
# The Next Leap Forward in Pulmonary Hypertension

*May 2024*

# Forward Looking Statements

*This presentation contains forward-looking statements. All statements other than statements of historical facts contained in this presentation, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions.*

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# Presenters on Today's Call

| Speaker | Title |
| --- | --- |
| Faheem Hasnain | Chief Executive Officer, Chairman, Co-Founder |
| Bryan Giraudo | Chief Financial Officer, Chief Operating Officer |
| Richard Aranda, MD | Chief Medical Officer |
| Jeff Boerneke | General Counsel & Secretary |

# Gossamer / Chiesi Seralutinib Partnership Overview

## Payments

Immediate Development Reimbursement:
**$160mm**

Regulatory milestones:
**up to $146mm**

Sales Milestones:
**up to $180mm**

## Structure

**50 / 50 US Profit Split**

**Mid-to-High Teens Royalties** to Gossamer (ex-US)

**50 / 50** Worldwide R&D **Cost Split***

**Gossamer Leads Global Development & US Commercialization** of PAH & PH-ILD

## Opportunity

**50k** PAH Patients in US[1];
Median 5-year survival: 57%[2];
**Q4:25E: Topline P3 Results**

**Est. 60-100k** PH-ILD Patients in US[3];
Median 5-year Survival: 23%[4];
**P3 to Begin Mid-2025**

* Gossamer remains fully financially responsible for PROSERA Phase 3 Study in PAH & related activities.
mm= millions; PAH = pulmonary arterial hypertension; PH-ILD = pulmonary hypertentsion associated with interstitial lung disease; R&D = research & development; P3 = Phase 3; Est. = estimated.
Source: 1. Kirson, et al 2011; 2. Chang et al, J Amer Heart Assoc 2022; 3. Based on internal company estimates using prevalence for various forms of ILD; 4. Gall et al, J Heart Lung Transplant 2017

# A Well-Suited Partner

- Global biopharmaceutical group with international R&D and commercialization infrastructure & operations, headquartered in Italy
- Over 85 years of experience, operations in >30 countries, >7,000 employees world-wide, including ~700 in R&D, and >€3 billion in revenue in 2023
- Chiesi's therapeutic focus perfectly aligns with seralutinib: AIR (respiratory disease), RARE (rare diseases), & CARE (specialty care, including cardiovascular disease)
- Global reach & areas of focus position Chiesi to enhance seralutinib's access to pulmonary hypertension (PH) patients across the globe

**air**

Encompasses products & services for the treatment of respiratory diseases among patients of all ages, from newborns to the elderly.

**Asthma • COPD • PAH • IPF**

**rare**

Focusing on the treatment of patients living with rare or ultra-rare diseases.

**Rare Immunologic Diseases**

**care**

Combines products & services that support special care provided by medical professionals, as well as consumer healthcare/over the counter.

**Cardiovascular Diseases**

# Value of Partnership to Gossamer

| | |
|---|---|
| Provides Adequate Capital & Global Commercial Partner for Investment in Commercial Launch of PAH | • Gossamer pro forma cash of $396mm[1]<br>• Gossamer & Chiesi can confidently invest in commercial planning during PROSERA study (expected Q4:25 topline readout)<br>• Chiesi is a global partner with significant commercial pulmonary & rare disease infrastructure |
| Accelerates Seralutinib into a Phase 3 Study in PH-ILD | • Pivotal Phase 3 Study in PH-ILD expected to begin in mid-2025, cutting years off potential development timeline<br>• Adds multi-billion-dollar peak sales opportunity in indication with high unmet medical need, strong biological rationale, & limited competition |
| Retained Strategic Optionality & Experienced, Motivated Partner | • Gossamer retains control over US commercialization & global development in PAH & PH-ILD<br>• Gossamer & Chiesi are committed to smart expansion into indications of unmet need that overlap with areas of expertise |

1) Pro forma cash includes $244 million of cash, cash equivalents & marketable securities, as of March 31, 2024, plus the $160 million development reimbursement fee from Chiesi, less $8mm prepayment made to retire MidCap facility in May 2024.
PAH = pulmonary arterial hypertension; PH-ILD = pulmonary hypertension associated with interstitial lung disease.

# Seralutinib is Poised to be a Potential Paradigm-Shifting Therapy in PAH

- **Seralutinib is a novel inhaled kinase inhibitor, currently in an ongoing registrational Phase 3 for the treatment of PAH**
- **In the Phase 2 TORREY study, seralutinib demonstrated statistically significant[3]:**
  - Reduction in pulmonary vascular resistance (PVR – primary endpoint)
  - Reduction in NT-proBNP, a biomarker of right heart strain
  - Changes in right heart structure & function
- **In an open-label extension study, seralutinib showed a continued reduction in PVR, with a near doubling of improvement from Week 24 to Week 72[4]**
- Seralutinib has been generally well tolerated to date with no reports of GI or CNS bleeding events, telangiectasia, or hemoglobin increases[4]
- PROSERA Phase 3 study initiated Q4:23; topline results expected Q4:25

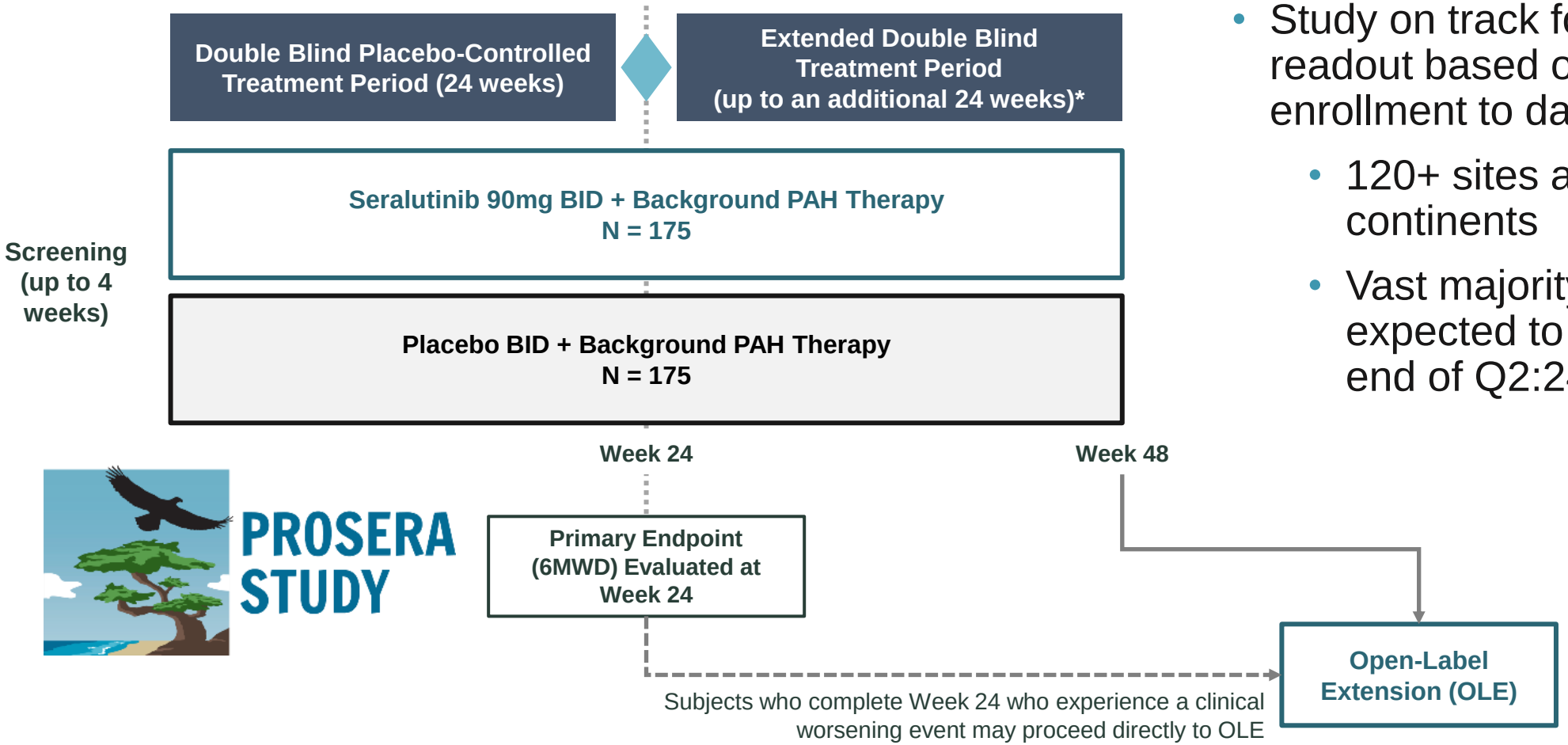
**~30-50K PAH patients in US[(1)]**

**Low long-term survival (5-year: 57%[2])**

PAH = pulmonary arterial hypertension; NT-proBNP = N-terminal pro b-type natriuretic peptide; GI = gastrointestinal; CNS = central nervous system.

Note: Source: 1. Kirson, et al 2011, prevalence estimates vary widely across sources; 2. Chang et al, J Amer Heart Assoc 2022; 3. Frantz et al, Lancet Respiratory 2024; 4. Data on file.

# Ongoing PROSERA Phase 3 Study




- Study on track for Q4:25 topline readout based on site activation & enrollment to date
  - 120+ sites active across 5 continents
  - Vast majority of planned sites expected to be active by the end of Q2:24

6MWD = six-minute walk distance.

# Seralutinib's Next Frontier: What is PH-ILD?

- WHO Group 3 PH is pulmonary hypertension due to lung diseases and / or hypoxia
  - PH associated with interstitial lung disease (PH-ILD) is a subgroup of Group 3 PH
  - PH-ILD includes PH related to idiopathic pulmonary fibrosis (IPF) & PH related to connective tissue disease-associated interstitial lung disease (CTD-ILD)
- Characterized by pulmonary vascular pathology associated with PH, in addition to thickening & scarring of the lung interstitium resulting from ILD
- Only Tyvaso® is approved for PH-ILD, & only in the US
- **Patients have poor disease prognosis & increased mortality rate as compared to PAH patients (40% 3-year survival rate[2])**

**~60-100K PH-ILD patients in US[(1)]**

**One approved therapy (US only)**

**Call point overlap with PAH**

WHO = World Health Organization; PH = pulmonary hypertension; PAH = pulmonary arterial hypertension.
1) Based on internal company estimates. Prevalence estimates of PH-ILD indicate the patient population is likely to be 1-2 times that of PAH.
2) Gall et al, J Heart Lung Transplant 2017.
Tyvaso is a registered trademark of United Therapeutics Corporation.

# PH-ILD is an Ideal Next Indication for Seralutinib

1

**Biologic Rationale:**
Demonstrated Positive Impact on Reducing Pulmonary Hypertension

TORREY STUDY

- The pulmonary hypertension in PH-ILD is caused by the same proliferative, inflammatory, & fibrotic pathways as PAH
- Seralutinib demonstrated statistically significant improvement in PVR, right heart function/structure measures, & NT-proBNP in TORREY

2

**Clinical Trial Patient Dynamics are Favorable**

- Lack of therapeutic options has fostered strong patient demand for clinical trials
- PH-ILD clinical trial patients have increased exercise impairment, as compared to PAH studies
  - Mean BL STELLAR (PAH) 6MWD: 401m
  - Mean BL INCREASE (PH-ILD) 6MWD: 260m
- Seralutinib demonstrated a stat. sig. pbo-controlled 38m increase in 6MWD in baseline FC III PAH patients* in TORREY (mean BL 6MWD = 367m)

3

**High Unmet Need**

- Only Tyvaso is approved for PH-ILD, & only in the US
  - No approved therapies in EU or Japan
- Patient population is potentially double the PAH population
- Patients have a high mortality rate, even compared to PAH

**Phase 3 design to be discussed after interactions with global regulatory authorities**

PH-ILD = pulmonary hypertension due to instertital lung disease; PAH = pulmonary arterial hypertension; PVR = pulmonary vascular resistance; NT-proBNP = N-terminal pro b-type natriuretic peptide; 6MWD = six-minute walk distance; BL = baseline. *TORREY Study pre-specified subgroup.

# Seralutinb MoA Aligned with Underlying Pathophysiology of Group 3 PH

| Disease Process | Cell Type / Mechanism | Potentially Relevant Pathway |
|---|---|---|
| Vascular Inflammation | Macrophages & ECs | • CSF1R<br>• KIT |
| Vascular fibrosis | Fibroblasts / myofibroblasts | • PDGFR |
| Pulmonary vasculopathy (plexiform lesions) | Endothelial-to-mesenchymal transition | • PDGFR |
| Pulmonary arteriolar hypertrophy / hyperplasia | Pulmonary arteriole vascular smooth muscle cells | • PDGFR<br>• BMPR2 |
| Parenchymal interstitial lung inflammation & fibrosis | Fibroblasts | • PDGFR<br>• CSF1R |
| | Epithelial-to-mesenchymal transition | • PDGFR |
| Shunt/hypoxia | V/Q mismatch | • Multiple |

**Seralutinib Was Rationally Designed For PH & Is Highly Relevant For Targeted Indications**



Source: Dotan, et al., BMC Open Res 2020; Yang, et al., Cell 2006; Song, et al., Cellular Signaling 2016; Wynn, J Pathol 2008; Tsutsumi, et al., PLoS One 2019.

# PH-ILD Presents a Significant Market Opportunity

| | PAH | PH-ILD |
|---|---|---|
| US Prevalence | ~30-50k[1] | ~60-100k+[3] |
| Competitive intensity | 16 marketed products | 1 marketed product (US Only) |
| 5-year survival rate | 57%[2] | 23%[4] |
| Generics | 8 generic products | 0 generic products |

**Patients living with PH-ILD are deeply underserved**

1. Kirson, et al 2011, prevalence estimates vary widely across sources; 2. Chang et al, J Amer Heart Assoc 2022; 3. Based on internal company estimates. Prevalence estimates of PH-ILD indicate the patient population is likely to be 1-2 times that of PAH. 4. Gall et al, J Heart Lung Transplant 2017

# Gossamer & Seralutinib are Well Positioned for Success

| | |
|---|---|
| Vastly Expanding Opportunity | • Accelerates commercial planning in Group 1 PH<br>• Move directly into PH-ILD Phase 3 study, based upon Phase 2 clinical success in PAH, leapfrogging potential competitors<br>• Sets stage for potential blockbuster, multi-indication PH franchise |
| Ability to Execute | • Veteran leadership with prior experience at Actelion, Acceleron, Johnson & Johnson, Merck & United Therapeutics<br>• Partnership with a global pharmaceutical company focused on pulmonary, rare disease, & specialized pharma products |
| US Strategic Optionality | • Lead global development & US commercialization in PAH, PH-ILD<br>• Book US sales in PAH & PH-ILD |
| Well Capitalized | • Well capitalized, with pro forma cash of ~$396mm(1) |

1) Pro forma cash includes $244 million of cash, cash equivalents & marketable securities, as of March 31, 2024, plus the $160 million development reimbursement fee from Chiesi, less $8mm prepayment made to retire MidCap facility in May 2024.

# Gossamer at ATS 2024 International Conference

**Date / Location:** May 17th - 22nd, 2024 / San Diego, California

**Session:** A14: “Building Lego(Land): Lessons Learned From Large Scale Clinical Trials In PAH”

**Session Date & Time:** Sunday, May 19th, 9:15 a.m. - 11:15 a.m. PT

**Talk Title:** Interim Results From the Phase 1B and Phase 2 TORREY Open-label Extension Study of Seralutinib in Pulmonary Arterial Hypertension (PAH)

**Location:** San Diego Convention Center, Room 29A-D (Upper Level)

**Presenting Author:** Olivier Sitbon, MD, PhD