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) January 5, 2024

SAVARA INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

001-32157 (Commission File Number)

84-1318182 (IRS Employer Identification No.)

1717 Langhorne Newtown Road, Suite 300 Langhorne, PA 19047 (Address of principal executive offices, including zip code)

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

 $\label{eq:NA} N/A$ (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):

	5F				
	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		
	cate by check mark whether the registrant is an emerging 30.405 of this chapter) or Rule 12b-2 of the Securities E	1)			
			Emerging growth company \Box		
If ar	n emerging growth company, indicate by check mark if the	he registrant has elected not to use th	e extended transition period for complying with any		

new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. $\ \Box$

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 <u>Savara Corporate Presentation</u>

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: January 5, 2024

SAVARA INC. a Delaware corporation

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



Developing New Therapies for Rare Respiratory Diseases

January 2024



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 disease awareness campaign and GM-CSF autoantibody 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. These forward-looking 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 c

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

Anne Erickson Chief Business Officer Dave Lowrance
Chief Financial & Administrative Officer

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

Ray Pratt, M.D. FACP Chief Medical Officer

Scott Wilhoit EVP, Global Commercial Yasmine Wasfi, M.D., Ph.D. SVP, Head of Clinical Development



Investment Thesis



Single Phase 3 program with high probability of success – Top line data expected end of 2Q24:

- Molgramostim nebulizer solution (molgramostim) in autoimmune pulmonary alveolar proteinosis (aPAP)
- Favorable efficacy and safety data generated from the first IMPALA trial
- Pivotal Phase 3 trial underway
 - Builds on key learnings from IMPALA



Strong global commercial opportunity

- Significant unmet need potential to be first and only approved treatment for aPAP globally
- Chronic dosing expected
- Market expansion opportunities



As a novel inhaled biologic, molgramostim has:

- 12-year biologic exclusivity in U.S.
- Potential for a long-term, durable revenue stream with biosimilar competition unlikely

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Molgramostim Key Highlights



*The Data Monitoring Committee (DMC) conducted two pre-planned evaluations of IMPALA-2 to assess safety and sample size. In both cases the DMC recommended that the study continue unmodified.

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Molgramostim

Molgramostim for Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

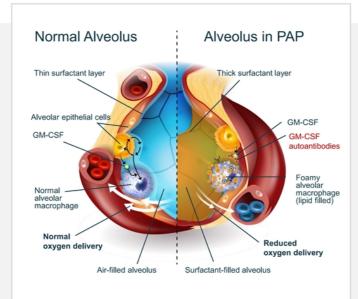
SAVARA

aPAP: An Autoimmune Disease of Alveolar Macrophage Dysfunction

NORMAL LUNG FUNCTION

Alveoli need surfactant to keep from collapsing

GM-CSF is critical for alveolar macrophage function and allows for alveolar surfactant homeostasis, structure, function, and host defense



aPAP



Rare lung disease

caused by GM-CSF autoantibodies which block GM-CSF signaling and reduce surfactant clearance. This results in:

Surfactant accumulation that blocks movement of oxygen from the alveoli into the blood

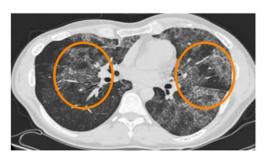
Reduced blood oxygenation that makes it hard to breath and, ultimately, hypoxemic respiratory failure



Molgramostim Has the Potential to Improve Lung Function

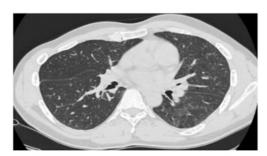
Molgramostim may improve lung function by stimulating alveolar macrophages to clear surfactant from the lungs

White lines, called "crazy paving," are a hallmark symptom of aPAP



High resolution chest CT scan of aPAP patient at baseline (week 0)

Following molgramostim treatment, a reduction in "crazy paving" was observed



High resolution chest CT scan of aPAP patient after treatment (week 24)

From IMPALA trial



aPAP is a Rare, Long-Term, Chronic Disease

Progressive Shortness of Breath



 At first it occurs upon exertion, but as disease progresses, it can occur even when a person is at rest

Cough and Episodes of Fever

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

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

Fibrosis and Lung Transplant

 In the long-term, the disease can lead to serious complications, including fibrosis, and may lead 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.



Unmet Need: aPAP Patients Have Significantly Higher Rates of Healthcare Utilization and Comorbidities¹



Charlson Comorbidity Index (CCI)*



PAP: 1.84 ± 2.48

Age and Gender Matched Controls: 0.55 ± 1.44

P value: <0.0001

*Developed to classify comorbid conditions which may influence mortality risk. Most widely used comorbidity index used to determine survival rates in patients with multiple comorbidities.



Outpatient visits (~17 per year)



PAP: 17.30 ± 13.77

Age and Gender Matched Controls: 10.40 ± 11.38

P value: <0.01



Emergency Room Visits

(~1.5 per year)



PAP: 1.49 ± 1.17

Age and Gender Matched Controls: 1.08 ± 0.27

P value: 0.014



Longer hospital stays

(~16 days per year)



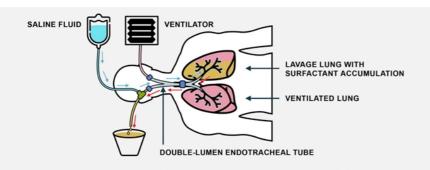
PAP: 15.96 ± 20.71

Age and Gender Matched Controls: 5.40 ± 5.07

P value: 0.027



- Whole lung lavage physically removes excess surfactant from the lungs and requires hospitalization
- Performed under general anesthesia
- Unavailable at many medical institutions



Requires insertion of doublelumen 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; 3: Udwadia, Jain. NEM, 2007; 35:719, 4. McCarthy, Autoimmune Pulmonary Alveolar Proteinosis, Amer. Journal of Respiratory and Critical Care Med., 2022.



Whole Lung Lavage is

an Invasive Procedure

Performed in a Tertiary



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)



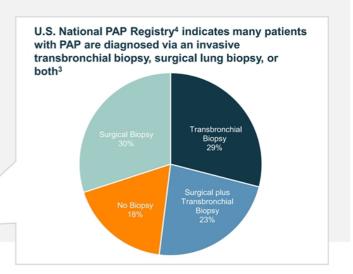
Short Comings

- Treatment fails to address underlying cause of the 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 (nor is requirement for WLL) and remains highly operatordependent

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Historically, Without a Broadly Available Diagnostic for aPAP, the Journey to Diagnosis Can Be Long and Misdiagnosis Common

- 3-36 months¹: Range for aPAP time-todiagnosis
- 18 months²: Average delay caused by misdiagnosis (e.g., pneumonia or asthma)
- Diagnostic workup frequently involves multiple tests and invasive procedures, including
 - Pulmonary function tests
 - Arterial blood gas analysis
 - Chest radiographs
 - CT scans
 - Bronchoalveolar lavage (BAL) cytology and/or lung histopathology³
 - · Transbronchial biopsy, surgical lung biopsy, or both



Sources: 1: Campo Orphanet J Rare Dis 2013; 2: Trapnell Nat Rev Dis Primers 2019; 3: McCarthy Chest 2019; 4: Trapnell PAP Registry http://clinicaltrials.gov/ct2/show/

SAVARA

Savara Investigational Drug-Device Treatment for aPAP

- Once daily 300 µg inhaled molgramostim
- Proprietary Pari eFlow® Nebulizer System
 - Optimized for molgramostim administration
 - Well-established manufacturer of devices used for inhalation therapy
 - Pari has 5 FDA approved nebulizers

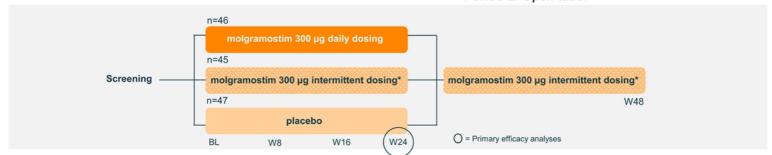




IMPALA Clinical Trial Design

Period 1: Double-blind

Period 2: Open-label



Primary Endpoint

Change from baseline in A-aDO₂**

Primary analysis was continuous dose vs. placebo

Key Secondary Endpoints

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

Secondary endpoints were analyzed in parallel and corrected for multiplicity

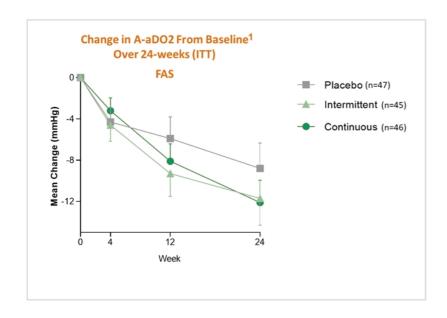
***St. George's Respiratory Questionnaire: Patient-reported Quality of Life tool measuring impact on overall health, daily life, and perceived well being



^{*}One week on, one week off

^{**}A-aDO2: Gas exchange measure used to calculate difference between oxygen concentration in the alveoli and arterial system

IMPALA Trial Did Not Meet the Primary Endpoint



Continuous Once Daily (QD) Dosing Regimen

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)

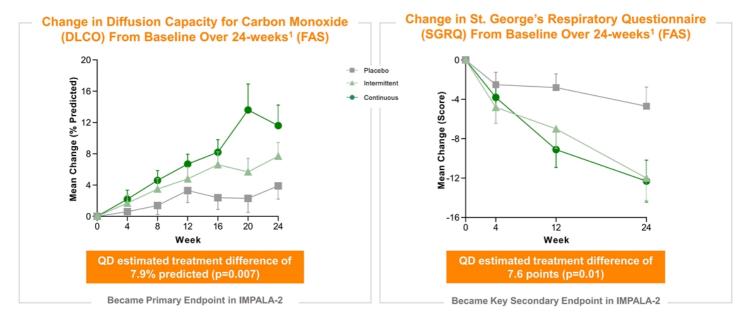
*Protocol specified analysis (ITT).

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



16 1: Trapnell, Inhaled Molgramostim Therapy in aPAP, NEJM, 2020.

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



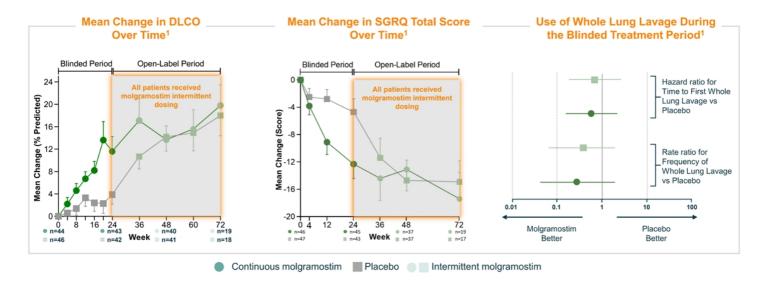
17 1: Trapnell, Inhaled Molgramostim Therapy in aPAP, NEJM, 2020.

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Results not adjusted for multiplicity.



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



Dosing schedules for blinded and open-label periods were different.

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IMPALA Safety Overview

% PATIENTS WITH ADVERSE EVENTS (AEs) DURING DOUBLE-BLIND TREATMENT PERIOD*

Category	Continuous molgramostim (Patients with AEs >5% in double-blind treatment period)	Placebo
	(n=46)	(n=47)
Any adverse event	84.8%	87.2%
Most common adverse events		
Cough	32.6%	23.4%
Chest pain	21.7%	2.1%
Nasopharyngitis	15.2%	12.8%
Headache	13.0%	14.9%
Dyspnea	10.9%	8.5%
Productive cough	8.7%	6.4%
Adverse events possibly or probably related to the intervention	32.6%	29.8%
Adverse events leading to discontinuation of the intervention	4.3%	2.1%

Trapnell, Inhaled Molgramostim Therapy in aPAP, NEJM Supplementary Appendix, 2020;





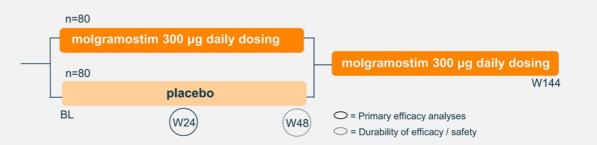
Phase 3 IMPALA-2 Trial Design Leverages IMPALA Key Learnings Top Line Data Expected End of 2Q24

Period 1: Double-blind

Period 2: Open-label

6-Week Screening

- DLCO ≤70% predicted at first screening and baseline
- Change in % predicted <15% points to ensure stably impaired patients



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

*Based on patient level data from IMPALA that best matches expected population for IMPALA-2



IMPALA-2 Study Design Leveraged Lessons from IMPALA



Primary Endpoint (Gas Exchange: surrogate measure): A-aDO2

- · Requires subject arterial blood draw
- Not repeatable

Supplemental Oxygen and Primary Endpoint: Supplemental oxygen not allowed during measurement of A-aDO2

DLCO Screening Criteria: Vital capacity not improved by more than 5% and/or DLCO not improved by more than 10% as assessed by medical records

DLCO Variability Management: No standardization across sites

Key Secondary Endpoints:

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

Patients Per Arm On Continuous Molgramostim: ~46

Double Blind Period: 24 weeks

Sites: 34

IMPALA-2



Primary Endpoint (Gas Exchange: surrogate measure): DLCO

- · Requires subject to blow into a tube
- Renestable

Supplemental Oxygen and Primary Endpoint: Not physically feasible to be on supplemental oxygen during measurement of DLCO

DLCO Screening Criteria: DLCO <70% predicted, <15-point % predicted change during screening

DLCO Variability Management: Device standardized across sites, real-time overread

Key Secondary Endpoints:

- SGRQ Total
- SGRQ Activity
- Exercise Treadmill Test

Patients Per Arm On Continuous Molgramostim: ~82

Double Blind Period: 48 weeks (Primary/key secondaries measured at W24)

Sites: 54

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DLCO: Lung Function Test

- · Diffusing capacity of the lungs for carbon monoxide (CO)
- · Measures how well oxygen passes from the air sacs of the lungs into the blood
- Can indicate the efficiency of lung gas transfer and the presence of respiratory problems

*American Thoracic Society (ATS), European Respiratory Society (ERS)

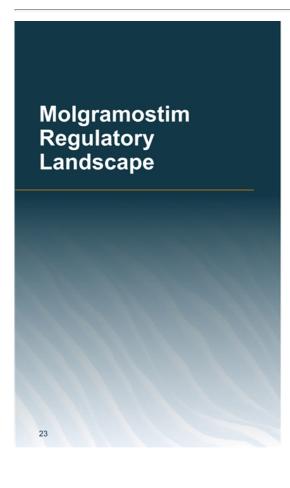
IMPALA-2 PROTOCOL FOR DLCO ASSESSMENT

- Conducted in accordance with ATS/ERS* guidelines
- Supplemental oxygen discontinued 15 minutes before assessment
- O₂ saturation must be stable before assessment (≤2% points over 5 min.)
- Up to 5 assessments allowed to obtain at least 2 acceptable/repeatable measurements
- Cloud-based, real-time overreads at the time of assessment ensure reliability and accuracy of the result

EasyOne Pro device used at all IMPALA-2 sites







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, U.S.
- Breakthrough Therapy Designation, U.S.
- Innovation Passport Designation, U.K.
- Promising Innovative Medicine Designation, U.K.

IMPALA-2

 Trial design endorsed by regulatory authorities in the U.S., Canada, Japan, South Korea, Australia, U.K., and 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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aPAP Diagnosed Prevalence <u>Before and After Broad Availability of GM-CSF Autoantibody Testing</u>

DIAGNOSED

PREVALENCE

PER MILLION

6.2 (3.8-10.3)

(5.2-7.6)

INCIDENCE PER MILLION Current REFERENCE **METHODOLOGY** Diagnosed Prevalence Before Broad GM-CSF Registry based in Niigata, Japan **0.48** (0.23-1.00) Inoue 2008 Autoantibody Testing US insurance claims data, 2008-2012 McCarthy 2018 Not reported

	IMPLIED US PATIENTS	IMPLIED EU PATIENTS	IMPLIED JAPAN PATIENTS	TOTAL IMPLIED PATIENTS
>				
	~2,058	~2,325	~775	~5,158
	~2,092	~2,363	~788	~5,243

Diagnosed
Prevalence After
Broad GM-CSF
Autoantibody
Testing

REFERENCE	METHODOLOGY	INCIDENCE PER MILLION	DIAGNOSED PREVALENCE PER MILLION	
DIAGNOSED PREVALENCE				
Kitamura 2019	Update of Niigata registry	1.66 (1.2-2.2)	26.6 (9.0-73.0)	
				İ

Published aPAP Epidemiology Studies

	IMPLIED US PATIENTS	IMPLIED EU PATIENTS	IMPLIED JAPAN PATIENTS	TOTAL IMPLIED PATIENTS
•				
	~8,831	~9,975	~3,325	~22,131



Re-analysis of Claims Dataset Estimates There Are ~5,000 aPAP Patients in the U.S.

ANALYSIS OF COMPREHENSIVE CLAIMS DATASET ~3,600* Real-World Claims Dataset: U.S. patients with at least 1 PAP ICD9/10 diagnosis 300M+ unique, active patients 89-99% providers/sites of care Counted PAP ICD9/10 diagnosis claims APPLIED MACHINE LEARNING (ML) MODEL TO SAME CLAIMS DATASET ~1,400 ML model identified patients who have high Additional U.S. patients with high likelihood of PAP, but are not yet diagnosed likelihood of aPAP based on (patients were required to have either a bronchoscopy, BAL, or lung lavage in their claims history)

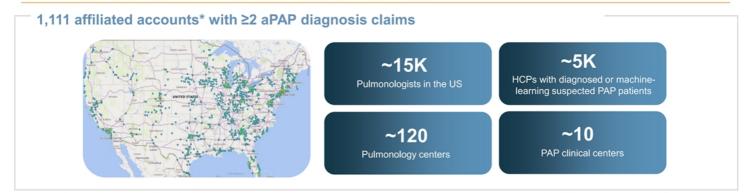
~5,000 estimated aPAP patients in the U.S., based on identified PAP claims history and machine learning assessment

*Data from 2023 U.S. insurance claims analysis conducted by Savara. Highly likely patients: ≥ 2 PAP diagnosis claims, likely patients: 1 PAP diagnosis claim

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December 2023: Launched HCP Disease Awareness Campaign and No-Cost GM-CSF Autoantibody Testing in U.S.



www.apapclearpath.com





U.S. HCP Website

- Increase HCP awareness of aPAP, including hallmark symptoms of the
- Educate HCPs on need for routine GM-CSF autoantibody testing
- REQUEST THE TEST: Order a simple, non-invasive, no-cost GM-CSF autoantibody blood test

Patient Advocacy Group Partnerships/Memberships







American Lung Association.

- Data on file.



Molgramostim: Global Commercial Opportunity

Significant Unmet Need

- High disease burden
- Strong market expansion potential via disease awareness campaign, broad access to GM-CSF autoantibody testing

Rare Disease Infrastructure

- Orphan disease-like infrastructure in U.S. – field-based team of ~15-30
- OUS commercial strategy optionality – go-it-alone, regional partnerships, etc.



Molgramostim

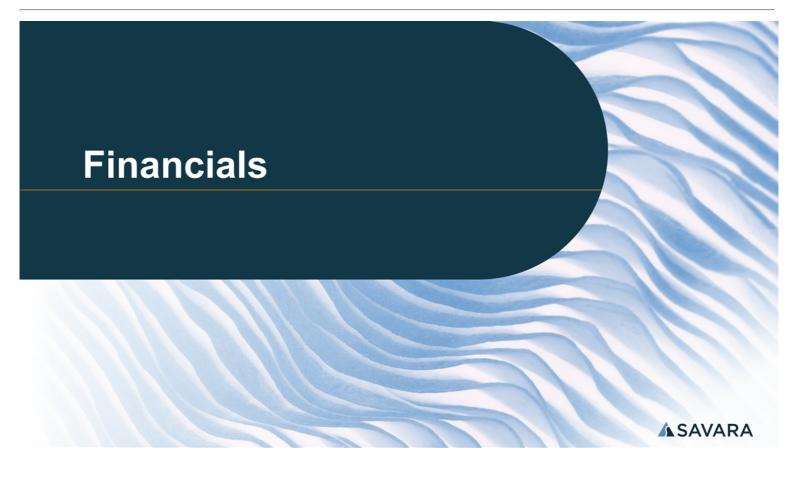
- Potential first and only approved treatment for aPAP globally – WLL (standard of care) is invasive and not standardized
- Dosing expected to be chronic, providing long-term revenue stream
- Assumed pricing power consistent with analogous orphan drug biologics

Long Term Exclusivity

 12-year biologic exclusivity in the U.S. and biosimilar competition unlikely

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28 *Compared to matched controls. Data on file



- Well capitalized into 2026
 - ~\$168M in cash*
- Strong investor support with coverage from 6 equity research analysts

ANALYST COVERAGE

Evercore ISI	Liisa Bayko, MSC, MBA
Guggenheim Securities	Vamil Divan, MD, MBA
H.C. Wainwright	Andrew Fein
Jefferies	Andrew Tsai
Oppenheimer	Francois Brisebois
Piper Sandler	Yasmeen Rahimi, PhD



30 *Cash, cash equivalents, and short-term investments as of 9/30/23

Investment Thesis



Single Phase 3 program with high probability of success – Top line data expected end of 2Q24:

- Molgramostim nebulizer solution (molgramostim) in autoimmune pulmonary alveolar proteinosis (aPAP)
- Favorable efficacy and safety data generated from the first IMPALA trial
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Thank You

SAVARA