Gossamer Bio Announces First Quarter 2025 Financial Results and Provides Business Update, Including Closure of New Patient Screening in Phase 3 PROSERA Study

May 15, 2025

- Enrollment Completion for Ongoing Registrational PROSERA Phase 3 Study in PAH Expected in Early June; New Patient Screening Closed -

- Topline Results Announcement from PROSERA Phase 3 Expected in February 2026 -

- To Date, Blinded Baseline Characteristics Align with Intended Study Population -

- First Site Activations for Planned Registrational Phase 3 SERANATA Study in PH-ILD Expected in the Fourth Quarter of 2025 -

- Cash, cash equivalents and marketable securities totaled $258 million as of March 31, 2025 -

SAN DIEGO--(BUSINESS WIRE)--May 15, 2025-- Gossamer Bio, Inc. (Nasdaq: GOSS), a late-stage, clinical biopharmaceutical company focused on the development and commercialization of seralutinib for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD), today announced its financial results for the first quarter ended March 31, 2025, and announced the closure of new patient screening for the ongoing registrational Phase 3 PROSERA Study in PAH patients.

Gossamer Bio and the Chiesi Group are jointly developing seralutinib under a global collaboration agreement.

"I am incredibly proud to announce that, following the recent closing of new patient screening, we are just weeks away from fully enrolling the PROSERA Phase 3 Study in PAH," said Faheem Hasnain, Chairman, Co-Founder, and CEO of Gossamer Bio.

"This achievement is the result of our team's unwavering dedication, tireless effort, and steadfast commitment to our mission. We expect to publicly announce topline data from this pivotal study in February of 2026. Enrolling the appropriate patients for this study was of paramount importance, and the baseline characteristics of those who have been randomized to date demonstrate that our diligence and focus on study quality has paid off. This reinforces our optimism for meaningful results and brings us one step closer to the potential of having a new, first-in-class therapy for patients with PAH."

Chief Medical Officer Dr. Richard Aranda added, "We are also delighted to unveil the clinical trial design for the Phase 3 SERANATA Study in PH-ILD, a landmark moment in our pursuit to address unmet patient need. A product of close collaboration and alignment with global regulatory authorities, including the FDA and EMA, this study represents a groundbreaking effort to offer new hope to patients with PH-ILD."

Seralutinib (GB002): Inhaled PDGFR, CSF1R and c-KIT Inhibitor

- On May 14th, we closed new patient screening for the ongoing PROSERA Study in Functional Class II and III PAH patients. To date, 343 patients have been enrolled or are scheduled to randomize into the PROSERA Study. With the additional patients currently in screening, we expect to complete enrollment with over 350 PAH patients in early June.
    - The Phase 3 PROSERA Study is a double-blind, placebo-controlled, global registrational clinical trial evaluating seralutinib in PAH patients, on top of background PAH therapy. Patients are assigned 1:1 to either the seralutinib or placebo arms. Patients receive blinded treatment for up to 48 weeks.
    - The primary endpoint of the PROSERA Study is change in six-minute walk distance (6MWD) from baseline as compared to placebo at week 24. Included in the key secondary endpoints is time to clinical worsening, as compared to placebo, up to week 48. In addition to other secondary and exploratory endpoints, safety and tolerability will be evaluated.
    - The patient population enrolled in PROSERA aligns with the target demographic, as evidenced by available baseline characteristics. The PROSERA Study utilizes enrichment criteria, including the REVEAL Lite 2 Risk Score and other criteria, to identify patients more likely to show a greater magnitude of effect on 6MWD at week 24, as informed by the Phase 2 TORREY study.
    - **Seralutinib Clinical Trial Baseline Characteristics: Phase 3 PROSERA Study* v. Phase 2 TORREY Study**

	PROSERA Phase 3*	TORREY Phase 2

Study Participants	n = 324 *(target: 350)*	n = 86
Mean 6MWD	376 meters	408 meters
Mean NT-proBNP	986 ng/L	628 ng/L
Functional Class III Patients	239 (74%)	36 (42%)
Geographic Distribution	North America: 61 (19%) Rest of World: 263 (81%)	North America: 59 (69%) Rest of World: 27 (31%)

**Characteristics shown are for the first 324 patients enrolled in the PROSERA Study, and all PROSERA Study percentages are out of 324. Given the patients scheduled to randomize and those still in screening, we expect to complete full enrollment in early June. Final baseline characteristics for the PROSERA Study are subject to change.*

    - We expect to announce topline results from the ongoing Phase 3 PROSERA Study in February 2026.

- We expect to activate clinical sites for the global, registrational Phase 3 SERANATA Study in PH-ILD patients in the fourth quarter of 2025.
    - Achieved alignment on study design and endpoints with global regulatory authorities, including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).
    - The planned SERANATA Study will be a 24-week, randomized, double-blind, placebo-controlled, global clinical trial in PH-ILD patients. Approximately 480 patients will be randomized 1:1:1 to receive either 90mg seralutinib twice-daily, 120mg seralutinib twice-daily or placebo.
    - The primary endpoint of the SERANATA Study is change in 6MWD from baseline as compared to placebo at week 24. Key secondary endpoints will include time to clinical worsening and change from baseline in forced vital capacity (FVC).
- One poster related to seralutinib will be presented at the American Thoracic Society (ATS) 2025 International Conference, taking place from May 16th through 21st, in San Francisco, California.
    - Poster Presentation
        - Title: *Seralutinib in Pulmonary Arterial Hypertension: Exploring Mechanisms of Reverse Remodeling Versus Vasodilation*
        - Poster Number: P920
        - Session: A76 Finger on the Pulse: Cardiopulmonary Dysfunction in Lung Disease
        - Date: Sunday, May 18th
        - Time: 11:30am – 1:15pm PDT
        - Location: Area G, Hall F (North Building, Exhibition Level), Moscone Center
    - Following its presentation at the ATS 2025 International Conference, the poster will also be made available on the "Posters & Publications" section of the Gossamer Bio website at gossamerbio.com/science/posters-and-presentations/.

Financial Results for Quarter Ended March 31, 2025

- **Cash, Cash Equivalents and Marketable Securities:** Cash, cash equivalents and marketable securities as of March 31, 2025, were $257.9 million. We expect the combination of current cash, cash equivalents and marketable securities will be sufficient to fund our operating and capital expenditures into the first half of 2027.
- **Revenue from Sale of Licenses and from Contracts with Collaborators:** For the quarter ended March 31, 2025, revenue associated with our collaboration with Chiesi was $9.9 million, including $6.6 million of cost reimbursement revenue.
- **Research and Development (R&D) Expenses:** For the quarter ended March 31, 2025, R&D expenses were $38.0 million, compared to $32.4 million for the same period in 2024.
- **General and Administrative (G&A) Expenses:** For the quarter ended March 31, 2025, G&A expenses were $8.7 million, compared to $9.6 million for the same period in 2024.
- **Net Loss:** Net loss for the quarter ended March 31, 2025, was $36.6 million, or $0.16 basic net loss per share, compared to a net loss of $41.9 million, or $0.19 basic net loss per share, for the same period in 2024.

Conference Call and Webcast

Gossamer's management team will host a conference call and live audio webcast at 4:30 p.m. ET today, Thursday, May 15th, to discuss its first quarter 2025 financial results and business update.

The live audio webcast may be accessed through the "Events / Presentations" page in the "Investors" section of the Company's website at gossamerbio.com. Alternatively, the conference call may be accessed through the following:

Domestic Dial-in Number: (800) 285-6670
International Dial-in Number: (713) 481-0091
Live Webcast: https://edge.media-server.com/mmc/p/m5ahx8qm

A replay of the audio webcast will be available for 30 days on the "Investors" section of the Company's website, gossamerbio.com.

About Gossamer Bio

Gossamer Bio is a late-stage, clinical biopharmaceutical company focused on the development and commercialization of seralutinib for the treatment of pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease. Its goal is to be an industry leader in, and to enhance the lives of patients living with, pulmonary hypertension.

Forward-Looking Statements

Gossamer cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: the anticipated timing of enrollment completion and a data readout from our Phase 3 PROSERA Study; the potential or likelihood for a meaningful data readout from our PROSERA Study; the development potential of seralutinib; the anticipated timing on commencing a Phase 3 clinical trial in PH-ILD; and the expected timeframe for funding our operating plan with current cash, cash equivalents and marketable securities. The inclusion of forward-looking statements should not be regarded as a representation by Gossamer that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Gossamer's business, including, without limitation: potential delays in the commencement, enrollment and completion of clinical trials; disruption to our operations from unexpected events, including clinical trial delays; the Company's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; the results of preclinical studies and early clinical trials are not necessarily predictive of future results; the success of Gossamer's clinical trials and preclinical studies for seralutinib; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of seralutinib that may limit its development, regulatory approval and/or commercialization, or may result in clinical holds, recalls or product liability claims; Gossamer's ability to obtain and maintain intellectual property protection for seralutinib; Gossamer's ability to comply with its obligations in collaboration agreements with third parties or the agreements under which it licenses intellectual property rights from third parties; unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may adversely affect our business and financial condition and the broader economy and biotechnology industry; Gossamer may use its capital resources sooner than it expects; and other risks described in the Company's prior press releases and the Company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's annual report on Form 10-K and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Gossamer undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Gossamer Bio Statement of Operations
Condensed Consolidated Statement of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three months ended March 31,	
	2025	**2024**
Revenue:		
Revenue from contracts with collaborators	$ 9,889	$ —
Total revenue	9,889	—
Operating expenses:		
Research and development	38,041	32,392
General and administrative	8,658	9,567
Total operating expenses	46,699	41,959
Loss from operations	**(36,810)**	**(41,959)**
Other income (expense)		
Interest income	294	344
Interest expense	(2,746)	(3,129)
Other income, net	2,624	2,816
Total other income, net	172	31
Net loss	**$ (36,638)**	**$ (41,928)**
Net loss per share, basic and diluted	$ (0.16)	$ (0.19)
Weighted average common shares outstanding, basic and diluted	226,818,051	225,735,236

Condensed Consolidated Balance Sheet
(in thousands)

BALANCE SHEET DATA:	March 31, 2025	December 31, 2024
	(unaudited)	
Cash, cash equivalents, and marketable securities	$ 257,934	$ 294,518
Working capital	227,252	264,878
Total assets	280,589	315,292
Total liabilities	286,839	285,800
Accumulated deficit	(1,305,206)	(1,268,568)
Total stockholders' equity (deficit)	(6,250)	29,492

View source version on businesswire.com: https://www.businesswire.com/news/home/20250515490367/en/

For Investors and Media:
Bryan Giraudo, Chief Financial Officer & Chief Operating Officer
Gossamer Bio Investor Relations
ir@gossamerbio.com

Source: Gossamer Bio, Inc.