NEWS RELEASE

Savara Reports Second Quarter 2025 Financial Results and Provides a Business Update

2025-08-13

-- Reached Alignment with the U.S. Food and Drug Administration (FDA) on Information Needed for Resubmission of the Biologics License Application (BLA) for MOLBREEVI* as a Treatment for Autoimmune Pulmonary Alveolar Proteinosis (Autoimmune PAP) --

-- Plan to Resubmit the BLA in December with FUJIFILM Biotechnologies (Fujifilm) as the Drug Substance Manufacturer and Will Request Priority Review --

-- Anticipate Submitting the MOLBREEVI Marketing Authorization Applications for Autoimmune PAP to the European Medicines Agency (EMA) and the UK Medicines and Healthcare Products Regulatory Agency (MHRA) in 1Q 2026 --

-- Reported ~$146M in Cash and Short-Term Investments as of June 30, 2025, Company Believes It Is Sufficiently Capitalized into 1Q 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 second quarter ending June 30, 2025 and provided a business update.

“Following a recent Type A meeting with the FDA, and receipt of the meeting minutes, we believe we have aligned on a path forward for the information needed to resubmit the BLA with Fujifilm as our drug substance manufacturer,” said Matt Pauls, Chair and CEO, Savara. “With the Process Performance Qualification campaigns now complete at Fujifilm, and finalization of the analytical data package expected early in the fourth quarter, we plan to resubmit the BLA in December. We are grateful for the constructive and timely dialogue with the FDA and are pleased to be working with Fujifilm, a top 10 biologics manufacturer with more than 20 approved drug

substances globally and a successful inspection history with numerous regulatory authorities."

Pauls continued, "With no approved therapies in the United States or Europe for autoimmune PAP, there is a high unmet medical need to treat this rare and debilitating lung disease. We are committed to our goal of providing these patients with the first and only pharmacologic treatment option. We continue our work, with urgency, to pursue approval for MOLBREEVI."

Second Quarter Financial Results (Unaudited)

Savara's net loss for the second quarter of 2025 was $30.4 million, or $(0.14) per share, compared with a net loss of $22.2 million, or $(0.12) per share, for the second quarter of 2024.

Research and development expenses increased by $3.1 million, or 17.8%, to $20.8 million for the three months ended June 30, 2025 from $17.6 million for the three months ended June 30, 2024. This increase was primarily due to the performance of tasks related to our MOLBREEVI program, which included approximately $3.3 million of costs related to our Chemistry, Manufacturing, and Controls activities, primarily driven by initiatives to establish our additional drug substance manufacturer and $1.1 million of costs related to Regulatory Affairs and Quality Assurance, partially offset by $1.3 million of reduced clinical costs.

General and administrative expenses increased by $5.1 million, or 92.3%, to $10.7 million for the three months ended June 30, 2025 from $5.5 million for the three months ended June 30, 2024. The increase was primarily attributable to the strategic addition of personnel and related costs of $2.5 million, certain commercial activities of $1.5 million, and other departmental overhead of $1.1 million.

As of June 30, 2025, the Company had cash, cash equivalents and short-term investments of ~$146.4 million and debt of ~$29.7 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** 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 reaching alignment with the FDA on the information needed to resubmit the BLA with Fujifilm as the drug substance manufacturer, the expected timing for resubmission of the BLA and requesting priority review, the anticipated timing of the MAA submissions to the EMA and MHRA, our belief regarding the capitalization and cash runway of the Company, the expected timing of the finalization of the analytical data package, our goal of providing patients with the first and only pharmacologic treatment option for autoimmune PAP, and that we continue our work, with urgency, to pursue approval for MOLBREEVI. 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 June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 20,751	$ 17,617	$ 39,910	$ 34,424
General and administrative	10,655	5,540	19,901	11,176
Depreciation and amortization	34	33	63	65
Total operating expenses	31,440	23,190	59,874	45,665
Loss from operations	(31,440)	(23,190)	(59,874)	(45,665)
Other income (expense), net:	1,039	947	2,834	3,076
Net loss attributable to common stockholders	$ (30,401)	$ (22,243)	$ (57,040)	$ (42,589)
Net loss per share - basic and diluted	$ (0.14)	$ (0.12)	$ (0.26)	$ (0.23)
Weighted average shares - basic and diluted	216,431,348	182,584,078	216,289,923	182,567,091
Other comprehensive (loss) gain	416	(138)	534	(609)
Total comprehensive loss	$ (29,985)	$ (22,381)	$ (56,506)	$ (43,198)

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

	June 30, 2025	December 31, 2024
Cash, cash equivalents, and short-term investments	$ 146,443	$ 196,327
Working capital	137,360	187,411
Total assets	163,765	212,879
Total liabilities	43,281	41,430
Stockholders' equity:	120,484	171,449

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Source: Savara Inc.