savarapharma.com)
(512) 961-1891

Savara Inc. PR and Media:
Anne Erickson (anne.erickson@savarapharma.com)
(512) 851-1366

For IR: Solebury Trout
Gitanjali Jain Ogawa (Gogawa@troutgroup.com)
(646) 378-2949

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