



NEWS RELEASE

Savara Reports Fourth Quarter and Year End 2024 Financial Results and Provides Business Update

2025-03-27

-- 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 (aPAP) --

-- Priority Review Was Requested, Commercial Launch Preparations Underway --

-- With ~\$196M in Cash and Short-Term Investments as of December 31, 2024, the Company Believes it is Sufficiently Capitalized through 2Q 2027, Excluding the Recent Debt Financing of Up To \$200M --

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 fourth quarter and full year ending December 31, 2024 and provided a business update.

"Completing submission of the BLA is an important milestone in potentially addressing the significant unmet need of people living with aPAP, a rare and debilitating lung disease," said Matt Pauls, Chair and Chief Executive Officer, Savara. "MOLBREEVI has the potential to be the first and only approved therapy for aPAP in the U.S. and Europe and could redefine the standard of care for the disease. If granted Priority Review, we could have a PDUFA date by the end of the year and are preparing for a commercial launch in early 2026. Lastly, with approximately \$196 million in cash, we are in a strong financial position and believe our cash runway extends through 2Q 2027, excluding our recent debt financing which adds additional low-cost capital options to further finance the Company."

In addition to Fast Track and Breakthrough Therapy Designations, MOLBREEVI has been granted Orphan Drug Designation for the treatment of aPAP by the FDA and the European Medicines Agency (EMA), as well as Innovation Passport (IP) and Promising Innovative Medicine (PIM) designations by the UK's Medicines and Healthcare Products

Regulatory Agency (MHRA).

Fourth Quarter Financial Results (Unaudited)

Savara's net loss for the fourth quarter of 2024 was \$29.0 million, or \$(0.13) per share, compared with a net loss of \$16.1 million, or \$(0.09) per share, for the fourth quarter of 2023.

Research and development expenses for the fourth quarter of 2024 and 2023 were \$23.3 million and \$12.7 million, respectively.

General and administrative expenses for the fourth quarter of 2024 and 2023 were \$7.8 million and \$4.9 million, respectively.

As of December 31, 2024, the Company had cash, cash equivalents and short-term investments of \$196.3 million.

Fiscal Year 2024 Financial Results

The Company's net loss for the year ended December 31, 2024 was \$95.9 million, or \$(0.48) per share, compared with a net loss of \$54.7 million, or \$(0.33) per share for the year ended December 31, 2023.

Research and development expenses increased \$33.8 million, or 76.3%, to \$78.0 million for the year ended December 31, 2024 from \$44.3 million for the year ended December 31, 2023. This increase was primarily due to the performance of tasks related to our MOLBREEVI program which includes approximately \$19.9 million related to our chemistry, manufacturing, and controls activities, primarily driven by initiatives to establish our second drug substance manufacturer, \$2.8 million of costs related to the IMPALA-2 trial, IMPACT trial in pediatric aPAP, and Savara Early Access Program, including CRO-related activities, \$4.1 million of costs related to regulatory affairs and quality assurance, and \$7.0 million due to an increase in personnel and related costs and other departmental overhead.

General and administrative expenses increased \$9.4 million, or 59.8%, to \$25.0 million for the year ended December 31, 2024 from \$15.7 million for the year ended December 31, 2023. The increase was due to personnel and related costs of \$4.3 million, certain commercial activities of \$3.8 million, and other overhead of \$1.3 million primarily driven by patient advocacy activities and consultant costs.

About Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

aPAP 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 aPAP, 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

Svara 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 (aPAP). 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.savapharma.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

Svara 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 belief regarding the capitalization and cash runway of the Company, statements related to potentially addressing the significant unmet need of people living with aPAP, MOLBREEVI having the potential to be the first and only approved therapy for aPAP in the U.S. and Europe and could redefine the standard of care for the disease, and statements related to the impact of Priority Review and the anticipated timing for commercial launch of MOLBREEVI. Svara 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 Svara'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 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 December 31, 2024	2023	Twelve months ended December 31, 2024	2023
Operating expenses:				
Research and development	\$ 23,294	\$ 12,746	\$ 78,029	\$ 44,262
General and administrative	7,848	4,852	25,037	15,668
Depreciation and amortization	32	32	130	77
Total operating expenses	<u>31,174</u>	<u>17,630</u>	<u>103,196</u>	<u>60,007</u>
Loss from operations	(31,174)	(17,630)	(103,196)	(60,007)
Other income, net:	2,130	1,531	7,315	5,309
Net loss attributable to common stockholders	\$ (29,044)	\$ (16,099)	\$ (95,881)	\$ (54,698)
Net loss per share - basic and diluted	\$ (0.13)	\$ (0.09)	\$ (0.48)	\$ (0.33)
Weighted average shares - basic and diluted	215,446,265	179,843,515	198,191,936	165,204,652
Other comprehensive loss	(1,049)	671	(479)	334
Total comprehensive loss	<u>\$ (30,093)</u>	<u>\$ (15,428)</u>	<u>\$ (96,360)</u>	<u>\$ (54,364)</u>

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

	December 31, 2024	December 31, 2023
Cash, cash equivalents, and short-term investments	\$ 196,327	\$ 162,319
Working capital	187,411	155,350
Total assets	212,879	177,564
Total liabilities	41,430	37,192
Stockholders' equity	171,449	140,372

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Source: Savara Inc.