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)
June 8, 2023

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 I, Suite 205
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/events-presentations/. 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 (the "SEC"), 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: June 8, 2023

SAVARA INC.
a Delaware corporation

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

Exhibit 99.1

Corporate Overview

Developing New Therapies *for* Rare Respiratory Diseases

June 2023

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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 Savara; the Savara investment thesis; 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; the potential market size, commercial opportunity, and competitive landscape for our product; Savara’s plans regarding disease awareness and anti-GM-CSF antibody testing, and the potential impact of those programs; 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 widespread health concerns impacting healthcare providers or patients and geopolitical conditions on our business and operations; 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, our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023.

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.

Executive Leadership Team

Matthew Pauls, J.D., M.B.A.
Chair & Chief Executive Officer

Dave Lowrance
Chief Financial & Administrative Officer

Rob Lutz, M.B.A.
Chief Operating Officer

Ray Pratt, M.D. FACP
Chief Medical Officer

Peter Clarke, Ph.D.
EVP, Global Technical Operations

Scott Wilhoit
EVP, Global Commercial

Anne Erickson
SVP, Head of Global Business Operations

Charles LaPree
SVP, Global Regulatory Affairs and Quality Assurance

Kate McCabe, J.D.
SVP, General Counsel

Pursuing Transformative Therapies for Rare Respiratory Diseases

Focused on single Phase 3 program: molgramostim nebulizer solution (molgramostim) in autoimmune pulmonary alveolar proteinosis (aPAP)

- Recombinant form of human granulocyte-macrophage colony-stimulating factor (GM-CSF)
- Favorable efficacy and safety data generated from the first IMPALA trial
- Pivotal Phase 3 trial underway – builds on key learnings from IMPALA

Seasoned management team

- Deep experience in the development and commercialization of rare respiratory therapeutics and pulmonary medicines

Capitalized through major clinical and regulatory milestones

- ~$115M* in cash expected to fund company ~18-months beyond Phase 3 data read-out, beyond BLA filing, and through potential approval

Quality investor base

*As of 3/31/23
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Investment Thesis

- **The molgramostim in aPAP clinical program has a high probability of success**
- **As a novel inhaled biologic, molgramostim has the potential for a long-term, durable revenue stream**
- **Significant global commercial opportunity**
- **Strong balance sheet – funded through 2025**

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Molgramostim Key Highlights

June 2019: IMPALA clinical trial results

- Randomized, double-blind, 24-week, placebo-controlled trial
- Primary endpoint of alveolar-arterial oxygen gradient (A-aDO2) not met
- Improvements in St. George's Respiratory Questionnaire (SGRQ) suggest molgramostim may improve health status in patients with aPAP

Sept. 2020: IMPALA results published in *New England Journal of Medicine*

Data demonstrating synchronous improvement across multiple outcome measures that reflect physiological, clinical, radiologic, and biochemical disease manifestations provide strong support for a beneficial treatment effect of molgramostim in aPAP

June-Aug. 2022: UK's Medicines and Healthcare Products Regulatory Agency (MHRA) awarded molgramostim Innovation Passport and Promising Innovative Medicine Designations

MHRA

May 2016: Phase 1 clinical trial of molgramostim:

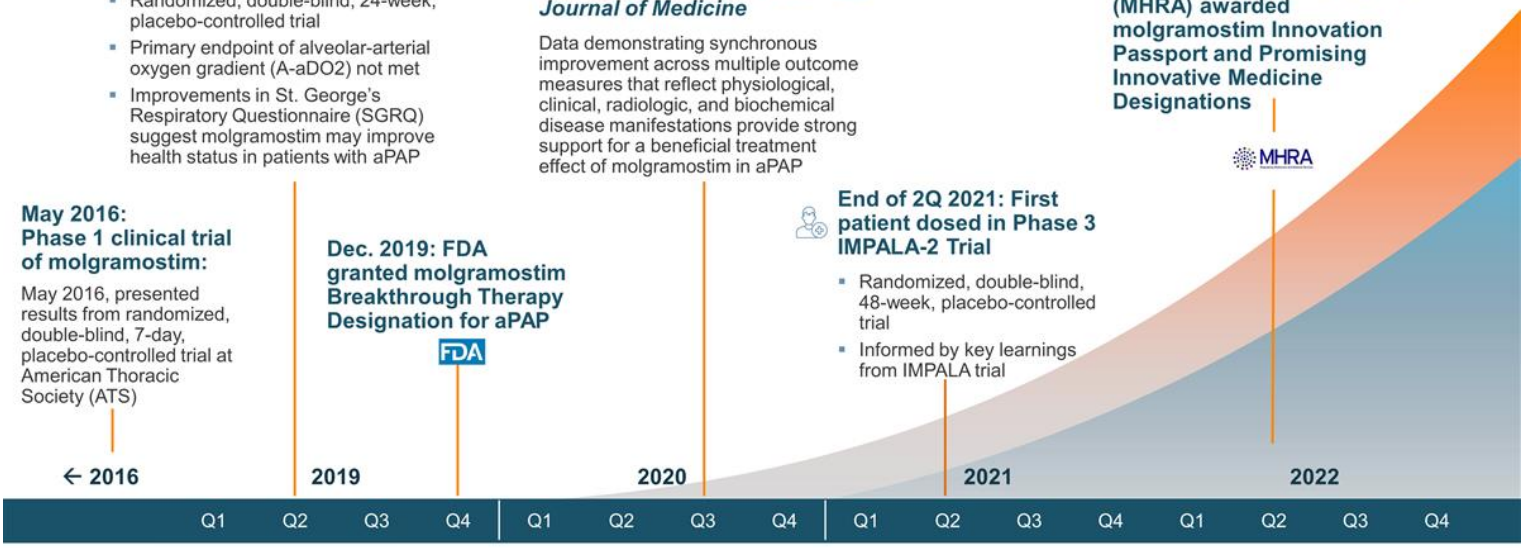
May 2016, presented results from randomized, double-blind, 7-day, placebo-controlled trial at American Thoracic Society (ATS)

Dec. 2019: FDA granted molgramostim Breakthrough Therapy Designation for aPAP

FDA

End of 2Q 2021: First patient dosed in Phase 3 IMPALA-2 Trial

- Randomized, double-blind, 48-week, placebo-controlled trial
- Informed by key learnings from IMPALA trial



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IMPALA-2 Key Milestones

- June 2023: Complete enrollment
- End of 2Q 2024: Top line data readout
- Upon a successful trial, Company plans to submit regulatory applications in the US, UK, EU, and Japan

Company operations funded through 2025 (~18-months beyond anticipated IMPALA-2 top line results)

Molgramostim

Molgramostim for Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

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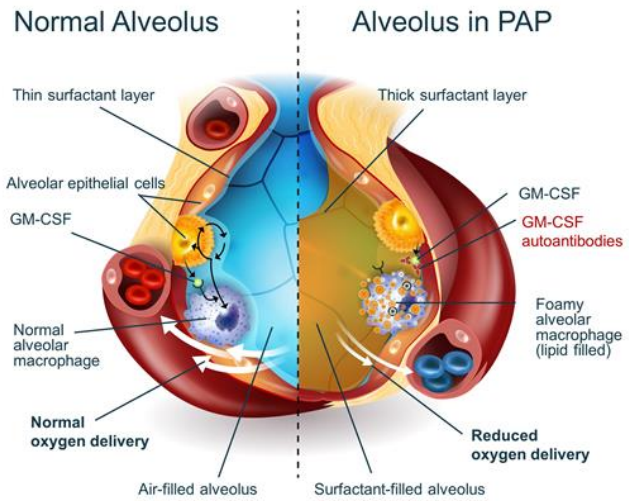
aPAP: A Disease of Alveolar Macrophage Dysfunction



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

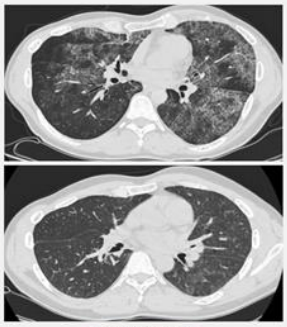
Caused by GM-CSF autoantibodies which block GM-CSF signaling and reduce surfactant clearance

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

aPAP PATIENT

Baseline (Week 0)

After Treatment (Week 24)



From IMPALA trial

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aPAP is a Rare, Long-Term, Chronic Disease

Progressive Shortness of Breath

- Gas exchange in the lungs is impaired and patients may experience shortness of breath
- At first it occurs upon exertion, but as disease progresses, it can occur even when a person is at rest

Fatigue, Decreased Exercise Tolerance

- Fatigue and significantly reduced exercise capacity can dramatically impact the simplest of daily activities, e.g., getting winded walking up a flight of stairs

Cough and Episodes of Fever

- Cough, sputum production, and episodes of fever, especially if secondary lung infection develops

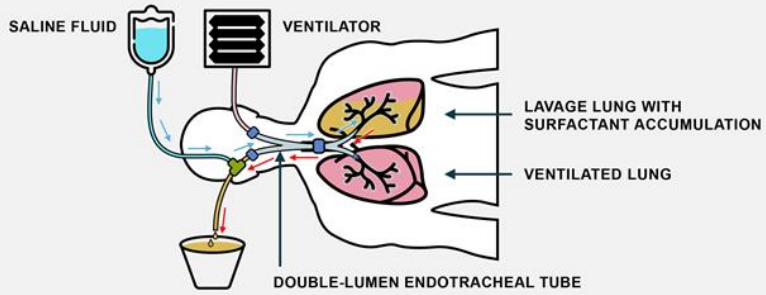
Fibrosis and Lung Transplant

- In the long-term, the disease can lead to serious complications, including fibrosis, often leading to the need for lung transplantation

There are no approved drugs for the treatment of aPAP.
Only option is whole lung lavage, an invasive procedure.

Whole Lung Lavage is a Highly Invasive Procedure Performed in a Tertiary Center and is Not Standardized

- Whole lung lavage is an invasive procedure to physically remove excess surfactant from the lungs and requires hospitalization
- Performed under general anesthesia by highly experienced physicians at certain sites



Requires insertion of double-lumen endobronchial tube for lung separation

Treated lung is repeatedly filled with up to 15-50L of saline and then drained by gravity

Patient is percussed to emulsify the surfactant sediment

Saline is drained by gravity and continued until lavage fluid becomes clear

Sources: 1: Campo, Assessment and Management of PAP in a Reference Center, Orphanet Jour. of Rare Dis., 2013; 2: Campo, Nat. History of PAP Data from Italian Nat. Reference Center, ERJ, 2019.; Seymour, J. J. Pulmonary alveolar proteinosis: Progress in the First 44 Years, Am. J. Respir Crit. Care Med, 2002.

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Complications and Short-Comings of Whole Lung Lavage

Potential Complications

- Rib fracture
- Hypoxia
- Pneumothorax (collapsed lung)
- Hydrothorax (fluid in pleural cavity)
- Superimposed infection
- Acute Respiratory Distress Syndrome (ARDS)

Short Comings

- Treatment fails to address pathophysiology of disease
- Patients continue to experience symptomatic deterioration between procedures – and can require more than one whole lung lavage
- Rollercoaster ride of improvement and decline
- The procedure, performed under general anesthesia, is not standardized and remains highly operator-dependent

Journey to Diagnosis Can Be Long and Misdiagnosis is Common

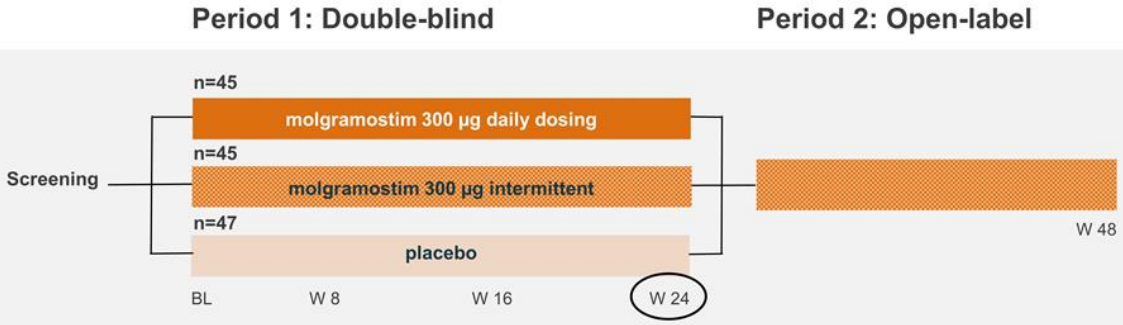
Due to aPAP's rarity and associated non-specific symptoms, patients are often misdiagnosed with more common pulmonary illnesses (e.g., recurrent pneumonia, chronic bronchitis, COPD, asthma)

Diagnostic tests typically conducted to rule-out other more common pulmonary diseases:

- Imaging
- Pulmonary function tests
- Secondary PAP testing
- Transbronchial biopsy and cytological analysis of bronchoalveolar lavage fluid

IMPALA Clinical Trial Design

= Primary efficacy analyses



Primary Endpoint*

- Change from baseline in A-aDO_2

Secondary Endpoints**

- 6-minute walk distance
- SGRQ
- Time to whole lung lavage/requirement for whole lung lavage

Primary analysis: Continuous dose vs. placebo

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

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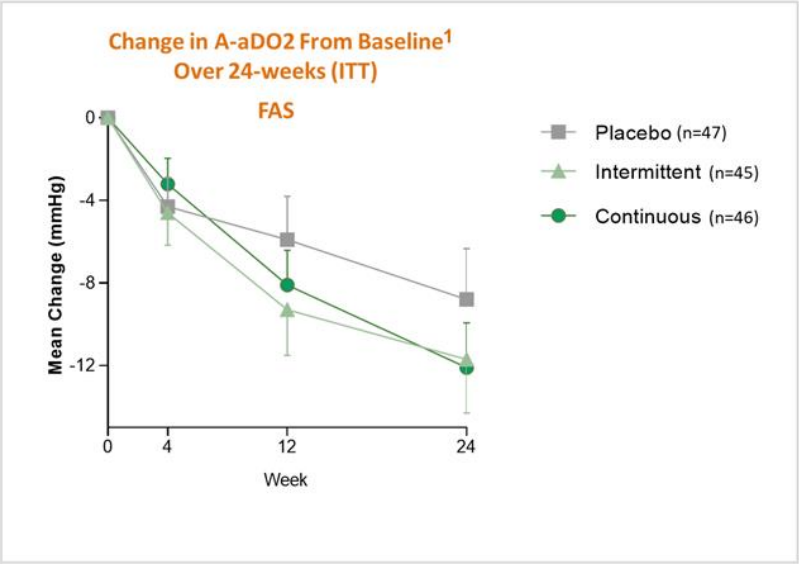
IMPALA Trial Did Not Meet the Primary Endpoint



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

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).

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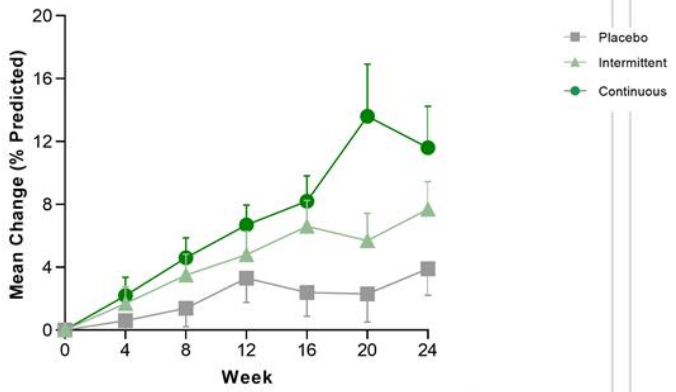
IMPALA: DLCO and SGRQ Showed Robust Improvement with Continuous Once Daily (OD) Dosing Regimen

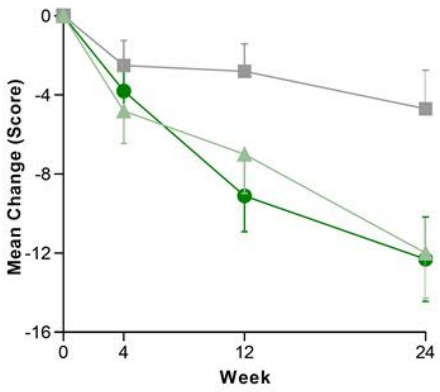
Change in Diffusion Capacity for Carbon Monoxide (DLCO) From Baseline Over 24-weeks[1] (FAS)



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[1] (FAS)



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.

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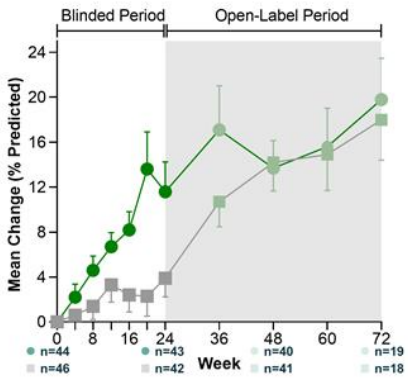
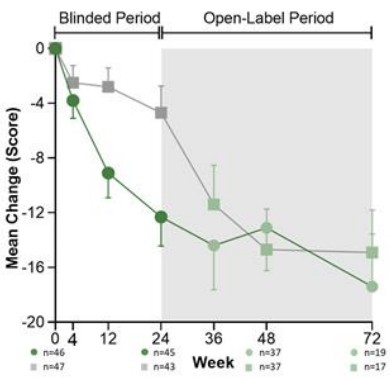
IMPALA Open-Label Data Show Sustained Effect, or Continued Improvement, after Longer-Term Drug Exposure

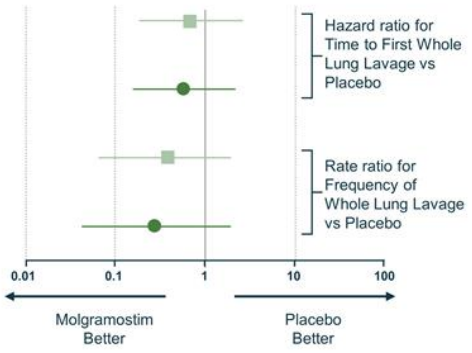
Mean Change in DLCO Over Time[1]



Mean Change in SGRQ Total Score Over Time[1]



Use of Whole Lung Lavage 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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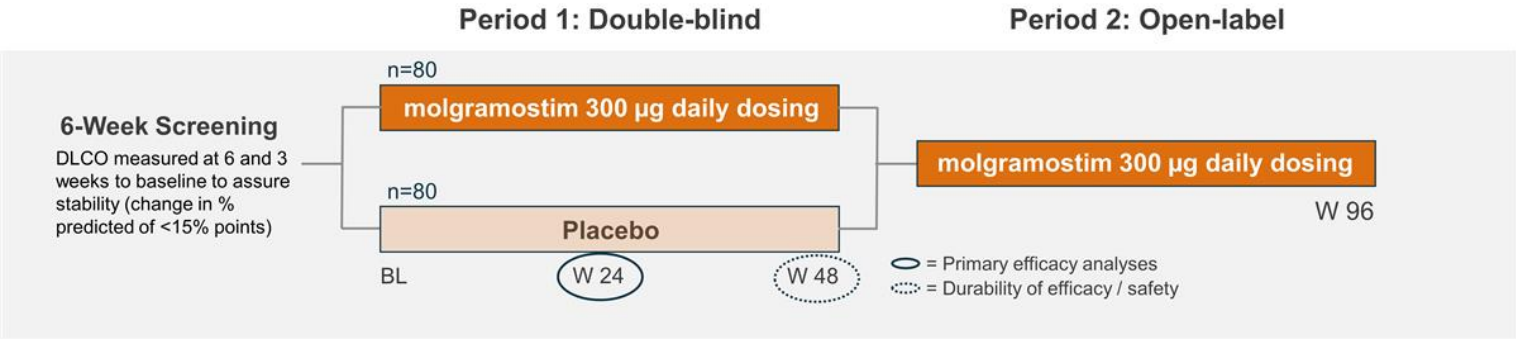
Phase 3 IMPALA-2 Trial Design Leverages Key Learnings from IMPALA



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 is being conducted at ~50 sites across ~18 countries. Patients needing whole lung lavage will have procedure prior to screening.

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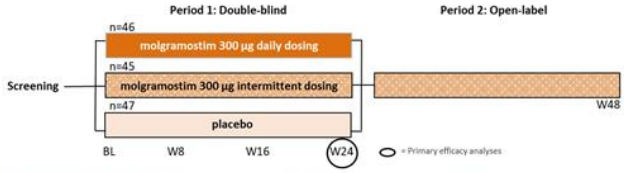
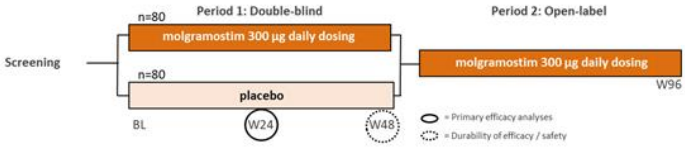
Clinical Trial Design: IMPALA vs. IMPALA-2

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
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:	~18 countries N. America, Europe, Japan, S. Korea
ENROLLMENT DURATION:	Currently enrolling
SUPPLEMENTAL OXYGEN:	Allowed as background, NOT during efficacy measure
DISEASE SEVERITY:	Stable moderate to severe disease

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Molgramostim Regulatory Landscape

MOLGRAMOSTIM IN aPAP REGULATORY DESIGNATIONS

- **Orphan Drug Designation, Europe (eligible for 10 years exclusivity)**
- **Orphan Drug Designation, US (eligible for 7 years exclusivity)**
- **Fast Track Designation, US**
- **Breakthrough Therapy Designation, US**
- **Innovation Passport Designation, UK**
- **Promising Innovative Medicine Designation, UK**

IMPALA-2

- Trial design endorsed by regulatory authorities in the US, 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

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Commercial Outlook

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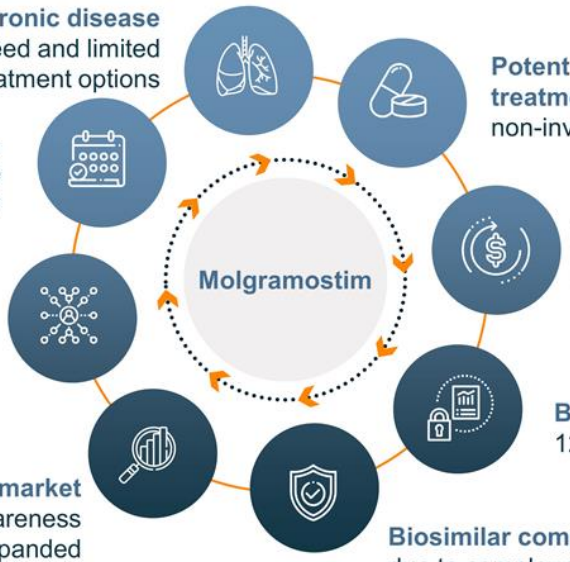
Significant Global Commercial Opportunity

aPAP is a rare chronic disease with high unmet medical need and limited treatment options

Dosing expected to be chronic, providing long-term, durable revenue stream

Orphan disease-like infrastructure (e.g., sales and support)

Potential for significant market expansion via disease awareness campaign (starting in 2H23), expanded testing for antibody to GM-CSF in the US, and approved new/novel treatment option



Potential first and only approved treatment for aPAP globally (well studied, non-invasive, and convenient dosing)

Assumed pricing power consistent with analogous orphan drug biologics

Biologic exclusivity protects for 12 years from approval (US)

Biosimilar competition unlikely due to complex manufacturing, exclusive drug/device combination product, and inhalation dosage form with local action of GM-CSF in the lung

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Published aPAP Epidemiology Studies

REFERENCE	METHODOLOGY	INCIDENCE PER MILLION	DIAGNOSED PREVALENCE PER MILLION	IMPLIED US PATIENTS	IMPLIED EU PATIENTS
Diagnosed Prevalence					
Inoue 2008	Registry based in Niigata, Japan	0.48 *(0.23-1.00)*	6.2 *(3.8-10.3)*	*~2,058*	*~2,325*
McCarthy 2018	US insurance claims data, 2008-2012	Not reported	6.3 *(5.2-7.6)*	*~2,092*	*~2.363*
Diagnosed Prevalence With Increased (Broad Access) Antibody Testing					
Kitamura 2019	Update of Niigata registry	1.66 *(1.2-2.2)*	26.6 *(9.0-73.0)*	*~8,831*	*~9,975*

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US Claims Database of 300M+ Lives Identified ~3,600 Diagnosed aPAP Patients*

COMPREHENSIVE CLAIMS DATA

300M+
Unique Patients

Rx Px
Dx Mx

- 99% HCPs
- 98% health systems
- 96% outpatient facilities
- 89% of hospitals

- Counted patients with PAP diagnoses codes and no subsequent diagnoses
- Reduced for aPAP and scaled up to reflect entire US population

~3,600 Diagnosed US aPAP Patients

** Data from 2023 US Insurance Claims analysis conducted by Savara*

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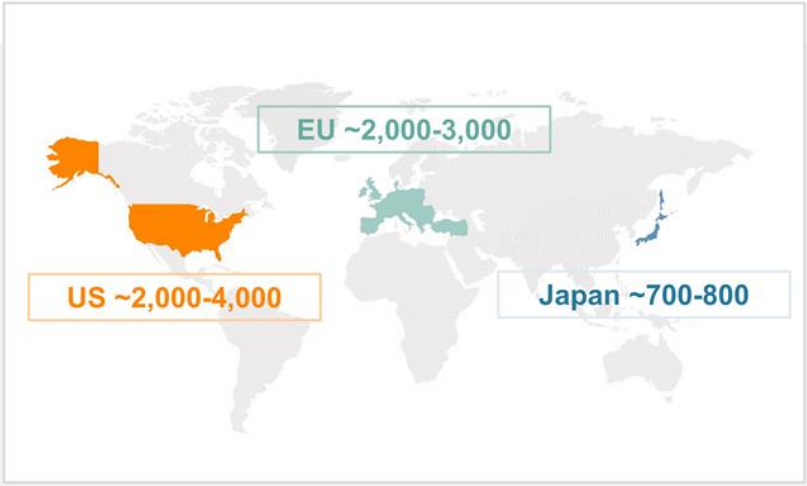
Current Global aPAP Market has Significant Potential: $1B+

- Estimated 5,000-7,000 currently diagnosed patients in US, EU, and Japan
- Standard of care is lung lavage
- No approved therapeutics for chronic treatment
- Potential for ultra-rare disease pricing



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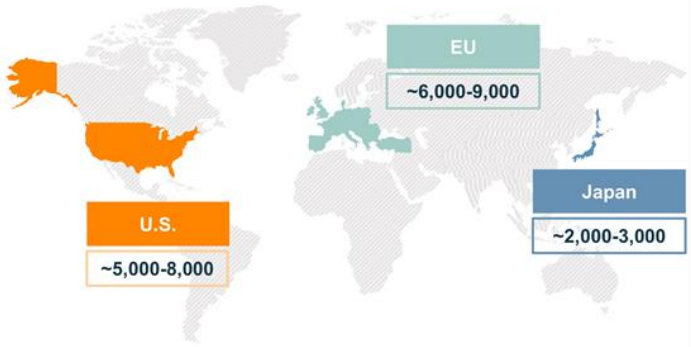
Improving aPAP Disease Awareness and Expanding Antibody Testing Could Increase Addressable Market 2-4x

- **Many aPAP patients are undiagnosed**
  - Ultra-rare disease
  - Current lack of routine testing
  - Lack of meaningful treatments
- **Kitamura (2019) study = aPAP prevalence may be underestimated**
  - With improved antibody testing, there was an estimated 3-4x increase in incidence/prevalence
- **Savara found disease prevalence doubled when undiagnosed patients were identified through machine learning to match known diagnosed patients**



Estimated True Prevalence in US, EU, and Japan: ~15,000-18,000
Room for growth in diagnosis

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Disease Awareness and Antibody Testing Campaigns

SAVARA PLANS TO

1. **Launch a Disease Awareness and Education Campaign:**
   - US Healthcare Provider (HCP) Website Launch in 2023
     - Increase HCP awareness of aPAP, including hallmark symptoms of the disease
     - Educate HCPs on the need for routine antibody testing
   - Seek to change clinical diagnostic guidelines to accelerate testing

2. **Offer No-Cost Antibody Testing**
   - Savara plans to offer a simple, accurate, no-cost, antibody blood test:
     - US: 2023
     - EU: 2024

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Analog: Pulmozyme® (dornase alpha)

Pulmozyme®

- Prototype inhaled biologic
- Approved by the FDA in 1993
- No biosimilar available

Pulmozyme is a registered trademark of Genentech

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Financials

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- **Well capitalized**
  - **~$115M** in cash (as of 3/31/23)
  - Cash **runway extends ~18-months** beyond anticipated IMPALA-2 top line results
- **Strong investor support with coverage from 6 equity research analysts**

ANALYST COVERAGE

Evercore ISI	Liisa Bayko, MSC, MBA
H.C. Wainwright	Andrew Fein
Jefferies	Andrew Tsai
Ladenburg Thalmann & Co.	Michael Higgins
Oppenheimer	Francois Brisebois
Piper Sandler	Yasmeen Rahimi, PhD

Financial Highlights

Investment Thesis

- **The molgramostim in aPAP clinical program has a high probability of success**
- **As a novel inhaled biologic, molgramostim has the potential for a long-term, durable revenue stream**
- **Significant global commercial opportunity**
- **Strong balance sheet – funded through 2025**

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Thank You

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