



NEWS RELEASE

Savara Reports Third Quarter 2021 Financial Results and Provides Business Update

2021-11-12

- Continued to Advance Pivotal Phase 3 IMPALA 2 Trial of Molgramostim Nebulizer Solution (Molgramostim) in Autoimmune Pulmonary Alveolar Proteinosis (aPAP); 20-Month Enrollment Guidance Remains On-Track
- Received Acceptance from Pediatric Committee of the European Medicines Agency (EMA) on Proposed Revised Pediatric Investigation Plan (PIP) for Molgramostim
- Ended Quarter with Cash Balance of ~\$171M—Company Believes it is Sufficiently Capitalized Through 2025, ~18 Months Beyond Anticipated IMPALA-2 Top-Line Data Readout at End of Q2 2024
- Bolstered Company Leadership with the Appointments of Peter Clarke, Executive Vice President of Global Technical Operations and Charles LaPree, Senior Vice President of Global Regulatory Affairs & Quality Assurance

AUSTIN, Texas--(BUSINESS WIRE)--Nov. 12, 2021-- **Savara Inc.** (Nasdaq: SVRA), a clinical stage biopharmaceutical company focused on rare respiratory diseases, today reported financial results for the third quarter ending September 30, 2021 and provided a business update.

“The team is focused and driving hard on advancing the pivotal Phase 3 IMPALA 2 trial,” said Matt Pauls, Chair and Chief Executive Officer, Savara. “Given that an increasing number of sites are actively screening and enrolling patients, and we completed an important regulatory milestone with EMA’s acceptance of our proposed revised PIP, we are pleased with our progress over the last quarter. While the potential impact of COVID-19 and the flu over the winter is unknown, we remain confident in our guidance of a 20-month enrollment timeframe and top-line data by the end of Q2 2024. Finally, we significantly bolstered our inhalation delivery and biological product expertise in the manufacturing, regulatory, and quality functions with the addition of Peter Clarke and Charles LaPree.”



Third Quarter Financial Results (Unaudited)

Savara's net loss attributable to common stockholders for the three months ended September 30, 2021, was \$10.5 million, or \$(0.07) per share, compared with a net loss attributable to common stockholders of \$11.1 million, or \$(0.18) per share, for the three months ended September 30, 2020.

Research and development expenses increased by \$0.9 million, or 16.6%, to \$6.5 million for the three months ended September 30, 2021 from \$5.6 million for the three months ended September 30, 2020. The increase was primarily attributable to an approximately \$3.2 million increase in costs associated with the screening of patients and progression of the IMPALA-2 trial for the molgramostim development program. This was partially offset by a \$2.1 million decrease in chemistry, manufacturing, and control ("CMC") and clinical operations activities associated with the wind down of the vancomycin study in methicillin-resistant *Staphylococcus aureus* (MRSA) lung infection.

General and administrative expenses decreased by \$2.0 million, or 36.7%, to \$3.4 million for the three months ended September 30, 2021 from \$5.4 million for the three months ended September 30, 2020. The decrease was primarily due to the recognition of a one-time non-recurring charge of \$0.8 million for non-cash stock-based compensation and approximately \$1.5 million of paid and accrued severance payments to former members of executive management during the three months ended September 30, 2020.

As of September 30, 2021, Savara had cash, cash equivalents, and short-term investments of approximately \$171 million and debt of approximately \$25 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 <https://savarapharma.com/>. (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 regarding the anticipated timing of enrollment for the IMPALA-2 trial; our belief the Company is

sufficiently capitalized through 2025; the anticipated timing of the top-line IMPALA-2 data read-out; that while the potential impact of COVID-19 and the flu this winter is unknown, we remain confident in our guidance for enrollment and top-line data read-out; and statements that Savara significantly bolstered our inhalation delivery and biological product expertise in the manufacturing, regulatory, and quality functions with the addition of new executive employees. 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 and uncertainties relating to the impact of the COVID-19 pandemic on our business and operations, the outcome of our ongoing and planned clinical trials for our product candidate, 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, the ability to obtain the necessary patient enrollment for our product candidate in a timely manner, the ability to successfully develop our product candidate, the risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates such as molgramostim that are safe and effective for use as human therapeutics, 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		Nine months ended	
September 30,		September 30,	
2021	2020	2021	2020

.....

+

.....

+

.....



Milestone revenue	\$ -	\$ 256	\$ -	\$ 256
Operating expenses:				
Research and development	6,532	5,603	21,373	24,881
General and administrative	3,400	5,375	9,331	11,474
Depreciation and amortization	40	63	134	189
Total operating expenses	9,972	11,041	30,838	36,544
Loss from operations	(9,972)	(10,785)	(30,838)	(36,288)
Other income, net:	(574)	(278)	(866)	414
Net loss attributable to common stockholders	\$ (10,546)	\$ (11,063)	\$ (31,704)	\$ (35,874)
Net loss per share - basic and diluted	\$ (0.07)	\$ (0.18)	\$ (0.25)	\$ (0.61)
Weighted average shares - basic and diluted	152,587,848	60,288,993	127,623,824	58,842,436
Other comprehensive (loss) gain	(307)	133	(657)	270
Total comprehensive loss	\$ (10,853)	\$ (10,930)	\$ (32,361)	\$ (35,604)

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

	September 30, 2021	December 31, 2020
Cash, cash equivalents, and short-term investments	\$ 170,806	\$ 82,188

Working capital	163,923	76,947
Total assets	187,274	97,745
Total liabilities	32,045	33,362
Stockholders' equity:	155,229	64,383

View source version on [businesswire.com](https://www.businesswire.com/news/home/20211112005309/en/): <https://www.businesswire.com/news/home/20211112005309/en/>

Savara Inc. IR & PR

Anne Erickson (anne.erickson@savarapharma.com)

(512) 851-1366

Source: Savara Inc.