#### **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): July 20, 2023

### **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)

П Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

П 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  $\square$ 

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 July 20, 2023, Gossamer Bio, Inc. provided an interim data update for its TORREY open-label extension (OLE) study of seralutinib in pulmonary arterial hypertension patients and details of the design of the planned PROSERA Phase 3 clinical trial, each contained in the corporate presentation attached hereto as Exhibit 99.1, which is incorporated by reference herein.

#### Item 9.01 Financial Statements and Exhibits.

Slide Presentation

(d) Exhibits

Exhibit Number 99.1

Description

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#### 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.

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

Date: July 20, 2023

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### **Forward Looking Statements**

This presentation contains forward-looking statements. All statements other than statements of historical facts contained in this presentation, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products, are forward-looking statements by terms such as "may," "will," "should," "intend," "anticipate," "could, " "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions.

These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements expressed or implied by the forward-looking statements. These risks, uncertainties and other factors include, without limitation: interim results of a clinical trial are not necessarily indicative of final results and one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data and as more patient data becomes available; potential delays in the commencement, enrollment, data readouts and completion of clinical trial segint and timing of initiation thereor) cour planned PROSERA Phase 3 trial may not support the registration of seralutini); our dependence on third parties in connection with product manufacturing, research and preclinical and clinical trials and preclinical studies are not necessarily predictive of future results; the success of our clinical trials for seralutinin by uncertain, regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of seralutinin bit anny limit its development, regulatory aproval and/or commercialization, or may result in clinical holds, recalls or product liability claims; our ability to obtain and maintain intellectual property rights from third parties; we may use our capital resources somer than we expect; and other risks described in our prior press releases and our filings with the Securities and Exchange Commission (SEC), including under the heading "*Risk Factors" in our annual report on Form* 10-K and any subsequent filings with the Securities and Exchange Commission (SEC), including under the heading "*Risk Factors" in our annual report on Form* 10-K and asyne developing statements could differ materially from those projected in our forward-looking statements may not be achieveed or occur and actual results actual results as a result of any new information, future events, w

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.



## Selected Baseline Disease Characteristics

(ITT Population)

Characteristic	Placebo (N=42)	Seralutinib	Total (N=86)	
Number of PAH background therapies – n (%)				
1	2 (4.8)	1 (2.3)	3 (3.5)	
2	16 (38.1)	18 (40.9)	34 (39.5)	Heavily pre-treated
3	24 (57.1)	25 (56.8)	49 (57.0)	patient population
WHO FC – n (%)	Hit Primary Endpoint			
Class II	20 (47.6)	30 (68.2)	50 (58.1)	Despite FC Imbalance in
Class III	22 (52.4)	14 (31.8)	36 (41.9)	Drug & Pbo Arms
PVR (dyne*s/cm <sup>5</sup> ) – mean (SD)	661.3 (164.91)	675.8 (240.35)	668.7 (205.90)	Mildest baseline
6MWD (m) – mean (SD)	407.1 (107.02)	408.6 (75.11)	407.9 (91.54)	PAH disease to see
T-proBNP (ng/L) – mean (SD)	645.6 (1158.75)	611.0 (714.58)	628.3 (956.83)	treatment effect*
		STELL/ mean PVR	AR Trial Phase 3 NT- baseline was 1,121. was 763.7 dyne*s/c	-proBNP .1ng/L; m <sup>5 (1)</sup>

1) Source: <a href="https://doi.org/10.1056/NEJMoa2213559">https://doi.org/10.1056/NEJMoa2213559</a> \*As determined by baseline PVR & 6MWD, we believe that TORREY enrolled the most well-controlled PAH patient trial population to meet its primary efficacy endpoint. 6MWD = six-minute walk distance; PC = Functional Class; NT-proBNP = N-terminal pro B-type natriuretic peptide; PVR = pulmonary vascular resistance; WHO = World Health Organization; ITT = intention-to-treat; SD = standard deviation; Pbo = placebo.

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## **TORREY Study Phase 2 Topline Results**

- Met Primary Endpoint: Statistically significant reduction in PVR in heavily-treated study population
- Consistent, favorable PVR benefit seen in all pre-specified sub-groups in favor of seralutinib with enhanced effects in patients with more severe disease at baseline<sup>§</sup>





## New Developments in the Seralutinib Program

- · Summary of OLE findings to date: Differentiated efficacy and safety profile emerging
  - · Continued improvement in reduction of PVR
    - · 30 patients with Week 72 PVR data
    - · Early enrollers; milder disease baseline than overall population
  - Continual improvement seen in ∆6MWD & ∆NT-proBNP
    - Increased magnitude of effect in Phase 3 target population
  - Attractive safety profile for chronic treatment
- · Regulatory feedback supportive of single registrational study evaluating 90mg BID dose
  - FDA and EMA aligned on all key components of study; protocol finalized
- · Phase 3 trial incorporating learnings from TORREY targeted to initiate in August
  - Use of REVEAL Lite and NT-proBNP as enrichment factors for 6MWD success
  - Use of PPD as CRO helps to de-risk execution of enrollment and 6MWT conduct
  - Anticoagulants allowed with important patient safety guardrails

OLE = open-label extension; PVR = pulmonary vascular resistance; 6MWD = six-minute walk distance; NT-proBNP = N-terminal pro B-type natriuretic peptide; BID = twice daily dosing; CRO = contract r 6MWT = six-minute walk test.

## III. Interim TORREY OLE Extension Results

Data available to date – Subject to change – Study is ongoing

Data as of June 23, 2023.

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## **TORREY Open-Label Extension Interim Update**

Randomization		)RREY FUDY	
Screening	Blinded Evaluation	Open-Label Extension	<b>&gt;</b>
	Seralutinib, n = 44	Continued-Seralutinib, n = 33	Patients Continue on OLE
	Placebo, n = 42	Placebo-Crossover to Seralutinib, n = 40	Patients Continue on OLE
Baseline	Week 2	4	Week 72

- Of 80 TORREY completers (38 seralutinib arm, 42 placebo arm), 73 (91.3%) elected to rollover into the open-label extension
- PVR measured via right heart catheterization at Baseline, Week 24, and Week 72 (approximately 1 year into OLE)
- As of interim data cutoff date, Week 72 PVR data available for 30 patients
  - 16 continued-seralutinib, 14 placebo-crossover

9 OLE = open-label extension; PVR = pulmonary vascular resistance

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## Seralutinib Profile Emerging From OLE

- ✓ Seralutinib treatment leads to hemodynamic improvement in ~60-70% of patients
  - ✓ Almost all patients who have short-term benefit (at 6 months) continue to improve with long-term treatment
- The continued improvement in PVR, along with the ECHO and FRI data gathered in TORREY, is supportive of a reverse remodeling mechanism of action
- Safety and tolerability remain relatively benign, with no safety signals emerging or worsening with long-term use
- Drug delivery via DPI twice daily well-accepted and easy to incorporate into a patient's daily routine
- Seralutinib has the potential to be used prior to more invasive / inconveniently delivered therapies and / or those with challenging safety / tolerability profiles (e.g., prostacyclins)

10 OLE = open-label extension; PVR = pulmonary vascular resistance; ECHO = echocardiogram; FRI = functional resonance imaging; DPI = dry powder inhaler

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# Interim Analysis Shows Deepening PVR Improvement in Continued-Seralutinib Group



### Further Improvements Seen in 6MWD and NT-proBNP for Phase 3 Target Population in Continued-Seralutinib Group





# **TORREY OLE Safety To Date**

- Safety results consistent with controlled period seralutinib generally well tolerated with no new safety concerns
  - Results support chronic treatment in PAH patients
- · Reports of cough diminish as patients get used to DPI
- Vast majority of patients have reached and maintained 90mg BID dose
  - · Limited dose reductions to date
- Limited liver enzyme elevations observed in OLE in similar pattern as TORREY (~5-10% ≥ 3x ULN, similar to placebo rate in TORREY), suggesting potential signal arises early in treatment course and easily monitorable
- Safety tables available in appendix

14 OLE = open-label extension; DPI = dry powder inhaler; BID = twice-daily dosing; ULN = upper limit of normal

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# **Regulatory Feedback**

- FDA & EMA Alignment on the following key design elements of Phase 3 protocol:
  - One Dose: Single dose of seralutinib (90 mg BID); 2-arm study, with ~175 patients per arm
  - Enriched Population: Eligibility criteria for a target PAH population based on prespecified subgroup in TORREY with more severe disease and/or who are at higher risk of disease progression, defined by risk score assessment, functional class, PVR and exercise capacity at baseline
  - Primary Endpoint: 6MWD at Week 24
- · Additional Comments:
  - FDA recommended consideration of a Phase 2 study to evaluate disease remodeling (withdrawal)
  - EMA recommended TTCW as key secondary
  - No safety concerns raised

BID = twice-daily dosing; PVR = pulmonary vascular resistance; 6MWD = six-minute walk distance; TTCW = time to clinical worsening.

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# PROSERA Phase 3 Study Design Schema



# PROSERA Study Overview

Design	<ul> <li>Randomized, double-blind, placebo-controlled, parallel group</li> <li>Up to 48-week double-blinded treatment period; primary endpoint assessed at Week 24</li> <li>Open-label extension option under separate protocol</li> </ul>
Primary Endpoint	Change in 6MWD at Week 24 from Baseline
Key Secondary Endpoints	<ul> <li>Time from 1<sup>st</sup> dose to 1<sup>st</sup> event of clinical worsening (TTCW)</li> <li>Proportion of subjects who achieve all components of a composite endpoint of clinical improvement at Week 24 in the absence of clinical worsening: <ul> <li>Decrease in WHO FC or maintenance of WHO FC II</li> <li>Decrease in NT-proBNP ≥ 30% or maintenance at &lt;300 ng/L</li> <li>Increase in 6MWD ≥ 10% or ≥ 30 m</li> </ul> </li> <li>Change vs. Baseline in NT-proBNP at Week 24</li> <li>Proportion of subjects with ≥ 1 point decrease in REVEAL Lite 2 Risk Score vs. Baseline at Week 24</li> </ul>
Stratification at Randomization	<ul> <li>WHO FC at screening: II vs III</li> <li>Receiving parenteral prostacyclin therapy at Screening (yes vs. no)</li> <li>CTD-APAH (yes vs. no)</li> <li>Participation in CT sub-study (yes vs. no)</li> </ul>

6MWD = six-minute walk distance; FC = functional class; NT-proBNP = N-terminal pro B-type CTD-APAH = connective tissue disease-associated PAH; CT = computerized tomography. gossamerbio\*

## **PROSERA Phase 3 Study Population**



#### Key Inclusion Criteria

- Adults ≥ 18 and ≤ 75 years old
- WHO Group 1 PAH
- WHO Functional Class II or III
- PVR ≥ 400 dyne•s/cm<sup>5</sup>
- Baseline 6MWD 150 450m\*
- Either REVEAL Lite 2 Risk Score ≥ 5 or NT-proBNP ≥ 300 ng/L\*
- Stable treatment with at least one SOC background therapy

19 \* Key enrichment citeria. WHO = World Health Organization; PVR = pulmonary vascular resistance; 6MWD = six-minute walk distance; NT-proBNP = N-terminal pro B-type natriuretic peptide; SOC = standard of care

### Broad Global Footprint with Trusted Sites and Clinical Partners



Latin America: ~25 Sites Europe: 75+ Sites Asia Pacific: 10+ Sites

- Broad global footprint planned:
   > 160 sites across ~30 countries
- Experienced global Gossamer team to support sites, educate, and drive enrollment
- Strong CRO partner (PPD) with deep experience in PAH
- Enrollment target: 18 months

20 CRO = contract research organization.

### Further Validation of REVEAL Lite 2 Enrichment for Phase 3 TORREY Week 24 Δ6MWD with REVEAL Lite 2 Score Incorporated





# Incidence of TEAEs by preferred term: $\geq$ 5% in total column (Safety Population)

Preferred term <sup>a</sup>	Placebo Switch (N=40)	Seralutinib Cont. (N=34*)	
Number of subjects with a TEAE	38 ( 95.0)	32 ( 94.1)	70 ( 94.6)
Headache	9 ( 22.5)	8 ( 23.5)	17 ( 23.0)
Cough	9 ( 22.5)	7 ( 20.6)	16 ( 21.6)
COVID-19	6 ( 15.0)	7 ( 20.6)	13 ( 17.6)
Diarrhoea	8 ( 20.0)	3 ( 8.8)	11 ( 14.9)
Nausea	6 ( 15.0)	5 ( 14.7)	11 ( 14.9)
Dyspnoea	7 ( 17.5)	2 ( 5.9)	9 ( 12.2)
Pyrexia	3 ( 7.5)	4 ( 11.8)	7 ( 9.5)
Rash	3 ( 7.5)	4 ( 11.8)	7 ( 9.5)
Dizziness	2 ( 5.0)	4 ( 11.8)	6 ( 8.1)
Influenza	2 ( 5.0)	4 ( 11.8)	6 ( 8.1)
Nasopharyngitis	4 ( 10.0)	2 ( 5.9)	6 ( 8.1)
Vomiting	4 ( 10.0)	2 ( 5.9)	6 ( 8.1)
Abdominal pain	4 ( 10.0)	1 ( 2.9)	5 ( 6.8)
Epistaxis	1 ( 2.5)	4 ( 11.8)	5 ( 6.8)
Fatigue	4 ( 10.0)	1 ( 2.9)	5 ( 6.8)
Hypokalaemia	3 (7.5)	2 ( 5.9)	5 ( 6.8)

\*One patient from the Ph Abbreviations: MedDRA, <sup>a</sup> Coded using MedDRA 23

# Incidence of TEAEs by preferred term: $\geq$ 5% in total column (Safety Population) - Continued

Droforrod torma	Placebo Switch	Seralutinib Cont.	
	(N=40)	(10-34)	(N=74)
Number of subjects with a TEAE	38 ( 95.0)	32 ( 94.1)	70 ( 94.6)
Pneumonia	3 ( 7.5)	2 ( 5.9)	5 ( 6.8)
Pulmonary arterial hypertension	3 ( 7.5)	2 ( 5.9)	5 ( 6.8)
Alanine aminotransferase increased	4 ( 10.0)	0	4 ( 5.4)
Arthralgia	3 (7.5)	1 ( 2.9)	4 ( 5.4)
Aspartate aminotransferase increased	4 ( 10.0)	0	4 ( 5.4)
Back pain	3 (7.5)	1 ( 2.9)	4 ( 5.4)
Complication associated with device	2 ( 5.0)	2 ( 5.9)	4 ( 5.4)
Flushing	3 ( 7.5)	1(2.9)	4 ( 5.4)
Iron deficiency	2 ( 5.0)	2 ( 5.9)	4 ( 5.4)
Nasal congestion	2 ( 5.0)	2 ( 5.9)	4 ( 5.4)
Pain	1 ( 2.5)	3 ( 8.8)	4 ( 5.4)
Pain in extremity	2 ( 5.0)	2 ( 5.9)	4 ( 5.4)
Palpitations	3 ( 7.5)	1 ( 2.9)	4 ( 5.4)
Throat irritation	3 ( 7.5)	1(2.9)	4 ( 5.4)
Upper respiratory tract infection	2 ( 5.0)	2 ( 5.9)	4 ( 5.4)
Vascular device infection	0	4 ( 11.8)	4 ( 5.4)
ase 1b clinical trial, who remains on drug, is included in this Medical Dictionary for Regulatory Activities: TEAE, treatme	group. ent-emergent adverse event.		

\*One patient from the Phase 1b Abbreviations: MedDRA, Medica <sup>a</sup> Coded using MedDRA v 24.0 24

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### Incidence of Related TEAEs in 2 or More Patients (Safety Population)

Preferred term <sup>a</sup>	Placebo Switch (N=40)	Seralutinib Cont. (N=34*)	Total (N=74)
Number of subjects with a related adverse event	16 ( 40.0)	11 ( 32.4)	27 ( 36.5)
Cough	7 ( 17.5)	3 ( 8.8)	10 ( 13.5)
Headache	2 ( 5.0)	3 ( 8.8)	5 ( 6.8)
Throat irritation	3 (7.5)	1 ( 2.9)	4 ( 5.4)
Alanine aminotransferase increased	2 ( 5.0)	0	2 ( 2.7)
Aspartate aminotransferase increased	2 ( 5.0)	0	2 ( 2.7)
Fatigue	1 ( 2.5)	1(2.9)	2 ( 2.7)
Thrombocytopenia	0	2 ( 5.9)	2 ( 2.7)

\*One patient from the Phase 1b clinical trial, who remains on drug, is included in this group. Abbreviations: MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event. <sup>a</sup> Coded using MedDRA v 24.0

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# Incidence of TEAEs Leading to Study Drug Discontinuation (Safety Population)

Preferred term <sup>a</sup>	Placebo Switch (N=40)	Seralutinib Cont. (N=34*)	Total (N=74)
No. with a TEAE leading to d/c of study drug	9 ( 22.5)	3 ( 8.8)	12 ( 16.2)
Cough	4 ( 10.0)	1 ( 2.9)	5 ( 6.8)
Alanine aminotransferase increased	2 ( 5.0)	0	2 ( 2.7)
Throat irritation	1 ( 2.5)	1 ( 2.9)	2 ( 2.7)
Abdominal pain	1 ( 2.5)	0	1(1.4)
Acute respiratory failure	1 ( 2.5)	0	1(1.4)
Aspartate aminotransferase increased	1 ( 2.5)	0	1(1.4)
Blood bilirubin increased	1 ( 2.5)	0	1(1.4)
Confusional state	1 ( 2.5)	0	1(1.4)
Liver function test abnormal	0	1 ( 2.9)	1(1.4)
Nausea	0	1 ( 2.9)	1(1.4)
Vomiting	0	1 ( 2.9)	1(1.4)

\*One patient from the Phase 1b clinical trial, who remains on drug, is included in this group. Abbreviations: :dc, discontinuation; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event. \* Coded using MedDRA v 24.0

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# Appendix II – FLUIDDA CT Sub-Study

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#### FLUIDDA CT Sub-Study: Assessing Pulmonary Vascular Remodeling in Patients Treated on Seralutinib

- Purpose: Provide evidence consistent with a reverse remodeling effect of seralutinib
- Hypothesis: volume of distal pulmonary arteries relative to volume of proximal pulmonary arteries will be increased by seralutinib as expressed by the ratio of BV5A to BV10A (BV510ARatio)
- Available data: Baseline and Week 24 HRCTs with pulmonary vascular reconstruction in 7 seralutinibtreated subjects and 12 placebo subjects

Thin Slice CTs with Pulmonary Vascular Segmentation at Baseline and Week 24



28 CT = computerized tomography; HRCT = high resolution computerized tomography

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Pulmonary Vascular Volume of Small Distal Arterial Vessels is Decreased in PAH, Leading to Dilation of Larger Proximal Vessels



### Seralutinib Treatment Increases BV510ARatio, Supporting Reverse Remodeling Hypothesis



# FRI Imaging Case Study (Placebo Patient) WHO FC2 IPAH Patient on PDE/PRA, treated with Placebo



 BVA5PRA = Proportion of pulmonary arteries smaller than 5 mm² in cross sectional area compared to all arteries

 BVA10PRA = Proportion of pulmonary arteries larger than 10 mm² in cross sectional area compared to all arteries

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 \* Measurements preliminary; do not include the hiltum

# FRI Imaging Case Study (Seralutinib Patient) WHO FC2 IPAH and Severe RA Patient on Triple Therapy, treated with Seralutinib



### Summary of FRI Sub-study and Plans for Phase 3

- The BV510ARatio correlates with important measures of RV-PA coupling as measured by pulmonary artery compliance and cardiopulmonary hemodynamics (i.e., Stroke Volume)
- There was a significant improvement in the ratio of blood vessel volume in distal vessels relative to larger vessels (BV510ARatio) consistent with a reverse remodeling effect of seralutinib
- To increase our understanding of the effect of seralutinib on pulmonary vascular remodeling, an FRI sub-study is planned for Phase 3