UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)
March 16, 2021

SAVARA INC.
(Exact name of registrant as specified in its charter)

Delaware	001-32157	84-1318182
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

6836 Bee Cave Road, Building III, Suite 200
Austin, TX 78746
(Address of principal executive offices, including zip code)

(512) 614-1848
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**SVRA**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

Savara has updated its corporate presentation, which is available on the Investor Relations page of Savara's website at https://savarapharma.com/investors. A copy of the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K. Savara undertakes no duty or obligation to update or revise the information contained in this presentation, although it may do so from time to time. Any such updates may be made through the Investor Relations page of the Savara website, the filing of other reports or documents with the U.S. Securities and Exchange Commission, press releases, or other public disclosure.

The information in Item 7.01 in this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section, nor shall it be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Savara Corporate Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 16, 2021

SAVARA INC.
a Delaware corporation

By: /s/ Dave Lowrance
Dave Lowrance
Chief Financial Officer

Savara Corporate Presentation (NASDAQ: SVRA)

March 2021

SAVARA

Safe Harbor Statement

Savara Inc. (“Savara” or the “Company”) cautions you that statements in this presentation that are not a description of historical fact are forward-looking statements which may be identified by the use of words such as “expect,” “intend,” “plan,” “anticipate,” “believe,” and “will,” among others. Such statements include, but are not limited to, statements regarding the nature, strategy and focus of our organization; the timing, design and other matters related to clinical trials of our product candidate; the safety, efficacy and projected development timeline of our product candidate; the potential health benefits of our product candidate; our anticipated corporate milestones and the market size or commercial potential for our product; and the sufficiency of our resources to fund the advancement of our development program and potential sources of additional capital. Savara may not actually achieve any of its plans or product development goals in a timely manner, if at all, or otherwise carry out its current intentions or meet the expectations or projections disclosed in its 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, the risks and uncertainties related to the impact of the COVID-19 pandemic on our business and operations; the outcome of our future interactions with regulatory authorities; risks and uncertainties associated with the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations; the availability of sufficient resources for our operations and to conduct or continue planned clinical development programs; the timing and ability of Savara to raise additional capital as needed to fund continued operations; the ability to successfully conduct clinical trials for our product candidate; the ability to successfully develop our product candidate; and the risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates that are safe and effective for use as human therapeutics. The risks and uncertainties facing Savara are described more fully in Savara's filings with the Securities and Exchange Commission including our filings on Form 8-K and our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

You are cautioned not to place undue reliance on our 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. Third-party information included herein has been obtained from sources believed to be reliable, but the accuracy or completeness of such information is not guaranteed by, and should not be construed as a representation by, the Company.

The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

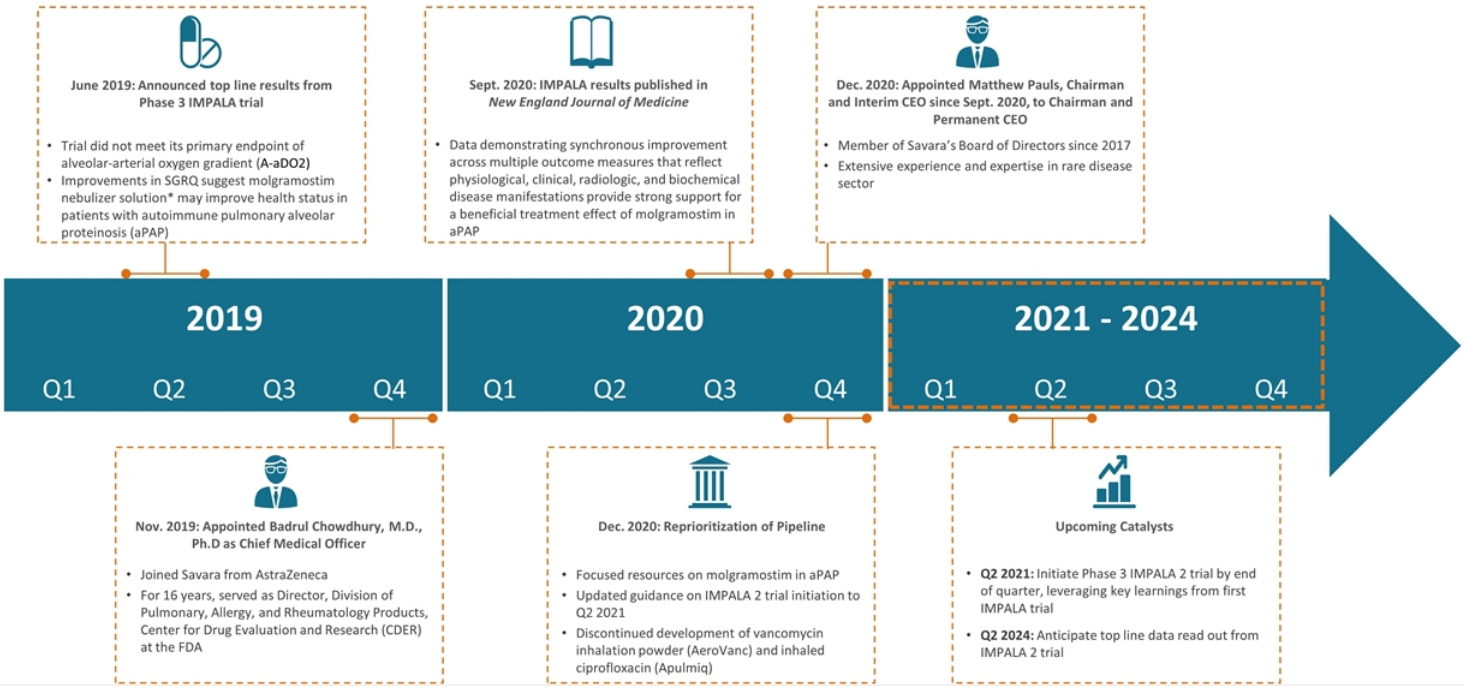
Savara: A Clinical-Stage Orphan Lung Disease Company Based in Austin and Copenhagen

Focused Therapeutic Area
Developing new therapeutics for rare lung diseases.

Clear Vision
To become THE orphan lung disease company.

Strong Management Team
Company leaders are experts in their field.

Transformational Evolution of Savara



** Molgramostim, formerly referred to as Molgradex.*

Executive Leadership

We are a team with deep expertise in orphan lung diseases and pulmonary medicine and a proven track record that spans from early clinical development through commercialization.

Matthew Pauls
Chairman and
Chief Executive Officer

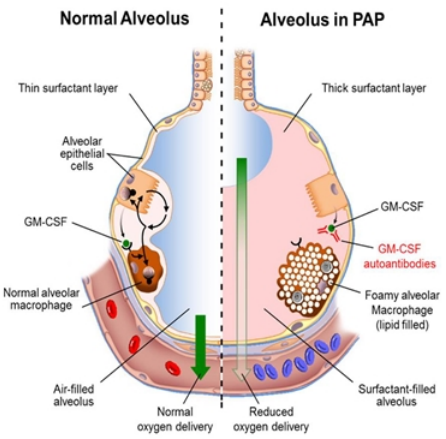
Dr. Badrul Chowdhury
Chief Medical Officer

Dave Lowrance
Chief Financial Officer

Molgramostim

Molgramostim for Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

aPAP: A Disease of Alveolar Macrophage Dysfunction



Alveolar macrophages

Need GM-CSF for maturation, expansion, and function (e.g., surfactant clearance)

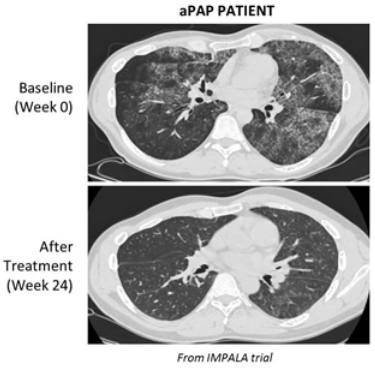
GM-CSF

Critical to alveolar homeostasis, structure, function, and host defense

aPAP

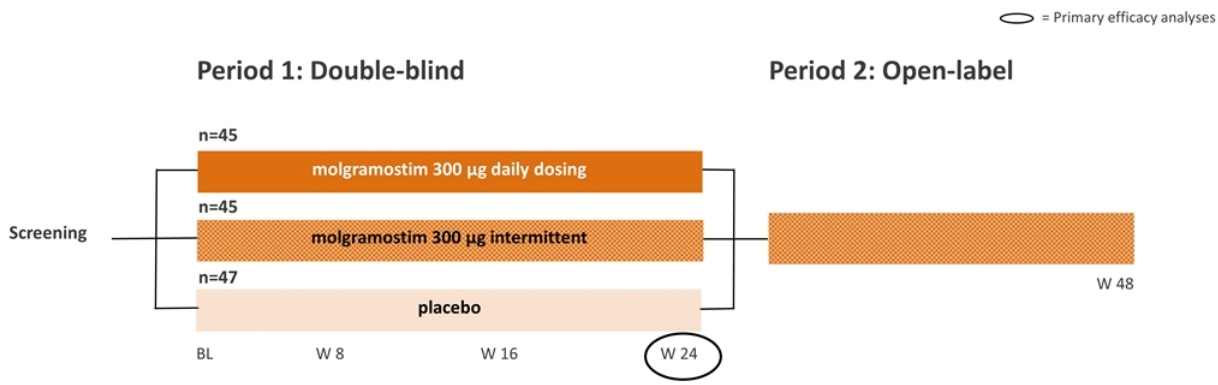
Caused by GM-CSF autoantibodies which block GM-CSF signaling and reduce surfactant clearance

Surfactant accumulation causes altered gas exchange in the lung, reduced blood oxygenation, and, ultimately, hypoxemic respiratory failure



From IMPALA trial

IMPALA Trial Design



Primary Endpoint*

- Change from baseline in A-aDO_2

**Primary analysis: Continuous dose vs. placebo*

Secondary Endpoints**

- 6-minute walk distance
- St. George's respiratory questionnaire
- Time to WLL/requirement for WLL

***Secondary endpoints: Analyzed in parallel and corrected for multiplicity*

IMPALA Trial Results Published in *New England Journal of Medicine* in September 2020

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Inhaled Molgramostim Therapy in Autoimmune Pulmonary Alveolar Proteinosis

Bruce C. Trapnell, M.D., Yoshikazu Inoue, M.D., Ph.D., Francesco Bonella, M.D., Ph.D., Cliff Morgan, B.M., Stéphane Jouneau, M.D., Ph.D., Elisabeth Bendstrup, M.D., Ph.D., Ilaria Campo, Ph.D., Spyros A. Papiris, M.D., Etsuro Yamaguchi, M.D., Ph.D., Erdogan Cetinkaya, M.D., Mikhail M. Ilkovich, M.D., Mordechai R. Kramer, M.D., et al., for the IMPALA Trial Investigators*

Published online on 9/2/2020.

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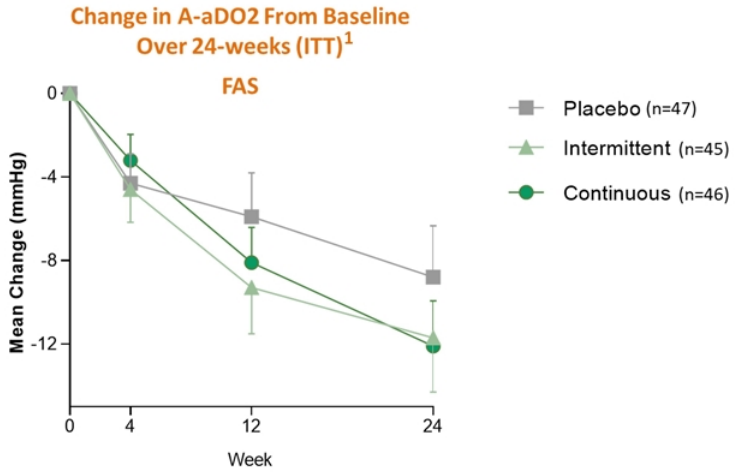
IMPALA Trial Did Not Meet Primary Endpoint



CONTINUOUS ONCE DAILY DOSING REGIMEN (OD)

Full Analysis Set (FAS)*
Estimated treatment difference of -4.6 mmHg (p=0.17)

Revised FAS†
Estimated treatment difference of -6.5 mmHG (p=0.025)

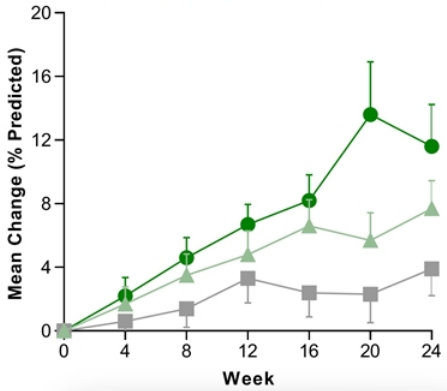
*Protocol specified analysis (ITT).

†Revised analysis excludes 4 patients using supplemental oxygen during testing (placebo: n=2, intermittent: n=1, continuous: n=1).

1: Trapnell, Inhaled Molgramostim Therapy in aPAP, NEJM, 2020.

IMPALA: DLCO and SGRQ Showed Robust Improvement with Continuous Once Daily Dosing Regimen (OD)

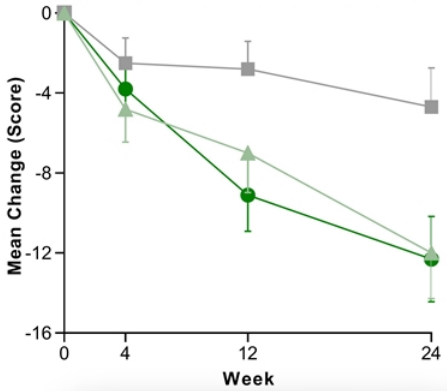
Change in Diffusion Capacity for Carbon Monoxide (DLCO) From Baseline Over 24-weeks (FAS) [1]



OD estimated treatment difference of 7.9% predicted (p=0.007)

IMPALA 2 Primary Endpoint

Change in St. George's Respiratory Questionnaire (SGRQ) From Baseline Over 24-weeks (FAS) [1]



OD estimated treatment difference of 7.6 points (p=0.01)

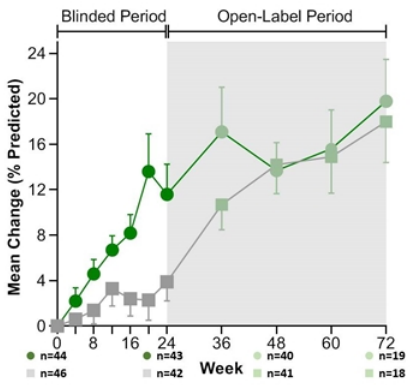
IMPALA 2 Secondary Endpoint

1: Trapnell, Inhaled Molgramostim Therapy in aPAP, NEJM, 2020.

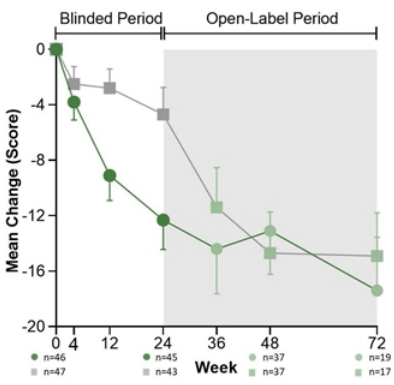
Results not adjusted for multiplicity.

IMPALA Open-Label Data Show Sustained Effect, or Continued Improvement, after Longer-Term Drug Exposure

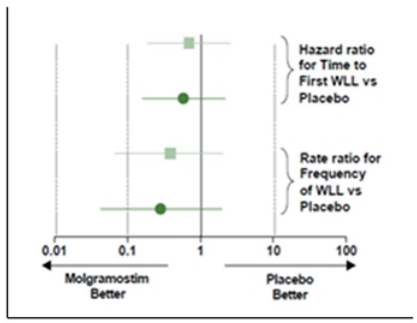
Mean Change in DLCO Over Time[1]



Mean Change in SGRQ Total Score Over Time[1]



Use of WLL During the Blinded Treatment Period[1]



Continuous molgramostim Placebo Intermittent molgramostim

Dosing schedules for blinded and open-label periods were different.
All patients received intermittent molgramostim during open-label period.

1: Trapnell, Inhaled Molgramostim Therapy in aPAP, NEJM, 2020.

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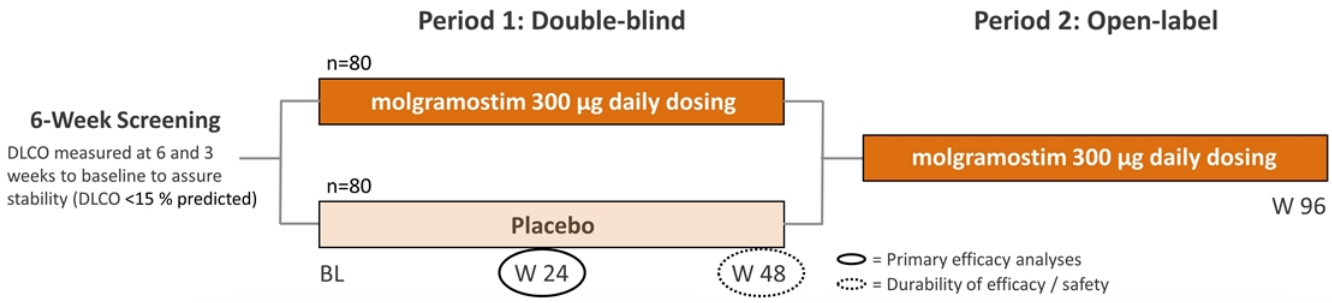
IMPALA 2 Trial Design Leverages Key Learnings from IMPALA



Primary Endpoint

- Change from baseline in DLCO
  - 90% powered to detect 5.7% predicted difference with standard deviation of 11

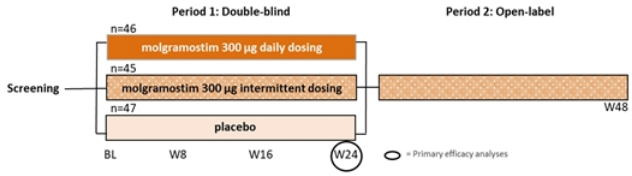
Secondary Endpoints

- SGRQ Total Score
- SGRQ Activity Score
- Exercise capacity using treadmill test

IMPALA 2 will be conducted at ~50 sites across ~14 countries.
Patients needing WLL will have procedure prior to screening.

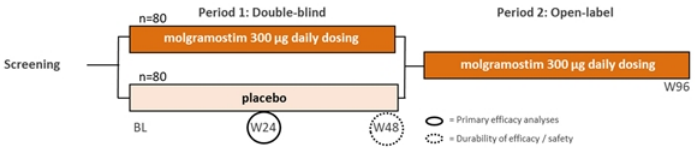
Clinical Trial Design: IMPALA vs. IMPALA 2

IMPALA



Primary endpoint: **(surrogate endpoint)**	Gas Exchange: A-aDO2
Secondary endpoints: **(direct patient benefit)**	SGRQ Total 6-minute walk distance Whole lung lavage
Device:	Pari e-Flow Nebulizer System
Number of trial sites:	34
Geographies:	18 countries N. America, Europe, Japan, S. Korea
Enrollment duration:	32 months, peak enrollment = 8 p/month
Supplemental oxygen:	Allowed as background and during efficacy measure (n=4)
Disease severity:	Stable moderate to severe disease

IMPALA 2



Primary endpoint: **(surrogate endpoint)**	Gas Exchange: DLCO
Secondary endpoints: **(direct patient benefit)**	SGRQ Total SGRQ Activity Exercise capacity test using treadmill
Device:	Pari e-Flow Nebulizer System
Number of trial sites:	~50
Geographies:	~14 countries N. America, Europe, Japan, S. Korea
Enrollment duration:	~20 months
Supplemental oxygen:	Will be allowed as background, NOT during efficacy measure
Disease severity:	Stable moderate to severe disease

Anticipated IMPALA 2 Timelines: ~20-Month Recruitment

Activity	Date
Start of patient randomization	2Q 2021
Top line data readout from double-blind period	2Q 2024

Molgramostim Regulatory Landscape

MOLGRAMOSTIM IN aPAP REGULATORY DESIGNATIONS

- Orphan Drug Designation, Europe (eligible for 10 years exclusivity)
- Orphan Drug Designation, U.S. (eligible for 7 years exclusivity)
- Fast Track Designation
- Breakthrough Therapy Designation

IMPALA 2

Trial design endorsed by regulatory authorities in the U.S., Canada, Japan, South Korea, and the countries in Europe where the trial is being conducted

BIOLOGIC EXCLUSIVITY

Upon Biologics License Application (BLA) approval FDA would grant 12 years marketing exclusivity

Financials and Milestones

Financial Overview as of December 31, 2020

**Reflects completion on March 15, 2021 of an underwritten public offering resulting in net proceeds of $122M to the Company.*