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)
June 26, 2024

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.)**

1717 Langhorne Newtown Road, Suite 300
Langhorne, PA 19047
(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 7.01. Regulation FD Disclosure.

On June 26, 2024, Savara Inc. ("Savara") issued a press release announcing positive topline results from the pivotal, Phase 3 IMPALA-2 clinical trial ("IMPALA-2") assessing the efficacy and safety of molgramostim nebulizer solution ("molgramostim"), an inhaled form of recombinant human granulocyte-macrophage colony-stimulating factor ("GM-CSF"), in patients with autoimmune pulmonary alveolar proteinosis ("aPAP"). A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Savara will host a conference call and live audiovisual webcast to discuss the IMPALA-2 results today, June 26, 2024, at 8:00 a.m. Eastern Time. The webcast can be accessed from the "Events & Presentations" section of Savara's website, and a replay will be available approximately 24 hours after the conclusion of the call and archived for 90 days.

The information in Item 7.01 in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section, nor shall it be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On June 26, 2024, Savara announced positive topline results from IMPALA-2, a Phase 3, 48-week, randomized, double-blind, placebo-controlled pivotal clinical trial designed to compare the efficacy and safety of molgramostim 300 µg administered once daily by inhalation with matching placebo in adult patients with aPAP. The trial met its primary endpoint, with molgramostim treatment achieving a statistically significant mean change from baseline in hemoglobin-adjusted percent predicted diffusing capacity of the lungs for carbon monoxide (DLCO) compared to placebo at Week 24. This statistically significant treatment difference was sustained at Week 48, a secondary endpoint, which demonstrated durability of effect.

Molgramostim showed evidence of clinical benefit in the three additional secondary efficacy endpoints: St. George's Respiratory Questionnaire ("SGRQ") Total Score, SGRQ Activity Component Score, and exercise capacity test using a treadmill as measured by peak METs, with each endpoint measured at Week 24 and Week 48. The treatment difference between molgramostim and placebo for change from baseline to Week 24 in SGRQ Total Score achieved statistical significance; the treatment difference between molgramostim and placebo for change from baseline to Week 24 in SGRQ Activity Score and change from baseline to Week 48 in exercise capacity test using a treadmill each reached nominal significance.

IMPALA-2 Top Line Efficacy Results (Full Analysis Set, n=164):

Lung Function Efficacy Endpoints		
	Molgramostim 300 mcg mean change from baseline compared to placebo	**P-value**
Primary: DLCO % predicted (Hgb-adjusted) at Week 24	6.00	0.0007
Secondary: DLCO % predicted (Hgb-adjusted) at Week 48	6.90	0.0008

Secondary Efficacy Endpoints Measuring Clinical Benefit				
	Molgramostim 300 mcg mean change from baseline to Week 24 compared to placebo	**P-value**	**Molgramostim 300 mcg mean change from baseline to Week 48 compared to placebo**	**P-value**
SGRQ Total Score (points)	-6.59	0.0072	-4.87	0.1046
SGRQ Activity Component Score (points)	-7.81	0.0149	-5.99	0.1216
Exercise Capacity (peak METs)	0.41	0.0845	0.55	0.0234

SGRQ is a patient-reported outcomes instrument that measures overall health, daily life, and a patient's perceived well-being. SGRQ Activity assesses the patient's ability to carry out daily physical activity. With SGRQ, a negative change from baseline corresponds to improvement. Exercise capacity as measured by a treadmill is a cardiorespiratory health (CRH) measurement.

Lung lavage was permitted as a rescue treatment during the trial. During the 48-week double-blind period, 17 patients underwent at least one lung lavage—6 patients, or 7%, had lung lavage in the active arm, and 11 patients, or 13%, had lung lavage in the placebo arm.

Molgramostim was well tolerated. The frequency of adverse events was generally similar between treatment groups. Two patients (2.5%) discontinued molgramostim treatment due to adverse events, both of which were considered unrelated to trial drug. The most commonly reported adverse events in the molgramostim group were COVID-19, cough and pyrexia. The summary of treatment-emergent adverse events and those occurring in at least 10% of patients is as follows:

IMPALA-2 Top Line Safety Results (Safety Analysis Set, n=164):

Treatment Related Adverse Events	**Molgramostim (N=81) n (%)**	**Placebo (N=83) n (%)**
Any	69 (85)	71 (86)
Most common		
COVID-19	18 (22)	8 (10)
Cough	17 (21)	18 (22)
Pyrexia	11 (14)	9 (11)
Nasopharyngitis	11 (14)	7 (8)
Arthralgia	9 (11)	7 (8)
Headache	9 (11)	7 (8)
Diarrhea	9 (11)	2 (2)
Alveolar proteinosis	4 (5)	12 (14)
Serious	14 (17)	20 (24)
Treatment related	20 (25)	16 (19)

Savara plans to complete the submission of a Biologics License Application with the U.S. Food and Drug Administration ("FDA") for molgramostim for the treatment of aPAP in the first half of 2025. Molgramostim has been granted Orphan Drug, Fast Track, and Breakthrough Therapy designation from the FDA, Orphan Drug designation from the European Medicines Agency and Innovative Passport and Promising Innovative Medicine designation from the UK's Medicines and Healthcare Products Regulatory Agency for the treatment of aPAP.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Savara Inc. Press Release dated June 26, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: June 26, 2024

SAVARA INC.
a Delaware corporation

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

Exhibit 99.1

SAVARA ANNOUNCES MOLGRAMOSTIM NEBULIZER SOLUTION (MOLGRAMOSTIM) ACHIEVED STATISTICAL SIGNIFICANCE FOR PRIMARY ENDPOINT AND MULTIPLE SECONDARY ENDPOINTS IN IMPALA-2, A PIVOTAL PHASE 3 CLINICAL TRIAL IN AUTOIMMUNE PULMONARY ALVEOLAR PROTEINOSIS (APAP)

- *Statistically Significant Improvement in Percent Predicted Diffusing Capacity of the Lungs for Carbon Monoxide (DLCO) Versus Placebo at Week 24 (Primary Endpoint) and Week 48 (Secondary Endpoint)*
- *Statistically Significant Improvement in St. George's Respiratory Questionnaire (SGRQ) Total Score at Week 24 (Secondary Endpoint)*
- *97% of Patients Completed Double-Blind Treatment Through Week 48 with No Trial Drug Related Adverse Events Leading to Discontinuation*
- *100% of Patients Completing the 48-Week Double-Blind Period Elected to Participate in the 96-Week Open-Label Period*
- *Company Plans to Complete BLA Submission in 1H 2025*
- *Company to Host Webcast Conference Call Today, June 26, 2024 at 8:00am ET*

LANGHORNE, PA – June 26, 2024 – Savara Inc. (Nasdaq: SVRA) (the Company), a clinical stage biopharmaceutical company focused on rare respiratory diseases, today announced positive results from the pivotal, Phase 3 IMPALA-2 clinical trial. IMPALA-2 is a 48-week, randomized, double-blind, placebo-controlled trial assessing the efficacy and safety of molgramostim 300 mcg administered once daily by inhalation with matching placebo in adult patients with aPAP (NCT04544293). Molgramostim is an inhaled form of recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF).

The trial met its primary endpoint. The treatment difference between molgramostim and placebo for mean change from baseline to Week 24 in hemoglobin-adjusted percent predicted DLCO achieved statistical significance. This statistically significant treatment difference was sustained at Week 48, a secondary endpoint, which demonstrated durability of effect.

The treatment difference between molgramostim and placebo for mean change from baseline to Week 24 in SGRQ Total Score achieved statistical significance. Two additional secondary endpoints reached nominal significance: SGRQ Activity Score at Week 24 and exercise capacity using a treadmill test at Week 48.

"There is a high unmet need for effective, disease-specific pharmacotherapy for autoimmune PAP," said Bruce Trapnell, M.D., Professor of Medicine and Pediatrics at the University of Cincinnati College of Medicine and the Lead Clinical Investigator of the IMPALA-2 trial. "Patients typically experience breathlessness, which begins slowly and progresses over time, often accompanied by cough and fatigue, and in some patients, serious infections, pulmonary fibrosis, and respiratory failure requiring lung transplantation. With convincing data from two large clinical trials, the evidence now clearly demonstrates molgramostim has the potential to be a safe and efficacious treatment option for these patients. This is a momentous day for the aPAP community."

IMPALA-2 Top Line Efficacy Results (Full Analysis Set, n=164):

Lung Function Efficacy Endpoints		
	Molgramostim 300 mcg mean change from baseline compared to placebo	**P-value**
Primary: DLCO % predicted (Hgb-adjusted) at Week 24	6.00	0.0007
Secondary: DLCO % predicted (Hgb-adjusted) at Week 48	6.90	0.0008

Secondary Efficacy Endpoints Measuring Clinical Benefit				
	Molgramostim 300 mcg mean change from baseline to Week 24 compared to placebo	**P-value**	**Molgramostim 300 mcg mean change from baseline to Week 48 compared to placebo**	**P-value**
SGRQ Total Score (points)	-6.59	0.0072	-4.87	0.1046
SGRQ Activity Score (points)	-7.81	0.0149	-5.99	0.1216
Exercise Capacity (peak METs)	0.41	0.0845	0.55	0.0234

SGRQ is a patient-reported outcomes instrument that measures overall health, daily life, and a patient's perceived well-being. SGRQ Activity assesses the patient's ability to carry out daily physical activity. With SGRQ, a negative change from baseline corresponds to improvement. Exercise capacity as measured by a treadmill is a cardiorespiratory health (CRH) measurement.

Molgramostim was well tolerated. The frequency of adverse events was generally similar between treatment groups. Two patients (2.5%) discontinued molgramostim treatment due to adverse events, both of which were considered unrelated to trial drug. The most commonly reported adverse events in the molgramostim group were COVID-19, cough, and pyrexia, with COVID-19 occurring more frequently with molgramostim than with placebo.

IMPALA-2 Top Line Safety Results (Safety Analysis Set, n=164):

Treatment Related Adverse Events	**Molgramostim (N=81) n (%)**	**Placebo (N=83) n (%)**
Any	69 (85)	71 (86)
Most common		
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Serious	14 (17)	20 (24)
Treatment related	20 (25)	16 (19)

"The IMPALA-2 results not only met, but exceeded, our expectations, validating our hypothesis that molgramostim provides clear, durable improvement in gas exchange, and beyond that, clinical benefits that positively impact quality of life for aPAP patients," said Matt Pauls, Chair and CEO, Savara. "The strong efficacy data and favorable benefit-risk profile potentially position molgramostim to be the first and only approved therapeutic for aPAP in the U.S. and Europe. We extend our gratitude to the patients and their families, clinicians, and site personnel for their contributions and ongoing participation in the largest clinical trial in aPAP. We look forward to analyzing the full data from IMPALA-2 and anticipate submitting it for presentation at a scientific conference later this year."

Molgramostim has been granted Orphan Drug, Fast Track, and Breakthrough Therapy designation from the U.S. Food and Drug Administration, Orphan Drug designation from the European Medicines Agency and Innovative Passport and Promising Innovative Medicine designation from the UK's Medicines and Healthcare Products Regulatory Agency for the treatment of aPAP.

Conference Call

Savara management will host a conference call and live audiovisual webcast to discuss the IMPALA-2 results at 8:00am ET today. To access the live webcast of the call with slides please click here or visit the "Events & Presentations" section of Savara's website. To access the call by phone, please use this registration link, and you will be provided with dial in details. A replay of the webcast will be available approximately 24 hours after the conclusion of the call and archived for 90 days under the "Events & Presentations" section of the Company's website at www.savarapharma.com.

About the IMPALA-2 Trial

IMPALA-2 is a global, pivotal, Phase 3, 48-week, randomized, double-blind, placebo-controlled clinical trial designed to compare the efficacy and safety of molgramostim 300 mcg administered once daily by inhalation with matching placebo in patients with aPAP. The trial is being conducted at 43 clinical trial sites across 16 countries in the U.S., Canada, Japan, South Korea, Australia and countries in Europe, including Turkey. The primary efficacy assessment is diffusing capacity of the lungs for carbon monoxide (DLCO), a gas exchange measure, and the primary endpoint is change from baseline to Week 24 in percent predicted DLCO, with a secondary endpoint of change from baseline to Week 48 in percent predicted DLCO. Three additional secondary efficacy variables evaluate clinical measures of direct patient benefit: St. George's Respiratory Questionnaire (SGRQ) Total Score, SGRQ Activity Score, and exercise capacity using a treadmill test, with each endpoint measured at Weeks 24 and 48. The primary time point for efficacy assessments is at Week 24; however, efficacy was assessed through Week 48 to evaluate durability of effect. Safety was assessed through Week 48. Pending applicable regulatory and ethics committee approvals, following the 48-week double-blind treatment period patients may continue in a 96-week open-label period and receive molgramostim 300 mcg administered once daily.

About aPAP

Autoimmune PAP is a rare lung disease characterized by the abnormal build-up of surfactant in the alveoli (or air sacs) of the lungs. Surfactant consists of proteins and lipids and is an important physiological substance that lines the alveoli to prevent them from collapsing. In a healthy lung, excess surfactant is cleared and digested by immune cells called alveolar macrophages. Alveolar macrophages need to be stimulated by granulocyte-macrophage colony-stimulating factor (GM-CSF) to function properly in clearing surfactant, but in autoimmune PAP, GM-CSF is neutralized by antibodies against GM-CSF, rendering the macrophages unable to adequately clear surfactant. As a result, an excess of surfactant accumulates in the alveoli, causing impaired gas exchange, resulting in clinical symptoms of shortness of breath, often with cough and frequent fatigue. Patients may also experience episodes of fever, chest pain, or coughing up blood, especially if secondary lung infection develops. In the long-term, the disease can lead to serious complications, including lung fibrosis and the need for a lung transplant.

About Savara

Savara is a clinical stage biopharmaceutical company focused on rare respiratory diseases. Our lead program, molgramostim nebulizer solution, is an inhaled granulocyte-macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis (aPAP). Molgramostim is delivered via an investigational eFlow® Nebulizer System (PARI Pharma GmbH) specifically developed for inhalation of a large molecule. Our management team has significant experience in rare respiratory diseases and pulmonary medicine, identifying unmet needs, and effectively advancing product candidates to approval and commercialization. More information can be found at www.savarapharma.com. (X, formerly known as 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 related to the anticipated timing of the submission of a Biologics License Application; that there is a high unmet need in aPAP for a pharmacotherapy; that the evidence now clearly demonstrates molgramostim has the potential to be a safe and efficacious treatment option for aPAP patients; statements regarding the therapeutic benefits of molgramostim in aPAP and the impact of molgramostim on quality of life for aPAP patients; that the strong efficacy data and favorable benefit-risk profile potentially position molgramostim to be the first and only approved therapeutic for aPAP in the U.S. and Europe; and that Savara anticipates submitting the full data from IMPALA-2 for presentation at a scientific conference later this year. 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 that analysis of the full data set from the IMPALA-2 clinical trial could result in observations not seen in the top line results; the risks associated with our ability to successfully develop, obtain regulatory approval for and commercialize molgramostim for aPAP; the risks and uncertainties relating to the impact of widespread health concerns impacting healthcare providers or patients and geopolitical conditions on our business and operations, 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, 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.

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