

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): September 23, 2026

GOSSAMER BIO, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38796
(Commission File Number)

47-5461709
(IRS Employer
Identification No.)

**3115 Merryfield Row, Suite 120
San Diego, California 92121**

(Address of Principal Executive Offices) (Zip Code)

(858) 684-1300
(Registrant's Telephone Number, Including Area Code)

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:

- ☐ 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, \$0.0001 par value per share	GOSS	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On September 23, 2026, Gossamer Bio, Inc. (the “Company”) 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 pulmonary arterial hypertension (“PAH”). This is the Company’s first NDA submission.

The NDA is supported by the Company’s Phase 3 PROSERA Study as one adequate and well-controlled clinical investigation, together with confirmatory evidence from the Company’s 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.

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, would be determined by the FDA during its substantive review of the complete NDA.

Note Regarding Forward-Looking Statements.

The Company cautions you that statements contained in this report 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; and the development potential and market opportunity for seralutinib. 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 report 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 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.

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.

GOSSAMER BIO, INC.

Date: September 23, 2026

By: /s/ Bryan Giraudo

Bryan Giraudo

Chief Financial Officer and Chief Operating Officer