Gossamer Bio Announces Fourth Quarter and Full-Year 2023 Financial Results and Provides Business Update

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- First PAH Patient Dosed in Ongoing Registrational Phase 3 PROSERA Study -

- Inclusion of Japan in Phase 3 PROSERA Study Following CTN Acceptance by PMDA -

- Cash, cash equivalents and marketable securities totaled $296 million at year-end 2023 -

SAN DIEGO--(BUSINESS WIRE)--Mar. 5, 2024-- Gossamer Bio, Inc. (Nasdaq: GOSS), a clinical-stage biopharmaceutical company focused on the development and commercialization of seralutinib for the treatment of pulmonary arterial hypertension (PAH), today announced its financial results for the fourth quarter and year ended December 31, 2023, and provided a business update.

“We were thrilled to enroll the first patient in the registrational PROSERA Study last year, and we are pleased with the pace of site activations and enrollment into the study,” said Faheem Hasnain, Chairman, Co-Founder and CEO of Gossamer Bio. “This advancement marks a significant milestone in Gossamer’s journey, and it was made possible due to the tireless efforts of the Gossamer team. We are excited to be one step closer to bringing seralutinib to patients.

“Additionally, we believe Gossamer is one of the first companies to take advantage of new Japanese regulatory guidelines, formally issued at the end of last year, to allow for the inclusion of Japanese subjects in our global registrational study of seralutinib without performing a pharmacokinetic bridging study. Subject to final results, PROSERA could form the basis of a Japanese New Drug Application, accelerating the potential commercial availability of seralutinib to PAH patients in Japan and unlocking a valuable geographic market for Gossamer.

“Beyond PAH, we remain excited about the potential of seralutinib to treat patients living with other forms of pulmonary hypertension, including pulmonary hypertension associated with interstitial lung disease, or PH-ILD. Patients with PH-ILD are in desperate need of safe and efficacious therapies, with just one therapy approved in the US and no approved therapies available in the rest of the world. We believe seralutinib holds great promise for these patients, and our team is eagerly working through a clinical development plan.”

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

- The first PAH patient in the ongoing Phase 3 PROSERA Study was dosed in the fourth quarter of 2023. The Phase 3 PROSERA Study is a global registrational clinical trial in patients with Functional Class II and III PAH. The primary endpoint is change in six-minute walk distance (6MWD) from baseline at week 24. Topline results from the PROSERA Study are expected in the fourth quarter of 2025.
- The Pharmaceuticals and Medical Devices Agency of Japan, or PMDA, allowed inclusion of Japanese clinical trial sites in the ongoing Phase 3 PROSERA Study. Subject to final clinical trial results, PROSERA could form the basis of a commercial marketing application in Japan.

Financial Results for Quarter and Full Year Ended December 31, 2023

- **Cash, Cash Equivalents and Marketable Securities**: Cash, cash equivalents and marketable securities as of December 31, 2023, were $296.4 million. As a result, we expect our current cash, cash equivalents and marketable securities will be sufficient to fund operating and capital expenditures into the first half of 2026.
- **Research and Development (R&D) Expenses**: For the quarter ended December 31, 2023, R&D expenses were $30.0 million compared to R&D expenses of $41.5 million for the same period in 2022. R&D expenses for the full year ended December 31, 2023, were $135.3 million compared to $170.9 million for the full year ended December 31, 2022.
- **General and Administrative (G&A) Expenses**: For the quarter ended December 31, 2023, G&A expenses were $9.1 million compared to $12.8 million for the same period in 2022. G&A expenses for the full year ended December 31, 2023, were $38.5 million compared to $47.6 million for the full year ended December 31, 2022.
- **Net Loss**: Net loss for the three months ended December 31, 2023, was $48.1 million, or $0.21 per share, compared to a net loss of $55.8 million, or $0.59 per share, for the same period in 2022. Net loss for the full year ended December 31, 2023, was $179.8 million, or $1.18 per share compared to a net loss of $229.4 million, or $2.71 per share, for the full year ended December 31, 2022.

About Gossamer Bio

Gossamer Bio is a clinical-stage biopharmaceutical company focused on the development and commercialization of seralutinib for the treatment of pulmonary arterial hypertension. Its goal is to be an industry leader in, and to enhance the lives of patients suffering from, 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 a data readout from our Phase 3 PROSERA Study; expectations on commencing a clinical development program in PH-ILD; the ability to file a commercial marketing application in Japan pending clinical data; 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 pandemics, 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, INC.

CONDENSED CONSOLIDATED FINANCIAL STATEMENT DATA

(UNAUDITED; IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

	Three months ended December 31,		**Year ended December 31,**	
STATEMENTS OF OPERATIONS DATA:	**2023**	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 29,970	$ 41,508	$ 135,304	$ 170,919
In process research and development	10,000	15	10,000	65
General and administrative	9,057	12,834	38,455	47,609
Total operating expenses	49,027	54,357	183,759	218,593
Loss from operations	**(49,027)**	**(54,357)**	**(183,759)**	**(218,593)**
Other income (expense)				
Interest income	310	594	1,997	1,583
Interest expense	(3,239)	(3,457)	(13,511)	(13,880)
Other income, net	3,808	1,456	15,456	1,512
Total other income (expense), net	879	(1,407)	3,942	(10,785)
Net loss	**$ (48,148)**	**$ (55,764)**	**$ (179,817)**	**$ (229,378)**

Net loss per share, basic and diluted	$ (0.21)	$ (0.59)	$ (1.18)	$ (2.71)
Weighted average common shares outstanding, basic and diluted	225,409,315	94,280,553	152,621,669	84,574,869

BALANCE SHEET DATA:	**December 31, 2023**	**December 31, 2022**
Cash, cash equivalents, and marketable securities	$ 296,425	$ 255,678
Working capital	254,921	212,650
Total assets	311,916	272,450
Total liabilities	249,147	260,373
Accumulated deficit	(1,212,040)	(1,032,223)
Total stockholders' equity	62,769	12,077

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