



NEWS RELEASE

# Savara Reports First Quarter 2025 Financial Results and Provides a Business Update

2025-05-13

-- Completed Submission of the Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for MOLBREEVI\* as a Treatment for Autoimmune Pulmonary Alveolar Proteinosis (Autoimmune PAP) and Requested Priority Review --

-- Company Remains on Track to Submit the MOLBREEVI Marketing Authorization Application (MAA) for Autoimmune PAP to the European Medicines Agency (EMA) and the Medicines and Healthcare Products Regulatory Agency (MHRA) by End of the Year --

-- Entered into a Non-Dilutive Debt Financing in March for up to \$200M Which Included \$30M at Close to Refinance Existing Debt Facility --

-- Reported ~\$172.5M in Cash and Short-Term Investments as of March 31, 2025, Company Believes it is Sufficiently Capitalized into 2H 2027 --

LANGHORNE, Pa.--(BUSINESS WIRE)-- **Savara Inc.** (Nasdaq: SVRA) (the Company), a clinical stage biopharmaceutical company focused on rare respiratory diseases, reported financial results for the first quarter ending March 31, 2025 and provided a business update.

"At the end of 1Q 2025, we announced the on-time submission of the MOLBREEVI BLA to the FDA for the treatment of autoimmune PAP and requested priority review," said Matt Pauls, Chair and Chief Executive Officer, Savara. "If Priority Review is granted, we anticipate a PDUFA date by the end of the year and are preparing for a U.S. commercial launch in early 2026. We are also on track to submit the MAA in both Europe and the U.K. by the end of the year. Lastly, with approximately \$172.5 million in cash, and the optionality to further finance the company

through access to low-cost capital from our recent debt financing, we are in a strong financial position and believe our current cash runway extends into 2H 2027, well beyond a U.S. launch.”

## Upcoming Presentations at American Thoracic Society (ATS) Conference

New data from the Phase 3 IMPALA-2 trial of MOLBREEVI in patients with autoimmune PAP will be presented at the ATS International Conference 2025 in San Francisco, May 16-21, 2025. The Company is also hosting an Industry Symposium with leading key opinion leaders in autoimmune PAP. For more information see our recent **press release**.

## First Quarter Financial Results (Unaudited)

Savara's net loss for the first quarter of 2025 was \$26.6 million, or \$(0.12) per share, compared with a net loss of \$20.3 million, or \$(0.11) per share, for the first quarter of 2024.

Research and development expenses increased by \$2.4 million, or 14.0%, to \$19.2 million for the three months ended March 31, 2025 from \$16.8 million for the three months ended March 31, 2024. This increase was primarily due to the performance of tasks related to our MOLBREEVI program with \$2.3 million related to regulatory affairs and quality assurance, and \$0.1 million in departmental overhead.

General and administrative expenses increased by \$3.6 million, or 64.1%, to \$9.2 million for the three months ended March 31, 2025 from \$5.6 million for the three months ended March 31, 2024. The increase was due to personnel and related costs of \$2.4 million, certain commercial activities of \$0.8 million, and other departmental overhead of \$0.4 million.

As of March 31, 2025, the Company had cash, cash equivalents and short-term investments of ~\$172.5 million and debt of ~\$29.5 million.

## About Autoimmune Pulmonary Alveolar Proteinosis (autoimmune PAP)

Autoimmune PAP is a rare lung disease characterized by the abnormal build-up of surfactant in the alveoli 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 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, MOLBREEVI\*, is a recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis (autoimmune PAP). MOLBREEVI 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](http://www.savarapharma.com) and [LinkedIn](#).

\*MOLBREEVI is the FDA and EMA conditionally accepted trade name for molgramostim inhalation solution. It is not approved in any indication. MOLBREEVI is a trademark of Savara Inc.

## 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 timing of the MAA submissions to the EMA and MHRA, our belief regarding the capitalization and cash runway of the Company, including the impact of our recent debt financing, statements related to the impact of Priority Review and the anticipated timing for a PDUFA date and commercial launch of MOLBREEVI, and statements relating to the Company’s planned presentations and activities at the ATS International Conference 2025. 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 associated with our ability to successfully develop, obtain regulatory approval for, and commercialize MOLBREEVI for autoimmune PAP; 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 March 31,	
	2025	2024
Operating expenses:		
Research and development	\$ 19,159	\$ 16,807
General and administrative	9,246	5,636
Depreciation and amortization	30	32
Total operating expenses	28,435	22,475
Loss from operations	(28,435)	(22,475)
Other income (expense), net:	1,796	2,129
Net loss attributable to common stockholders	\$ (26,639)	\$ (20,346)
Net loss per share - basic and diluted	\$ (0.12)	\$ (0.11)
Weighted average shares - basic and diluted	216,146,934	182,550,109
Other comprehensive (loss) gain	118	(471)
Total comprehensive loss	\$ (26,521)	\$ (20,817)

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

	March 31, 2025	December 31, 2024
Cash, cash equivalents, and short-term investments	\$ 172,500	\$ 196,327
Working capital	165,546	187,411
Total assets	189,316	212,879
Total liabilities	41,466	41,430
Stockholders' equity:	147,850	171,449

## Media and Investor Relations Contact

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