



NEWS RELEASE

Savara Reports Second Quarter 2024 Financial Results and Provides Business Update

2024-08-12

LANGHORNE, Pa.--(BUSINESS WIRE)--Aug. 12, 2024-- **Savara Inc.** (Nasdaq: SVRA) (the Company), a clinical stage biopharmaceutical company focused on rare respiratory diseases, reported financial results for the second quarter ending June 30, 2024 and provided a business update.

Recent Business Highlights

- Reported positive top line results from IMPALA-2, a pivotal, Phase 3 clinical trial of molgramostim nebulizer solution (molgramostim) for the treatment of 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)
 - Nominally significant improvements in SGRQ Activity Score at week 24 and exercise capacity using a treadmill test at week 48 (secondary endpoints)
 - 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
- Abstracts accepted for presentation at 2024's European Respiratory Society (ERS) Congress, the CHEST Annual Meeting, and the British Thoracic Society (BTS) Winter Meeting
 - Abstracts highlight new IMPALA-2 data and the aPAP patient journey



— Company-sponsored industry symposia to be held at the ERS Congress and the CHEST Annual Meeting

- FDA conditionally accepted the trade name MOLBREEVI™ for molgramostim
- Company to host investor webinar on September 30, 2024

— Data from the IMPALA-2 trial will be presented and updates on the global commercial landscape and aPAP market development work will be provided

— Details for accessing the webinar forthcoming

- In July 2024, further strengthened balance sheet with an ~\$100M equity financing, which added ~\$94M to the ~\$122M in cash, cash equivalents, and short-term investments reported as of June 30, 2024; Company expects to be sufficiently capitalized through 2026

“Following strong top line results in the IMPALA-2 trial, we plan to complete the BLA submission for MOLBREEVI, the trade name that the FDA has conditionally accepted for molgramostim, in the first half of 2025,” said Matt Pauls, Chair and CEO, Savara. “In parallel, we are now significantly ramping up global market development activities and look forward to presenting this work, as well as data from the IMPALA-2 trial, during our investor webinar in September.”

Pauls continued, “The IMPALA-2 data support our view that MOLBREEVI could fundamentally change the way aPAP is treated. With approximately 3,600 currently diagnosed U.S. patients and literature suggesting prevalence may be underestimated, plus our increased focus on developing the aPAP market and the potential for MOLBREEVI to be the first and only approved therapy for aPAP in the U.S. and Europe, we believe the global commercial opportunity is significant.”

Abstract Acceptances and Symposia

ERS 2024 (September 7-11)

Abstract: “Inhaled Molgramostim Improves Pulmonary Gas Exchange and Respiratory Health-Related Quality of Life (HRQoL) in Patients with Autoimmune Pulmonary Alveolar Proteinosis (aPAP): Results from IMPALA-2”

Session: Details are forthcoming

Date and Time: Details are forthcoming

The Company is also sponsoring a symposium entitled “Pulmonary Alveolar Proteinosis: Pathophysiology, Diagnosis, and Management.”

- Date and Time: ERS Congress Industry Theater, September 8, 2024, 5:30PM – 7:00PM (CET)

CHEST 2024 (October 6-9)

Abstract: "A Patient Journey Map for People Living with Autoimmune Pulmonary Alveolar Proteinosis (aPAP)"

Poster Session: Diffuse Lung Disease Abstracts Posters (D)

Date and Time: October 8, 2024; 1:45PM – 2:30PM (EDT)

The Company is also sponsoring a symposium entitled "Pulmonary Alveolar Proteinosis: Pathophysiology, Diagnosis, and Management."

- Date and Time: CHEST Learning Theater, October 8, 2024, 2:00PM – 2:45PM (EDT)

BTS Winter Meeting 2024 (November 27-29)

Abstract: "Molgramostim Improves Pulmonary Gas Exchange in Patients with Autoimmune Pulmonary Alveolar Proteinosis (aPAP): Results from the IMPALA-2 Phase 3 Clinical Trial"

Session: Details are forthcoming

Date and Time: Details are forthcoming

Second Quarter Financial Results (Unaudited)

Savara's net loss for the second quarter of 2024 was \$22.2 million, or \$(0.12) per share, compared with a net loss of \$11.4 million, or \$(0.07) per share, for the second quarter of 2023.

Research and development expenses increased by \$8.7 million, or 97.7%, to \$17.6 million for the three months ended June 30, 2024 from \$8.9 million for the three months ended June 30, 2023. This increase was primarily due to the performance of tasks related to the molgramostim program, which include ~\$4.8 million of costs related to chemistry, manufacturing, and controls activities, primarily driven by initiatives to establish a second drug substance manufacturer, ~\$1.2 million of costs related to the IMPALA-2 trial and pediatric study, including CRO-related activities, ~\$1.3 million of costs related to regulatory affairs and quality assurance, and ~\$1.4 million due to an increase in personnel and other departmental overhead.

General and administrative expenses increased by \$2.2 million, or 67.8%, to \$5.5 million for the three months ended June 30, 2024 from \$3.3 million for the three months ended June 30, 2023. The increase was due to personnel and related costs of ~\$1.1 million, certain commercial activities of ~\$0.8 million, and other overhead of ~\$0.3 million primarily driven by consultant costs.

As of June 30, 2024, the Company had cash, cash equivalents and short-term investments of ~\$121.5 million and debt of ~\$26.5 million.

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). 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](https://twitter.com/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, our expectation the Company is sufficiently capitalized through 2026, statements related to the timing and contents of our planned investor webinar in September 2024 and upcoming meetings and symposia, the anticipated timing of our BLA submission, that we are significantly ramping up global market development activities, that the IMPALA-2 data support our view that MOLBREEVI could fundamentally change the way aPAP is treated, our belief that the global commercial opportunity for MOLBREEVI is significant and the basis for that belief. 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 risk that further analysis of the full data set from the IMPALA-2 clinical trial could result in unexpected observations; the risks associated with our ability to successfully develop, obtain regulatory approval for, and commercialize molgramostim for aPAP; the risks and uncertainties related to the impact of widespread health concerns or changing economic or geopolitical conditions; 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.

Financial Information to Follow

Savara Inc. and Subsidiaries Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except for share and per share amounts) Unaudited

	Three months ended		Six months ended	
	June 30, 2024	2023	June 30, 2024	2023
Operating expenses:				
Research and development	\$ 17,617	\$ 8,911	\$ 34,424	\$ 17,649
General and administrative	5,540	3,302	11,176	6,668
Depreciation and amortization	33	8	65	16
Total operating expenses	23,190	12,221	45,665	24,333
Loss from operations	(23,190) (12,221) (45,665) (24,333
Other income (expense), net:	947	778	3,076	2,333
Net loss attributable to common stockholders	\$ (22,243) \$ (11,443) \$ (42,589) \$ (22,000
Net loss per share - basic and diluted	\$ (0.12) \$ (0.07) \$ (0.23) \$ (0.14
Weighted average shares - basic and diluted	182,584,078	152,796,617	182,567,091	152,778,031
Other comprehensive loss	(138) (158) (609) (14
Total comprehensive loss	\$ (22,381) \$ (11,601) \$ (43,198) \$ (22,014

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents, and short-term investments	\$ 121,516	\$ 162,319

Working capital	116,408	155,350
Total assets	139,670	177,564
Total liabilities	37,939	37,192
Stockholders' equity:	101,731	140,372

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