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): April 25, 2022

GOSSAMER BIO, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38796**	**47-5461709**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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 2.02 Results of Operations and Financial Condition.

Gossamer Bio, Inc. (the "Company" or "Gossamer") estimates that its cash, cash equivalents and marketable securities were approximately $272 million as of March 31, 2022. This amount is unaudited and preliminary and is subject to completion of financial closing procedures. As a result, this amount may differ from the amount that will be reflected in the Company's financial statements as of and for the quarter ended March 31, 2022.

The information in this Item 2.02 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On April 25, 2022, the Company announced topline results from its Phase 2 SHIFT-UC Study clinical trial studying GB004 in patients with mild-to-moderate active ulcerative colitis (UC). Neither GB004 treatment arm met the primary or secondary endpoints at week 12. Based on the totality of the available data, Gossamer will terminate the ongoing treat-through and open-label extension portions of the Phase 2 SHIFT-UC Study for lack of treatment benefit.

The Phase 2 SHIFT-UC Study (NCT04556383) enrolled 236 patients with mild-to-moderate active UC who were treatment naïve to approved biologic therapies. The clinical trial assessed the effects of GB004 added to background therapy of 5-aminosalicylate (5-ASA) with or without systemic steroids during a 36-week placebo-controlled period and a 24-week open-label extension period. In the placebo-controlled period, two active dose regimens of GB004 were compared to placebo (GB004 480mg once-daily [QD], n = 78; GB004 480mg twice-daily [BID], n = 80; placebo, n = 78). The primary endpoint was the proportion of participants with clinical remission, as defined by the modified Mayo Score, at week 12.

Neither statistically significant nor clinically meaningful differences were observed for the primary endpoint at week 12 (GB004 480mg QD: 15.4%; GB004 480mg BID: 22.5%; placebo: 17.9%). There were also no meaningful differences in secondary endpoints, including histologic and mucosal healing endpoints, for either GB004 treatment group relative to placebo at week 12. An assessment of available 36-week data showed no meaningful improvement on efficacy endpoints.

The safety and tolerability profile of GB004 observed in the trial was generally consistent with prior clinical trials. Dizziness, nausea, and somnolence were the most commonly reported adverse events among GB004-treated patients, with incidences higher than placebo. Adverse events were generally mild in severity.

Additionally, Gossamer reached its target enrollment by enrolling its 80th patient in its Phase 2 TORREY clinical trial of seralutinib in pulmonary arterial hypertension (PAH) patients in April 2022, and the Company anticipates topline results from such study in the fourth quarter of 2022.

Gossamer also anticipates the initiation of its Phase 1b/2 STAR CNS clinical trial of GB5121 in patients with primary CNS lymphoma later in the second quarter of 2022.

Forward-Looking Statements

Gossamer cautions you that statements contained in this current 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: the termination of the Phase 2 SHIFT-UC trial; the anticipated timing of initiation and enrollment of clinical trials for the Company's product candidates, including the expected initiation of the Phase 1b/2 STAR CNS trial of GB5121 in patients with primary CNS lymphoma; plans to advance the Company's product candidates; expectations on the timing of data readouts from the Company's clinical studies, including the timing of topline results for the Phase 2 TORREY trial for seralutinib; and the Company's estimated cash and cash equivalents as of March 31, 2022. 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 current report 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 the Company's operations from the ongoing COVID-19 pandemic, including clinical trial delays and clinical site staff shortages; 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 its product candidates; interim results do not necessarily predict final results and one or more of the outcomes may materially change as the trial continues and more patient data become available and following more comprehensive audit and verification procedures; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of our product candidates that may limit their development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; Gossamer's ability to obtain and maintain intellectual property protection for its product candidates; 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; Gossamer may use its capital resources sooner than it expects; potential changes in estimated cash and cash equivalents based on the completion of financial closing procedures and release of complete first quarter 2022 results; and other risks described under the heading "Risk Factors" in documents the Company files from time to time with the Securities and Exchange Commission. 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 thereunto duly authorized.

GOSSAMER BIO, INC.

Date: April 25, 2022

By: /s/ Christian Waage
Christian Waage
Executive Vice President