

**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): May 3, 2024

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.)

**3013 Science Park Road
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 (see General Instructions A.2. below):

- 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 1.01 Entry into a Material Definitive Agreement.

On May 3, 2024, Gossamer Bio, Inc. (“Gossamer” or the “Company”), GB002, Inc., a Delaware corporation and wholly-owned subsidiary of the Company (“GB002”), and Gossamer Bio 002 Ltd., a corporation organized and existing under the laws of Ireland and indirect wholly-owned subsidiary of the Company, entered into a global collaboration and license agreement (the “Chiesi Collaboration Agreement”) with Chiesi Farmaceutici S.p.A and Chiesi USA, Inc. (collectively, “Chiesi”). The collaboration is focused on the development and commercialization of seralutinib and licensed products including seralutinib and related licensed compounds (“Licensed Products”) in the US (“US Territory”) and the rest of the world (“ROW Territory”), for therapeutic, prophylactic and diagnostic uses in humans and animals, for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD) and other indications, as may be permitted under the Chiesi Collaboration Agreement.

Pursuant to the Chiesi Collaboration Agreement, the Company granted exclusive, sublicensable (with Gossamer’s consent required in the US Territory for third party sublicenses) licenses to Chiesi under intellectual property rights controlled by Gossamer relating to seralutinib and Licensed Products, for the worldwide development, manufacture and commercialization of seralutinib and Licensed Products. The licenses granted to Chiesi are subject to retained rights of Gossamer for the worldwide development and manufacture of seralutinib and Licensed Products, commercialization of Licensed Products in the US Territory, and performance of its obligations and exercise of its rights that may be set forth in the global development plan and US commercialization plan, in each case in accordance with the Chiesi Collaboration Agreement.

Chiesi granted Gossamer non-exclusive, sublicenseable (with Chiesi’s consent required in the US Territory for third party sublicenses) licenses under certain practiced intellectual property rights relating to seralutinib and Licensed Products and arising intellectual property rights, in each case as controlled by Chiesi, for the worldwide development and manufacture of seralutinib and Licensed Product and a co-exclusive license (with Chiesi) to commercialize seralutinib and Licensed Products in the US Territory.

The parties agreed to use commercially reasonable efforts to conduct development and commercialization activities in relation to seralutinib and Licensed Products, under the global development plan and US commercialization plan in accordance with the timelines therein. Gossamer will continue to lead global development of seralutinib in PAH and PH-ILD, and the parties will equally share the costs for the activities included in the global development plan for all Licensed Products, with the exception of the PROSERA Phase 3 study, which Gossamer will be solely responsible for conducting at Gossamer’s own cost and expense. With respect to each country in the ROW Territory, such obligation to equally share such development costs shall end when regulatory approval is received for a Licensed Product in such country. With respect to US Territory, the development costs incurred following regulatory approval shall continue to be shared equally. Gossamer will lead commercialization for PAH and PH-ILD in the US, with both parties contributing 50 percent of commercial efforts, including performing 50 percent of the commercialization activities. Chiesi will lead commercialization in the US Territory in additional indications, and Chiesi will have the exclusive right to commercialize Licensed Products in the ROW Territory. Chiesi further agreed to use commercially reasonable efforts to commercialize Licensed Product in certain specified countries in the ROW Territory following receipt of regulatory approvals. Generally, Gossamer will have the right to lead in manufacturing commercial supply of seralutinib and Licensed Products for the US Territory for PAH and PH-ILD, and, subject to any existing obligations of Gossamer to third party manufacturers, Chiesi will have the right to lead in manufacturing commercial supply of seralutinib and Licensed Products in the ROW Territory, in each case in accordance with the Chiesi Collaboration Agreement.

Pursuant to the Chiesi Collaboration Agreement, neither party nor its affiliates is permitted to develop or commercialize any compound or product throughout the term whose primary mechanism of action is inhibition of a tyrosine kinase for the treatment of PAH or PH-ILD in the US Territory or ROW Territory, subject to certain restrictions for the EU and UK.

In consideration and as reimbursement for the Company’s development costs, Chiesi agreed to pay Gossamer \$160 million. Additionally, Gossamer will be eligible to receive up to \$146 million in regulatory milestones and \$180 million in sales milestones. In the US Territory, the parties agreed to share commercial profits and losses equally. In the ROW Territory, Chiesi will pay Gossamer an escalating mid-to-high teens percentage royalty on net sales of Licensed Product for PAH and additional indications on a Licensed Product-by-Licensed Product and country-by-country basis with such payment obligations beginning on the first commercial sale of Licensed Product in such country and expiring on a country-by-country basis on the latest of (a) the expiration of a valid claim to a Gossamer patent right in such country, (b) the expiration of regulatory exclusivity, and (c) the date that is 10 years after the first commercial sale of such Licensed Product in such country.

In addition, Gossamer granted to Chiesi an option to purchase directly from Gossamer, on one or more occasions, up to an aggregate number of shares of Gossamer’s common stock such that immediately following such issuance, Chiesi’s beneficial ownership of Gossamer’s common stock shall not exceed 9.9% of the total number of issued and outstanding shares of

Gossamer’s common stock (the “Equity Option”). The Equity Option shall be exercisable by Chiesi, in whole or in part, at any time prior to the earliest to occur of the date on which (a) the last patient is last dosed in either (i) the PROSERA Phase 3 study for PAH or (ii) a Phase 3 clinical trial for the PH-ILD Indication, (b) any third party commences a tender offer or exchange offer for more than 50% of the outstanding shares of Gossamer’s common stock, and (c) Gossamer publicly announces its intent to consummate a GB002 change of control. The purchase price of each share Gossamer’s common stock subject to the Equity Option shall be equal to 107.5% of the daily volume-weighted average per share price of Gossamer’s common stock on The Nasdaq Stock Market over the 30-trading day period ending on and including the last trading day prior to the date on which Chiesi delivers an exercise notice to Gossamer; provided that such purchase price shall be no less than \$1.63 per share. The shares of Gossamer’s common stock to be issued will be issued in a private placement in reliance on Section 4(a)(2) of the Securities Act of 1933, as amended, for transactions by an issuer not involving any public offering, pursuant to the terms of a stock issuance agreement to be entered into between Gossamer and Chiesi in connection with each such exercise of the Equity Option.

Unless earlier terminated, the Chiesi Collaboration Agreement will remain in force until no Licensed Products are being developed or commercialized in the US Territory and in the ROW Territory, on a country-by-country basis, until no royalty terms are in effect for all countries. Either party may terminate the Chiesi Collaboration Agreement for the other party’s material breach, subject to a specified notice and cure periods, or due to an insolvency event of the other party. In lieu of termination upon a party’s material breach due to non-payment of development costs within a specified time the non-breaching party may elect an alternative remedy which may involve modifications to their performance and payment obligations. Gossamer has the right to terminate by providing written notice in the event Chiesi or its affiliates or sublicensee brings a patent challenge and Chiesi does not take certain steps to withdraw from or cease supporting such challenge. Chiesi may terminate the Chiesi Collaboration Agreement for any reason upon prior written notice to Gossamer, subject to a notice period.

The foregoing description of the Chiesi Collaboration Agreement is not complete and is qualified in its entirety by reference to the full text of the Chiesi Collaboration Agreement, a copy of which will be filed as an exhibit to the Company’s Quarterly Report on Form 10-Q to be filed with respect to the fiscal quarter ending June 30, 2024.

Item 1.02 Termination of a Material Definitive Agreement.

On May 2, 2019, the Company, and certain of its subsidiaries, as borrowers, entered into a credit, guaranty and security agreement, as amended on September 18, 2019, July 2, 2020, December 7, 2022 and February 14, 2023 (the “Credit Facility”), with MidCap Financial Trust (“MidCap”), as agent and lender, and the additional lenders party thereto from time to time (together with MidCap, the “Lenders”), pursuant to which the Lenders agreed to make term loans available to the Company. In connection with the entry into the Chiesi Collaboration Agreement, on May 3, 2024, the Credit Agreement and the other loan documents associated therewith were terminated, the payment and other obligations of Gossamer under the Credit Agreement were paid in full and discharged, and Lenders’ security interests in the Company’s assets and property were released.

Item 3.02 Unregistered Sales of Equity Securities.

The disclosure set forth in Item 1.01 above with respect to the issuance of the shares of Gossamer’s common stock in respect of the Equity Option is incorporated in this Item 3.02 by reference.

Item 8.01 Other Events.

On May 6, 2024, the Company issued a press release announcing the Chiesi Collaboration Agreement. A copy of the press release is attached as Exhibit 99.1 hereto and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated May 6, 2024
101	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 thereunto duly authorized.

GOSSAMER BIO, INC.

Date: May 6, 2024

By: /s/ Christian Waage
Christian Waage
Executive Vice President, Technical Operations & Administration



Gossamer Bio and Chiesi Group Announce Transformative Global Collaboration to Develop and Commercialize Seralutinib in PAH, PH-ILD & Other Indications

- *Gossamer to receive \$160 million development reimbursement payment and eligible to receive up to \$146 million in regulatory and \$180 million in sales milestones -*
- *Gossamer leading US commercialization activities in PAH and PH-ILD; 50 / 50 commercial profit split in US and global development cost sharing arrangement -*
- *Chiesi, a global leader in the pulmonary and rare disease spaces, obtains exclusive ex-US commercial rights, with Gossamer to receive mid-to-high teens royalties on net sales -*
- *Gossamer and Chiesi plan to initiate Phase 3 Trial of Seralutinib in PH-ILD in Mid-2025 -*

SAN DIEGO, CA and PARMA, ITALY — (BUSINESS WIRE) — May 6, 2024 — Gossamer Bio, Inc. (“Gossamer”) (Nasdaq: GOSS), a clinical-stage biopharmaceutical company focused on the development and commercialization of seralutinib for the treatment of pulmonary hypertension, and Chiesi Farmaceutici S.p.A (“Chiesi Group”), an international, research-focused biopharmaceutical group, today announced that they have entered into a global collaboration and license agreement to develop and commercialize seralutinib.

This global collaboration combines the strengths of both Chiesi and Gossamer to support ongoing work in pulmonary arterial hypertension (PAH) and to accelerate development in pulmonary hypertension associated with interstitial lung disease (PH-ILD), enabling the expansion of the seralutinib franchise to reach more patients with pulmonary hypertension world-wide. Patients will benefit from both Chiesi’s expertise in global respiratory, rare disease, and inhaled drug development and commercialization and Gossamer’s world-class PAH and PH-ILD development and commercialization teams.

“This partnership with Chiesi allows us to meaningfully deepen and rapidly accelerate our investment in seralutinib as a potential treatment for PAH, PH-ILD, and other indications of high unmet medical need,” said Faheem Hasnain, Co-Founder, Chairman and CEO of Gossamer. “We are particularly thrilled that this collaboration enables seralutinib to move directly into a Phase 3 trial in PH-ILD, an indication with a paucity of available treatments, and a disease which we believe seralutinib is specifically designed to address.”

“Seralutinib is a potential paradigm shifting therapy in PAH and PH-ILD, and we could not be more excited to partner with Gossamer to develop and bring this therapy to patients world-wide,” said Giuseppe Accogli, Group CEO of Chiesi. “Gossamer shares Chiesi’s commitment to using innovation to promote the health and well-being of people around the world and we are proud to add this collaboration as a key pillar to our next phase of growth.”

Prevalence estimates vary widely, but PAH is believed to affect approximately 30,000 to 50,000 people in the US, with a similar prevalence in Europe. While many approved PAH treatments are available, most are primarily vasodilators and do not impact the progressive course of the disease.

Median 5-year overall survival rate for patients with PAH is approximately 57%. In the past, PH-ILD has not been as readily diagnosed as PAH, in part due to a lack of approved treatment options for these patients. Based on prevalence figures for various forms of ILD and reported rates of PH in ILD patient cohorts, we estimate that PH-ILD affects approximately 60,000-100,000 patients in the US. Patients with PH-ILD in the US have access to only one approved therapy, while no therapies to treat PH-ILD are approved outside of the US. Median 5-year overall survival rate for patients with PH-ILD is approximately 23%.

Seralutinib is an inhaled PDGFR α/β , CSF1R, and c-KIT inhibitor designed to be delivered via dry powder inhaler for the potential treatment of pulmonary hypertension. Following the positive readout of the Phase 2 TORREY Study in patients with PAH, Gossamer initiated the Phase 3 PROSERA Study in 2023. Gossamer and Chiesi plan to initiate a global Phase 3 registrational study in PH-ILD in mid-2025 and to evaluate seralutinib in additional indications of high unmet need.

Under the terms of the agreement, Gossamer will continue to lead global development of seralutinib in PAH and PH-ILD, and the companies will evenly split development costs, except with respect to the PROSERA Study, for which Gossamer will remain financially responsible. In the US, the companies will evenly share commercial profits and losses. Gossamer will lead commercialization and book sales for PAH and PH-ILD in the US, with both companies contributing 50 percent of commercial efforts. Chiesi will lead US commercialization in additional indications. Chiesi will have the exclusive right to commercialize seralutinib outside of the US and will pay Gossamer an escalating mid-to-high teens royalty on net sales. Chiesi will pay Gossamer \$160 million as a development reimbursement. Additionally, Gossamer will be eligible to receive up to \$146 million in regulatory milestones and \$180 million in sales milestones. "We are pleased with the progress our team has made with the launch of the seralutinib Phase 3 PROSERA Study. With sites opening up across the globe, we are hearing incredible enthusiasm and interest from investigators, patients and patient advocates, alike," said Faheem Hasnain, Chairman, Co-Founder and CEO of Gossamer Bio.

Conference Call and Webcast

Gossamer's management team will host a conference call and live audio webcast to discuss the partnership today, May 6th, at 8:30 a.m. EDT.

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

Date / Time: May 6, 8:30am EDT

Domestic Dial-in Number: 1-800-285-6670

Conference Reference: Gossamer Bio Announcement Presentation

Live Webcast: <https://edge.media-server.com/mmc/p/5y35ojfx>

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

About Gossamer Bio

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

About Chiesi Group

Chiesi is research-oriented international biopharmaceutical group that develops and markets innovative therapeutic solutions in respiratory health, rare diseases, and specialty care. The company's mission is to improve people's quality of life and act responsibly towards both the community and the environment.

By changing its legal status to a Benefit Corporation in Italy, the US, and France, Chiesi's commitment to create shared value for society as a whole is legally binding and central to company-wide decision-making. As a certified B Corp since 2019, we're part of a global community of businesses that meet high standards of social and environmental impact. The company aims to reach Net-Zero greenhouse gases (GHG) emissions by 2035.

With over 85 years of experience, Chiesi is headquartered in Parma (Italy), with 31 affiliates worldwide, and counts more than 7,000 employees. The Group's research and development centre in Parma works alongside 6 other important R&D hubs in France, the US, Canada, China, the UK, and Sweden.

For further information please visit www.chiesi.com

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 potential reimbursement, regulatory and sales milestones payable to Gossamer pursuant to the collaboration and license agreement; the development and commercialization potential of seralutinib; the worldwide expansion of the seralutinib franchise; the anticipated timing of commencing a Phase 3 registrational study in PH-ILD; the ability to develop seralutinib in additional indications; and each of Gossamer's and Chiesi's respective obligations under the collaboration and license agreement to lead commercialization efforts and split development costs. 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 expected benefits of, and opportunities related to, the partnership with Chiesi may not be realized by Gossamer or may take longer to realize than anticipated; 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.

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