NEWS RELEASE

Savara Reports Third Quarter 2024 Financial Results and Provides Business Update

2024-11-12

Recently Completed Pre-BLA Meeting with FDA for MOLBREEVI* in Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

Company Plans to Initiate Biologics License Application (BLA) Rolling Submission by End of Year

Updates Guidance on MOLBREEVI BLA Submission Completion Date to End of 1Q 2025 from 1H 2025 – Intends to Request Priority Review

Expects to Submit MOLBREEVI Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) by End of 2025

With ~$219M in Cash and Short-Term Investments, the Company Believes it is Sufficiently Capitalized through 2Q 2027

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

“After a productive pre-BLA meeting with the FDA, we are working diligently to initiate a rolling submission for MOLBREEVI by the end of this year, with plans to complete the BLA submission by the end of 1Q 2025—thus enabling a potential approval in the U.S. by the end of 2025, if priority review is granted,” said Matt Pauls, Chair and CEO, Savara. “BLA submission, coupled with the submission of the MAA to the EMA by the end of 2025, are major regulatory milestones that could bring us one step closer to providing aPAP patients in the U.S. and Europe with the

first and only approved therapeutic option for this rare and debilitating lung disease. In parallel, we are accelerating the build-out of our commercial capabilities, complimented by ongoing market development initiatives, to ensure the approximately 3,600 diagnosed aPAP patients in the U.S. get access to MOLBREEVI post-approval. Lastly, after strengthening our balance sheet, we believe our cash runway now extends from the end of 2026 through the second quarter of 2027."

Third Quarter Financial Results (Unaudited)

Savara's net loss for the third quarter of 2024 was $24.2 million, or $(0.11) per share, compared with a net loss of $16.6 million, or $(0.10) per share, for the third quarter of 2023.

Research and development expenses increased by $6.4 million, or 46.5%, to $20.3 million for the three months ended September 30, 2024 from $13.9 million for the three months ended September 30, 2023. This increase was primarily due to the performance of tasks related to our MOLBREEVI program, which includes ~$3.7 million of costs related to our chemistry, manufacturing, and controls activities, primarily driven by initiatives to establish our second drug substance manufacturer, ~$0.2 million of clinical costs driven by the pediatric study, ~$1.0 million of costs related to regulatory affairs and quality assurance, and ~$1.5 million due to an increase in personnel and related costs as well as other departmental overhead.

General and administrative expenses increased by $1.9 million, or 45.0%, to $6.0 million for the three months ended September 30, 2024 from $4.1 million for the three months ended September 30, 2023. The increase was due to personnel and related costs of ~$0.8 million, certain commercial activities of ~$0.9 million, and other departmental overhead of ~$0.2 million.

As of September 30, 2024, the Company had cash, cash equivalents and short-term investments of ~$219.4 million and debt of ~$26.6 million.

About aPAP

Autoimmune PAP (aPAP) 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 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 (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.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 our BLA submission and the potential timing for approval if priority review is granted, statements related to the anticipated timing of our MAA submission, statements related to the build-out of our commercial capabilities and our ongoing market development initiatives, and our expectation the Company is sufficiently capitalized through the second quarter of 2027. 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 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.

*MOLBREEVI is the FDA and EMA conditionally accepted trade name for molgramostim inhalation solution.

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 September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 20,311	$ 13,867	$ 54,735	$ 31,516
General and administrative	6,013	4,147	17,189	10,816
Depreciation and amortization	33	30	98	45
Total operating expenses	26,357	18,044	72,022	42,377
Loss from operations	(26,357)	(18,044)	(72,022)	(42,377)
Other income (expense), net:	2,109	1,445	5,185	3,778
Net loss attributable to common stockholders	$ (24,248)	$ (16,599)	$ (66,837)	$ (38,599)
Net loss per share - basic and diluted	$ (0.11)	$ (0.10)	$ (0.35)	$ (0.25)
Weighted average shares - basic and diluted	211,847,651	174,696,191	192,398,514	152,778,072

Other comprehensive loss	1,179	(323)	570	(337)
Total comprehensive loss	$ (23,069)	$ (16,922)	$ (66,267)	$ (38,936)

Savara Inc. and Subsidiaries

Condensed Consolidated Balance Sheet Data

(in thousands)

(Unaudited)

	September 30, 2024	December 31, 2023
Cash, cash equivalents, and short-term investments	$ 219,440	$ 162,319
Working capital	213,607	155,350
Total assets	238,817	177,564
Total liabilities	39,468	37,192
Stockholders' equity:	199,349	140,372

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