# Gossamer Bio Submits New Drug Application to U.S. FDA for Seralutinib for the Treatment of Pulmonary Arterial Hypertension

September 23, 2026

***– NDA Supported by the Phase 3 PROSERA Study, Phase 2 TORREY Study and Additional Supportive Analyses –***

SAN DIEGO--(BUSINESS WIRE)--Sep. 23, 2026-- Gossamer Bio, Inc. (Nasdaq: GOSS) (the "Company" or "Gossamer"), a clinical-stage 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 that it submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in September 2026 for seralutinib for the treatment of PAH. This is the Company's first NDA submission.

The NDA is supported by the Phase 3 PROSERA Study as one adequate and well-controlled clinical investigation, together with confirmatory evidence from the Phase 2 TORREY Study and supportive analyses. The NDA submission follows the Company's Pre-NDA Type B meeting with the FDA in June 2026 and the FDA's official written meeting minutes, in which the FDA characterized the degree of statistical significance and the magnitude of the treatment effect observed in PROSERA as review issues rather than filing issues, and provided feedback on the format and content of the planned submission.

"Submitting our first NDA is a significant milestone for Gossamer and, more importantly, for patients living with PAH," said Faheem Hasnain, Chairman, Co-Founder and Chief Executive Officer of Gossamer. "We are grateful to the patients, families, investigators and site staff who made PROSERA and TORREY possible, and to our employees for the work it took to reach this point."

"This submission is the result of years of scientific rigor and the collective effort of colleagues across clinical development, biostatistics, regulatory affairs, manufacturing, quality and many other functions," said Caryn Peterson, Chief Development Officer of Gossamer. "It brings us one step closer to delivering seralutinib as a potential new therapy for PAH patients who need better options."

The FDA will determine whether to accept the NDA for filing following its initial review of the application, which the Company anticipates could occur later this year. The acceptability of the individual elements of the application, including the efficacy and safety evidence, will be determined by the FDA during its review of the complete NDA.

**About Gossamer Bio**

Gossamer Bio is a 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 Company's interpretation of the FDA minutes from the Company's Pre-NDA Type B meeting with the FDA; the FDA's review, potential acceptance for filing and approval of an NDA for seralutinib in PAH and the timing thereof; the potential significance, interpretation and implications of data from the Phase 3 PROSERA study and Phase 2 TORREY study and supportive analyses; the development potential and market opportunity of seralutinib in PAH, PH-ILD and other indications and the potential for seralutinib as a new therapy for PAH patients. 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: the risk that the Company's NDA submission is based in part on its views following its recent meeting with the FDA and the official minutes therefrom and later feedback from the FDA, which may be inconsistent with such meeting or the Company's views from such meeting; later developments with the FDA may be inconsistent with the feedback from prior meetings; the FDA may determine that the Company's NDA does not qualify for filing and may not accept or approve the filing; the results of the Company's clinical trials, including the Phase 3 PROSERA and Phase 2 TORREY studies, may not be deemed sufficient by the FDA to serve as the basis for regulatory approval of seralutinib, including the risk that the FDA determines that the overall benefit-risk assessment of seralutinib is not favorable; any path forward may require additional capital and other resources, which may not be available on reasonable terms, if at all, or may limit the commercial opportunity for seralutinib; the Company's future performance is dependent entirely on the success of seralutinib; the Company's interpretation, significance and regulatory relevance of data from the Phase 3 PROSERA study, including the CT FRI substudy, may be

inconsistent with the views of the FDA or others; adverse side effects or inadequate efficacy of seralutinib may limit its development, regulatory approval and/or commercialization, or may result in clinical holds, recalls or product liability claims; the Company 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.

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Source: Gossamer Bio, Inc.