# 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, 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** | **SVRA** | **The Nasdaq Global Select Market** |

**share**

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.**

On November 7, 2019, Savara Inc. issued a press release announcing its financial results for the quarter ended September 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 November 7, 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: November 7, 2019

SAVARA INC.
a Delaware corporation

By: /s/ Dave Lowrance

Dave Lowrance
Chief Financial Officer

**Exhibit 99.1**

**SAVARA REPORTS THIRD QUARTER 2019 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE**

*Company in Discussions with Regulatory Agencies on Best Path Forward for the Molgradex Autoimmune Pulmonary Alveolar Proteinosis (aPAP) Program*

**AUSTIN, TX – November 7, 2019** – Savara Inc. (Nasdaq: SVRA), an orphan lung disease company, today reported financial results for the third quarter ending September 30, 2019 and provided a business update.

"Based on the totality of evidence, we continue to believe that Molgradex has a clinically meaningful treatment effect on aPAP and we are committed to this program," said Rob Neville, Chief Executive Officer, Savara. "In the near-term, gaining clarity on the best regulatory path forward is our highest corporate priority and we look forward to further collaborating with the FDA and EMA in this regard."

**Recent Developments and Upcoming Highlights**

**Molgradex for aPAP**

- Announced U.S. Food and Drug Administration (FDA) feedback from Type C meeting that indicated the data included in the briefing package did not provide sufficient evidence of efficacy and safety.
- Working in consultation with the FDA to determine the best regulatory path forward for the program.
- Presented efficacy and safety results from IMPALA, a Phase 3 study evaluating Molgradex for the treatment of aPAP, at the European Respiratory Society (ERS) International Congress. (Slides from the meeting can be found here .)
- Expect to announce data from the open-label follow-up period of IMPALA (weeks 24-48) in Q1 2020.
- Plan to initiate discussions with the European Medicines Agency (EMA) regarding the suitability of the IMPALA data for a potential Marketing Authorization Application (MAA).

**Molgradex for nontuberculous mycobacterial (NTM) lung infection**

- Continue to 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**

- Anticipate enrollment completion for AVAIL, a pivotal Phase 3 clinical study of AeroVanc for the treatment of persistent methicillin-resistant *Staphylococcus aureus* (MRSA) lung infection in CF, in the first half of 2020 with top line results expected in late 2020 or early 2021.
    - As of November 1, 2019, the study had completed enrollment in the adult population and had enrolled 123 out of a target of 150 patients in the primary analysis population (younger subjects between 6-21 years of age).

**Third Quarter Financial Results (Unaudited)**

Savara's net loss attributable to common stockholders for the three months ended September 30, 2019 was $12.4 million, or $(0.30) per share, compared with a net loss attributable to common stockholders of $12.6 million, or $(0.36) per share, for the three months ended September 30, 2018.

Research and development expenses were $9.6 million for the three months ended September 30, 2019, compared with $9.5 million for the three months ended September 30, 2018. The increase was primarily due to approximately $0.6 million in increased costs associated with the development of Molgradex, which was offset by $0.5 million in decreased AeroVanc study costs related to Phase 3 activities.

General and administrative expenses for the three months ended September 30, 2019 were $2.8 million, compared with $3.1 million for the three months ended September 30, 2018. The decrease was primarily due to an approximately $0.6 million noncash stock-based compensation charge incurred in the third quarter of 2018 offset in part by $0.2 million increased personnel costs for the three months ended September 30, 2019.

As of September 30, 2019, Savara had a carrying value of its debt of approximately $25.0 million and had cash, cash equivalents, and short-term investments of approximately $106.3 million. Under the current operating plan, the Company believes this is sufficient capital to fund planned operations well into 2021.

**Conference Call/Webcast with Slides**

Savara management will host a conference call/webcast with accompanying slides 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 November 14, 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 10135923. 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. 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 that we continue to believe that Molgradex has a clinically meaningful treatment effect on aPAP and we are committed to this program, that gaining clarity on the best regulatory path forward is our highest corporate priority and we look forward to collaborating with the FDA and EMA, working with the FDA to determine the best path forward, expecting to announce data from the open-label follow-up period of IMPALA (weeks 24-48) in Q1 2020, initiating discussions with the EMA regarding the suitability of the IMPALA data for a potential MAA,

expecting top line results from OPTIMA in Q1 2020, anticipating enrollment completion for AVAIL in the first half of 2020 with top line results expected in late 2020 or early 2021, that we believe this is sufficient capital to fund planned operations well into 2021 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 outcome of our ongoing discussions with the FDA regarding our IMPALA data and the 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 September 30, (Unaudited) | | Nine months ended September 30, (Unaudited) | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Operating expenses: | | | | |
| Research and development | $ 9,575 | $ 9,509 | $ 30,058 | $ 27,316 |
| General and administration | 2,811 | 3,148 | 9,785 | 7,402 |
| Impairment of acquired IPR&D | — | — | — | 21,692 |
| Impairment of goodwill | — | — | 7,420 | — |
| Depreciation and amortization | 56 | 127 | 253 | 387 |
| Total operating expenses | 12,442 | 12,784 | 47,516 | 56,797 |
| Loss from operations | $ (12,442) | $ (12,784) | $ (47,516) | $ (56,797) |
| Other income, net | 39 | 224 | 1,062 | 1,240 |
| Loss before income taxes | $ (12,403) | $ (12,560) | $ (46,454) | $ (55,557) |
| Income tax benefit | — | — | — | 4,555 |
| Net loss | $ (12,403) | $ (12,560) | $ (46,454) | $ (51,002) |
| Net loss per share - basic and diluted | $ (0.30) | $ (0.36) | $ (1.20) | $ (1.57) |
| Weighted average shares - basic and diluted | 41,727,259 | 34,483,563 | 38,749,002 | 32,423,510 |
| Other comprehensive expense | (448) | (92) | (436) | (594) |
| Total comprehensive loss | $ (12,851) | $ (12,652) | $ (46,890) | $ (51,596) |

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

| | September 30, 2019 | December 31, 2018 |
|---|---|---|
| Cash, cash equivalents, and short-term investments | $ 106,281 | $ 110,830 |
| Working capital | 100,055 | 106,090 |
| Total assets | 140,628 | 152,287 |
| Total liabilities | 33,825 | 44,068 |
| Stockholders' equity | 106,803 | 108,219 |

**Contacts:**

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