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 12, 2020

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.

On May 12, 2020, Gossamer Bio, Inc. (the "Company") issued a press release reporting its financial results for the quarter ended March 31, 2020. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information contained or incorporated herein, including the press release attached as Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated May 12, 2020

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 12, 2020

By: /s/ Bryan Giraudo
Bryan Giraudo
Chief Financial Officer

Gossamer Bio Announces First Quarter 2020 Financial Results and Provides Corporate Update

- GB001 interim analysis of LEDA trial in moderate-to-severe eosinophilic asthma completed -

- GB001 intellectual property estate strengthened with issuance of new patent by USPTO covering lysine salt drug substance forms -

- GB004 completed successful Phase 1b in ulcerative colitis; Phase 2 trial planned to commence in 2020 -

- GB004 license agreement with Aerpio amended to provide financial, milestone and royalty benefit to Gossamer -

- Chief Medical Officer Jakob Dupont, M.D. to depart Gossamer; will continue to provide medical support to Gossamer's GB1275 oncology program as a consultant -

- Cash, cash equivalents and marketable securities totaled $346 million as of March 31, 2020 -

SAN DIEGO—(BUSINESS WIRE)—May 12, 2020—Gossamer Bio, Inc. (Nasdaq: GOSS), a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutics in the disease areas of immunology, inflammation and oncology, today announced its financial results for the first quarter 2020 and provided a corporate update.

"We are very pleased today to share initial results of the Gossamer team's great execution and hard work, including that we have successfully completed the interim analysis of the LEDA study of GB001," said Sheila Gujrathi, M.D., Co-Founder and Chief Executive Officer of Gossamer. "We have begun initial Phase 3 planning and supportive activities, while awaiting final data from the study which will inform our decision to proceed to Phase 3."

"We are also excited to share topline results from our four-week Phase 1b study of GB004 in patients with active mild-to-moderate ulcerative colitis," said Dr. Gujrathi. "The safety and tolerability data, in addition to the promising efficacy data observed in the study, give us confidence as we move into Phase 2."

"The trends observed in the clinical endpoints from a 28-day study with a limited number of patients, especially those endpoints that reflect GB004's novel mechanism of action, such as histologic remission and mucosal healing, are very exciting," said William Sandborn, M.D., Chief of the Division of Gastroenterology of University of California San Diego. "An oral, gut-targeted therapy with a non-immunosuppressive mechanism of action and a robust effect on mucosal healing would be a very meaningful addition to the treatment options for patients with ulcerative colitis. These early signals of activity, combined with the tolerability data generated to date, position GB004 as a promising and differentiated potential treatment for IBD."

Clinical-Stage Product Candidate Updates

GB001: Oral DP2 Antagonist for Eosinophilic Asthma and Chronic Rhinosinusitis (CRS)

- Gossamer recently completed a pre-specified interim analysis of LEDA, its Phase 2b clinical study of GB001 in moderate-to-severe eosinophilic asthma. The interim analysis was based on approximately the first two thirds (~320) of patients who either completed or withdrew from the study. The Independent Data Monitoring Committee (IDMC) reviewed results from the interim analysis and recommended continuation of the study to its completion without modification. Based on the results of the interim analysis and the IDMC recommendation, Gossamer has commenced initial Phase 3 planning and supportive activities in anticipation of the completion of the study and final analysis of the study data. The final decision to proceed to Phase 3 will be made based on the totality of the final data from the LEDA study, as well as discussions with global regulatory authorities. Topline results from LEDA continue to be expected in the second half of 2020.

- On April 21, 2020, the United States Patent and Trademark Office issued patent US 10,626,089. This key patent protects the lysine salt that is being studied in the clinical development of GB001. These compound claims further enhance the intellectual property protection around GB001. This patent is not due to expire before 2037.

- The TITAN Phase 2 clinical study of GB001 in CRS, both with and without nasal polyps, is on track to report topline data in the second half of 2020.

GB004: Oral HIF-1α Stabilizer for Inflammatory Bowel Disease

- Gossamer today announced promising topline results from its Phase 1b study of GB004 in patients with active mild-to-moderate ulcerative colitis (UC). GB004 is designed to restore intestinal epithelial barrier integrity and function in patients with inflammatory bowel disease.

- The Phase 1b study was designed to evaluate the safety, tolerability, and pharmacokinetics of a 120mg once-daily dose of GB004 in a solution formulation over a 28-day treatment period in UC patients with active disease despite treatment with 5-ASA therapy. In addition, pharmacodynamics and certain outcomes related to clinical activity were studied as exploratory measures. Thirty-four patients were randomized 2:1 to receive either GB004 (n=23) or placebo (n=11).

    - **Safety and Tolerability:** GB004 was well tolerated during the study with no effects on systemic erythropoietin or vascular endothelial growth factor observed. The most frequent adverse events experienced by patients on the GB004 arm were nausea and dysgeusia, all of which were mild in severity aside from one case of moderate nausea. All patients completed the study, except for a single patient on the GB004 arm who experienced a serious adverse event of worsening UC, which was deemed by the investigator to be unrelated to study drug.

    - **PK / PD and Target Engagement:** The gut-targeted pharmacokinetic (PK) profile of GB004 was shown with rapid clearance from systemic circulation and multi-fold higher concentrations of drug in the gut as compared to the plasma after eight hours of dosing. Preliminary data from gut biopsies showed increased expression of genes

associated with HIF-1α stabilization and enhanced epithelial barrier function, such as TJP1 and CLDN1, and evidence of reduced gut epithelial neutrophil activity in the GB004 arm compared to the placebo arm.

- **Clinical Activity:** While this four-week study was not powered to show differences in clinical outcomes, several encouraging trends related to treatment with GB004 were observed at Day 28. Mucosal healing, defined as the achievement of both histologic remission and endoscopic improvement in the sigmoid or rectum, was observed in 4 of 23 patients (17%) in the GB004 arm compared to 0 of 11 patients in the placebo arm. Ten of 23 patients (43%) in the GB004 arm achieved histologic remission in either the sigmoid or rectum compared to 2 of 11 patients (18%) in the placebo arm. Favorable trends were also observed in clinical response (6/20 [30%] vs. 2/11 [18%]) and improvement in the rectal bleeding sub-score (13/21 [62%] vs. 5/11 [45%]). One patient in the GB004 arm achieved clinical remission; no patients in the placebo arm achieved clinical remission.

- Further data from the Phase 1b study will be presented at future medical conferences.

- Gossamer also recently completed a successful Phase 1 clinical study in healthy volunteers to support the selection of a tablet formulation to be used in future clinical studies of GB004. In the study, the tablet formulation showed improved tolerability compared to solution at higher doses.

- Subject to the developments in the ongoing COVID-19 viral pandemic, Gossamer plans to initiate a Phase 2 study of GB004 in UC with an oral tablet formulation of the product candidate in a 12-week induction setting in the second half of 2020.

- Gossamer gives its thanks to the patients and physicians that participated in its Phase 1b study of GB004. We are grateful for the opportunity to take this novel mechanism to patients in need.

GB002: Inhaled PDGFR Inhibitor for Pulmonary Arterial Hypertension (PAH)

- GB002 is currently being evaluated in an ongoing Phase 1b study in PAH. Given COVID-19 related delays in study enrollment, Gossamer now anticipates reporting initial results from this study in the second half of this year.

- Subject to the developments in the ongoing COVID-19 viral pandemic, Gossamer plans to commence a Phase 2 study in functional class II and III PAH patients in the second half of 2020. The primary endpoint for this 24-week study will be change in pulmonary vascular resistance (PVR) from baseline. A key secondary endpoint will be change from baseline in 6-minute walk distance at week 24.

GB1275: Oral CD11b Modulator for Oncology Indications

- Enrollment continues in the KEYNOTE-A36 Phase 1/2 study to evaluate GB1275 as a monotherapy and in combination with either KEYTRUDA® (pembrolizumab) or chemotherapy in patients with selected solid tumors.

- The American Society for Clinical Oncology (ASCO) accepted an abstract for poster presentation (abstract 3085; poster 149) containing initial dose-escalation data from the KEYNOTE-A36 study, which will be presented in the Developmental Therapeutics—Immunotherapy Poster Session at the ASCO20 Virtual Scientific Program. Gossamer also expects to present further data from the study in the second half of the year.

- During the first quarter 2020, the European Medicines Agency granted orphan designation to GB1275 for the treatment of pancreatic cancer. GB1275 had previously received orphan drug designation from the U.S. Food and Drug Administration for the treatment of pancreatic cancer.

Corporate Updates

- On May 11, 2020, Gossamer paid Aerpio Pharmaceuticals, Inc. $15 million as part of an amendment to the GB004 license agreement. Under the amended terms, all development milestones have been obviated, total remaining milestones were reduced from $400 million to $90 million, and royalties on worldwide net sales now range from a low- to mid-single digit percentage. Gossamer continues to be responsible for the remaining development, regulatory, and commercialization expenses for GB004. Aerpio's participation right on a disposition of GB004 remains.

- Chief Medical Officer Jakob Dupont, M.D. will depart Gossamer to pursue oncology opportunities closer to his family in the San Francisco Bay Area. He will serve as a consultant to Gossamer to support the development of GB1275 through a transitional period. Chief Executive Officer Sheila Gujrathi, M.D., together with Richard Aranda, M.D., Senior Vice President for Clinical Development, Caryn Peterson, Senior Vice President for Regulatory and Quality, Heather Smith, Senior Vice President for Clinical Operations, and Matt Cravets, Vice President for Biometrics will assume Dr. Dupont's responsibilities.

  "I would like to thank our Chief Medical Officer, Jakob Dupont, for his contributions to Gossamer, especially with respect to our GB1275 program, which Jakob will continue to support as a consultant," said Dr. Gujrathi. "I respect and support his personal decision to be closer to his family in the Bay Area in this unprecedented time," she added.

- Gossamer will participate in the upcoming Bank of America Securities Virtual Healthcare Conference. Chief Executive Officer Dr. Sheila Gujrathi will present at the conference on Thursday, May 14, 2020, at 6:40 p.m. ET. A live webcast will be available on the "Events & Presentations" page within the Investors section of the Gossamer website and a replay will be available for 30 days following the event.

Financial Results for the Quarter Ended March 31, 2020

- **Cash, Cash Equivalents and Marketable Securities**: Cash, cash equivalents and marketable securities as of March 31, 2020, were $346.2 million. The Company expects the combination of current cash, cash equivalents and marketable securities, and access to our debt facility will be sufficient to fund its operating and capital expenditures to mid-2022.

- **Research and Development (R&D) Expenses**: For the quarter ended March 31, 2020, R&D expenses were $41.4 million, compared to R&D expenses of $25.0 million for the same period in 2019. This increase reflects a continued ramp-up of clinical expenses in connection with

the further advancement of the GB001, GB002, GB004 and GB1275 programs and increased expenses related to the development of proprietary pre-clinical programs.

- **In-Process Research and Development (IPR&D) Expenses**: For the quarter ended March 31, 2020, IPR&D expenses were $2.8 million, compared to $1.0 million for the same period in 2019.

- **General and Administrative (G&A) Expenses**: For the quarter ended March 31, 2020, G&A expenses were $10.7 million, compared to $8.0 million for the same period in 2019.

- **Net Loss**: Net loss for the quarter ended March 31, 2020, was $54.1 million, or $0.87 per share, compared to a net loss of $32.6 million, or $0.90 per share, for the same period in 2019.

Conference Call and Webcast

Gossamer's management team will host a conference call and live audio webcast at 4:30 p.m. ET today, Tuesday, May 12, to discuss its first quarter 2020 financial results and provide a corporate update.

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:

Conference ID: 8593375
Domestic Dial-in Number: (833) 646-0603
International Dial-in Number: (929) 517-9782
Live Webcast: https://edge.media-server.com/mmc/p/wf9kdou9

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 the GB004 Phase 1b Study

The Phase 1b study of GB004 was a multi-center, randomized, double-blind, placebo-controlled study which enrolled 34 patients with active mild-to-moderate ulcerative colitis. Patients were randomized 2:1 to receive either a 120mg once-daily dose of a solution formulation of GB004 (n=23) or placebo (n=11). The primary objective of the study was to evaluate the safety and tolerability of GB004 administered over 28 days. Pharmacokinetics were evaluated as a secondary objective, while exploratory objectives included measurements of pharmacodynamics and clinical outcomes. Histology, endoscopic improvement, and mucosal healing were evaluated individually in two segments of the large intestine: the sigmoid colon and rectum.

Exploratory clinical outcomes in the study were defined as follows:

- Histology: evaluated using the Robarts Histopathology Index, or RHI.
- Histologic remission: RHI ≤ 3 with lamina propria neutrophils sub-score = 0 and neutrophils in epithelium sub-score = 0, among patients with baseline RHI > 3 and baseline lamina propria neutrophils and neutrophils in epithelium sub-scores > 0.
- Endoscopic improvement: endoscopic sub-score of 0 or 1 if baseline endoscopic sub-score > 1, or 0 if baseline endoscopic sub-score = 1.
- Mucosal healing: achievement of both histologic remission and endoscopic improvement in the same segment.
- Clinical response: reduction in Mayo score of ≥ 3 points and ≥ 30% from baseline with an accompanying decrease in rectal bleeding sub-score of ≥ 1 point or absolute rectal bleeding sub-score of ≤ 1 point, among patients with baseline rectal bleeding sub-score ≥ 1 and baseline sigmoid endoscopy sub-score ≥ 1.
- Clinical remission: Mayo score ≤ 2, with no individual sub-score > 1, among patients with baseline sigmoid endoscopy sub-score ≥ 1.
- Improvement in rectal bleeding: reduction from baseline in rectal bleeding sub-score of ≥ 1, among patients with a baseline rectal bleeding sub-score ≥ 1.

About Gossamer Bio

Gossamer Bio is a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutics in the disease areas of immunology, inflammation and oncology. Its goal is to be an industry leader in each of these therapeutic areas and to enhance and extend the lives of patients suffering from such diseases.

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: our plans to begin Phase 3 planning and supportive activities for GB001; the anticipated timing of initiation and enrollment of clinical trials for our product candidates; plans to advance our product candidates; expectations on the timing of data readouts from our clinical studies; the potential clinical benefits of our product candidates; the expected impact of COVID-19; the length of our intellectual property protection; 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 the recent global outbreak of the COVID-19 pandemic, 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 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; Gossamer may not proceed into Phase 3 clinical trials for GB001 whether based on final data or otherwise; 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; 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 Statement of Operations
Condensed Consolidated Statement of Operations
(in thousands, except share and per share amounts)
(unaudited)

STATEMENTS OF OPERATIONS DATA:	Three months ended March 31, 2020	2019
Operating expenses:		
Research and development	$ 41,414	$ 24,983
In process research and development	2,805	1,000
General and administrative	10,748	8,034
Total operating expenses	54,967	34,017
Loss from operations	**(54,967)**	**(34,017)**
Other income, net	893	1,406
Net loss	**$ (54,074)**	**$ (32,611)**
Net loss per share, basic and diluted	$ (0.87)	$ (0.90)
Weighted average common shares outstanding, basic and diluted	61,890,323	36,317,230

Condensed Consolidated Balance Sheet
(in thousands)
(unaudited)

BALANCE SHEET DATA:	March 31, 2020	December 31, 2019
Cash, cash equivalents, and marketable securities	$ 346,165	$ 401,829
Working capital	327,076	372,394
Total assets	371,478	426,604
Total liabilities	65,015	74,119
Accumulated deficit	(388,244)	(334,170)
Total stockholders' equity (deficit)	306,463	352,485

For Investors and Media:
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