



NEWS RELEASE

# Savara Reports Fourth Quarter and Full Year 2017 Financial Results and Provides Business Update

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AUSTIN, TX -- (Marketwired) -- 03/14/18 --

- Anticipating completion of enrollment in Molgradex Phase 3 IMPALA study in Q3 2018
- Anticipating completion of enrollment in AeroVanc Phase 3 AVAIL study in Q1 2019
- Anticipating completion of enrollment in Molgradex Phase 2a OPTIMA study in Q3 2018
- Conference call scheduled for today at 5:30 p.m. E.T.

**Savara Inc.** (NASDAQ: SVRA), an orphan lung disease company, today reported fourth quarter and full year 2017 financial results and provided a business update.

"2017 was transformative for Savara and served as a solid foundation as we aim to build a preeminent orphan lung disease company," stated Rob Neville, chief executive officer of Savara. "Our public listing in the capital markets, two successful public offerings, the progression of our two lead programs into Phase 3 development in PAP and CF, as well as our expansion into a new and exciting therapeutic area, NTM, exceeded even our most aggressive plans, and was an outstanding achievement for our entire team. With two late-stage clinical studies ongoing, our focus in 2018 will be on the continued advancement of our core programs, while actively exploring further expansion of our pipeline."

## Upcoming Milestones and Recent Developments

- Anticipating completion of enrollment in the Molgradex Phase 3 **IMPALA** study in Q3 2018. The IMPALA



study is evaluating an inhaled formulation of granulocyte-macrophage colony-stimulating factor, or GM-CSF, for the treatment of pulmonary alveolar proteinosis, or PAP. In February, the FDA approved our Investigational New Drug application, allowing for the expansion of the IMPALA study into the U.S. In addition, based on a blinded interim check of the variability of two of the key secondary endpoints, the study size was adjusted to further increase the likelihood of a robust and convincing study outcome. Enrollment remained ahead of guidance prior to the sample size adjustment, with completion of enrollment now expected in Q3 2018 and topline data anticipated in Q2 2019.

- **Anticipating completion of enrollment in the AeroVanc Phase 3 AVAIL study in Q1 2019.** The AVAIL study is evaluating a vancomycin hydrochloride inhalation powder for the treatment of persistent methicillin-resistant *Staphylococcus aureus* (MRSA) lung infection in individuals living with cystic fibrosis (CF). Enrollment began in line with guidance in September 2017 and is expected to be completed in Q1 2019 with topline data anticipated in H2 2019.
- **Anticipating completion of enrollment in the Molgradex Phase 2a OPTIMA study in Q3 2018 .** The OPTIMA study is evaluating inhaled GM-CSF for the treatment of nontuberculous mycobacterial (NTM) lung infection, a rare and serious lung disorder. Patient enrollment began in line with guidance in March 2018 and is expected to be completed in Q3 2018.
- **Announced publication of two case reports exploring the use of aerosolized granulocyte-macrophage colony stimulating factor (GM-CSF) for the treatment of *Mycobacterium abscessus* ( *M. abscessus*) lung infection.** In February, two case reports were published in the **European Respiratory Journal**, exploring the use of aerosolized GM-CSF for the treatment of *M. abscessus*, a species of multidrug-resistant NTM, in individuals living with CF. The case reports, authored by clinicians at the **Mayo Clinic College of Medicine**, demonstrated that inhaled GM-CSF eradicated or dramatically reduced *M. abscessus* infection, improved clinical outcome and was well tolerated.
- **Selected for addition to the NASDAQ Biotechnology Index® (NASDAQ: NBI).**
- **Received \$5 million award from Cystic Fibrosis Foundation Therapeutics, Inc.** The award is available to support the continued development of AeroVanc including the Company's ongoing Phase 3 pivotal **AVAIL** study. The \$5 million award can be drawn down by Savara as needed upon the achievement of continued progress and certain milestones of the AeroVanc program and the AVAIL study.

#### Fourth Quarter Financial Results (Unaudited)

Savara's net loss for the fourth quarter of 2017 was \$6.5 million, or \$(0.23) per share, compared with a net loss of \$4.0 million, or \$(1.31) per share, for the fourth quarter of 2016.

Research and development expenses were \$6.4 million for the fourth quarter of 2017, compared with \$3.5 million

for the fourth quarter of 2016.

General and administrative expenses for the fourth quarter of 2017 were \$2.8 million, compared with \$0.9 million for the fourth quarter of 2016.

As of December 31, 2017, we had cash of \$22.1 million and short-term investments of \$72.2 million. The Company's operating expenses for the fourth quarter of 2017 were approximately \$9.3 million. Savara ended the fourth quarter of 2017 with approximately \$14.8 million outstanding in long-term debt on its balance sheet, which we utilized to bolster operations.

### **Fiscal Year 2017 Financial Results**

Savara's net loss for the year ended December 31, 2017 was \$29.8 million, or \$(1.76) per share, compared with a net loss of \$10.9 million, or \$(5.62) per share for the year ended December 31, 2016.

Research and development expenses increased by \$10.3 million, or 126%, to \$18.5 million for the year ended December 31, 2017 from \$8.2 million for the year ended December 31, 2016. The increase was primarily due to \$7.8 million in increased development costs associated with the development of Molgradex, which was not part of the Savara development plan until mid-July 2016, and an increase of \$1.5 million in AeroVanc CMC and study costs as we initiated our Phase 3 clinical trial. Additionally, in April 2017 we began incurring costs for our Aironite program which totaled \$1.0 million for the year ended December 31, 2017 versus \$0 for the year ended December 31, 2016.

General and administrative expenses increased by \$8.3 million, or 292%, to \$11.1 million for the year ended December 31, 2017 from \$2.8 million for the year ended December 31, 2016. The increase was due to \$2.2 million of expense in connection with the changes in fair value of the contingent consideration associated with the Serendex acquisition and approximately \$2.8 million of expense in connection with the merger with Mast Therapeutics, Inc. and financing activities and related costs including legal and accounting expenditures. Savara personnel costs increased \$1.5 million due to increased administrative personnel costs which includes the addition of several finance and accounting personnel. In 2017, Savara incurred increased costs associated with being a public company. These costs included certain legal, accounting and filing costs, as well as public company insurance costs, all of which totaled approximately \$1.0 million. Additionally, administrative costs of Savara ApS (Denmark) totaled \$0.8 million during the year ended December 31, 2017 and such entity was not part of Savara until July 15, 2016, and had costs of only \$0.3 million for the five and a half months under our ownership through December 31, 2016.

### **Conference Call and Webcast**

Savara will hold a conference call today beginning at 5:30 p.m. Eastern Time / 4:30 p.m. Central Time to provide an

overview and business update. Shareholders and other interested parties may access the conference call by dialing (855) 239-3120 from the U.S., (855) 669-9657 from Canada and (412) 542-4127 from elsewhere outside the U.S., and should request the Savara Inc. call. A live webcast of the conference call will be available online from the Investors section of Savara's website at <http://www.savarapharma.com/investors/events/>. Replays of the webcast will be available on Savara's website for 30 days, and a telephone replay will be available through March 21, 2018 by dialing (877) 344-7529 from the U.S., (855) 669-9658 from Canada, and (412) 317-0088 from elsewhere outside the U.S. by entering replay access code 10117656.

### **About Savara**

Savara Inc. is an orphan lung disease company. Savara's pipeline comprises: Molgradex, an inhaled granulocyte-macrophage colony-stimulating factor, or GM-CSF, in Phase 3 development for PAP, and in Phase 2a development for NTM lung infection; and AeroVanc, a Phase 3 stage inhaled vancomycin for treatment of MRSA infection in cystic fibrosis. Savara's strategy involves expanding its pipeline of potentially best-in-class products through indication expansion, strategic development partnerships and product acquisitions, with the goal of becoming a leading company in its field. Savara's management team has significant experience in orphan drug development and pulmonary medicine, in identifying unmet needs, developing and acquiring new product candidates, and effectively advancing them to approvals and commercialization. More information can be found at [www.savarapharma.com](http://www.savarapharma.com). (Twitter: [@SavaraPharma](https://twitter.com/SavaraPharma))

### **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 about our aim to build a preeminent orphan lung disease company, our expansion into NTM as a new and exciting therapeutic area, our focus in 2018 being on the continued advancement of our core programs and actively exploring further expansion of our pipeline, the timing of the completion of enrollment and topline data of our Molgradex Phase 3 IMPALA study, the timing of completion of enrollment and topline data of our AeroVanc Phase 3 AVAL study, the timing of completion of enrollment of our Molgradex Phase 2a OPTIMA study and Savara's strategy. 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. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such 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, risks and uncertainties associated with the outcome of our ongoing

clinical trials for our product candidates, 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 candidates in a timely manner, the timing and ability of Savara to raise additional equity capital to fund continued operations; the ability to successfully develop our product candidates, and the risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates such as Molgradex and AeroVanc that are safe and effective for use as human therapeutics. 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.

Tables to follow

Savara Inc. and Subsidiaries  
Condensed Consolidated Statements of Operations  
(In thousands, except for share and per share amounts)

|  | Three months ended<br>December 31,<br>(Unaudited) |                   | Year ended<br>December 31, |                    |
|--|---|-------------------|----------------------------|--------------------|
|  | 2017  | 2016              | 2017                       | 2016               |
| Total net revenue                                  | \$ -  | \$ 400            | \$ -                       | \$ 400             |
| Operating expenses:                                |   |                   |                            |                    |
| Research and development                           | 6,434   | 3,488             | 18,512                     | 8,182              |
| General and administration                         | 2,771   | 866               | 11,081                     | 2,820              |
| Depreciation and amortization                      | 91  | 90                | 363                        | 346                |
| Total operating expenses                           | <u>9,296</u>                                      | <u>4,444</u>      | <u>29,956</u>              | <u>11,348</u>      |
| Loss from operations                               | \$ (9,296)  | \$ (4,044)        | \$ (29,956)                | \$ (10,948)        |
| Interest and other (expense)/income, net           | (16)  | (282)             | (3,475)                    | (332)              |
| Loss before income taxes                           | <u>\$ (9,312)</u>                                 | <u>\$ (4,326)</u> | <u>\$ (33,431)</u>         | <u>\$ (11,280)</u> |
| Income tax benefit                                 | 2,810   | 357               | 3,634                      | 357                |
| Net loss   | <u>\$ (6,502)</u>                                 | <u>\$ (3,969)</u> | <u>\$ (29,797)</u>         | <u>\$ (10,923)</u> |
| Other expenses attributable to common shareholders | -   | (24)              | (982)                      | (94)               |
| Net loss attributable to common shareholders       | <u>\$ (6,502)</u>                                 | <u>\$ (3,993)</u> | <u>\$ (30,779)</u>         | <u>\$ (11,017)</u> |
| Net loss per share - basic and diluted             | <u>\$ (0.23)</u>                                  | <u>\$ (1.31)</u>  | <u>\$ (1.76)</u>           | <u>\$ (5.62)</u>   |
| Weighted average shares - basic and diluted        | <u>28,652,104</u>                                 | <u>3,045,672</u>  | <u>17,521,119</u>          | <u>1,960,490</u>   |

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Savara Inc. and Subsidiaries  
Balance Sheet data  
(In Thousands)

|   | December 31,<br>2017 | December 31,<br>2016 |
|---|----------------------|----------------------|
| Cash, cash equivalents and short-term investments | \$ 94,313            | \$ 13,373            |
| Working capital                                   | 91,849               | 11,158               |
| Total assets                                      | 159,628              | 28,934               |
| Total liabilities                                 | 40,319               | 20,948               |
| Redeemable convertible preferred stock            | -                    | 43,861               |
| Stockholders' equity (deficit)                    | 119,309              | (35,875)             |

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Source: Savara Inc.