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 4, 2022

GLOBAL BLOOD THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37539**	**27-4825712**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

181 Oyster Point Blvd.
South San Francisco, California 94080
(Address of Principal Executive Offices) (Zip Code)

(650) 741-7700
(Registrant's telephone number, including area code)

Not Applicable
(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, par value $0.001 per share	GBT	The 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. ☐

In this report, "GBT," "Company," "we," "our," and "us" means Global Blood Therapeutics, Inc., and/or one or more of our subsidiaries, unless the context otherwise provides.

Item 2.02. Results of Operations and Financial Condition.

On May 4, 2022, Global Blood Therapeutics, Inc. reported financial results for the first quarter ended March 31, 2022, and recent business progress. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release, dated May 4, 2022, furnished herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

Global Blood Therapeutics, Inc.

Date: May 4, 2022

By: /s/ Jeffrey Farrow
Jeffrey Farrow
Chief Financial Officer

EXHIBIT 99.1

GBT Reports First Quarter 2022 Financial Results

Achieved Oxbryta® (voxelotor) net revenues of $55.2 million in the first quarter 2022, a 41% increase year over year

Strong new prescription growth driven by the recent launch for children ages 4 to less than 12 years and improving trends for patients ages 12 years and over

Reinitiated GBT601 Phase 1 trial in sickle cell disease (SCD) patients to study 150 mg daily dose; on track to initiate Phase 2/3 trial by mid-year

Conference call today at 4:30 p.m. ET

SOUTH SAN FRANCISCO, Calif., May 04, 2022 (GLOBE NEWSWIRE) -- Global Blood Therapeutics, Inc. (GBT) (NASDAQ: GBT) today reported financial results for the first quarter ended March 31, 2022, and recent business progress.

“In the first quarter, we achieved two major milestones in our journey to expand patient access to Oxbryta,” said Ted W. Love, M.D., president and chief executive officer of GBT. “In the U.S., we launched Oxbryta for patients ages 4 to 11, including a new age-appropriate formulation, giving us the potential to expand our reach to more SCD patients. We’ve received positive feedback on the launch, with encouraging trends during the quarter in new prescriptions for this age group as well as some incremental growth for the ages 12 and older population. In addition, we received marketing authorization from the European Commission for Oxbryta, making it the first medicine approved in the EU that directly inhibits the molecular basis of sickling and destruction of red blood cells in SCD. This milestone is a key step on our path to reach patients in Europe, with an initial focus on launching in Germany and establishing reimbursement in key countries.”

“On the clinical front, we are enrolling patients in our two Phase 3 trials evaluating inclacumab for the potential reduction of the frequency of vaso-occlusive crises and related hospital readmissions. In addition, we expect to soon restart our GBT601 Phase 1 trial due to interest from the patients, which will also give us the opportunity to study an increased dose of 150 mg, and we plan to advance GBT601 into a Phase 2/3 trial by mid-year. We continue to be excited about GBT601, which we believe has the potential to improve clinical outcomes for people living with SCD, in a low-dose, once-daily pill,” added Dr. Love.

Recent Business Progress

Commercial

- Recorded Oxbryta® (voxelotor) net sales of $55.2 million in the first quarter, an increase of 41% year over year. On a sequential basis, sales decreased 2%, driven primarily by distributors reducing inventory in the first quarter following purchases at the end of 2021 and a higher gross-to-net adjustment, partially offset by higher patient demand. The net number of patients taking Oxbryta increased compared to the prior quarter and has increased each quarter since launch in 2019.
- Achieved more than 1,200 new prescriptions for Oxbryta in the first quarter, including a strong launch in children ages 4 to less than 12 years, which began in early January 2022. GBT continues to believe that as the COVID-19 pandemic subsides, the number of new Oxbryta prescriptions will improve. GBT anticipates that eventually, in future periods, new prescriptions will surpass pre-COVID-19 levels.
- Oxbryta continues to have broad payer coverage for patients ages 12 years and older, with more than 90% of covered lives having access through their healthcare plans. For patients ages 4 to less than 12 years, GBT continues to work towards securing Oxbryta reimbursement coverage and is on track to achieve its goal of broad payer coverage in this age group by mid-year.
- Launched Oxbryta in the United Arab Emirates (UAE) via GBT's distributor partnership with Biopharma-MEA. This is the first commercial launch of Oxbryta outside of the U.S.
- Following the receipt of European Commission (EC) marketing authorization in February 2022, GBT is actively working to commercially launch Oxbryta in Germany, which is anticipated by mid-May. In addition, GBT initiated reimbursement discussions in Germany, France and England, and is educating healthcare providers across Europe on Oxbryta.

Clinical

- Enrollment is ongoing in two global, randomized, placebo-controlled, pivotal Phase 3 trials, collectively named THRIVE, evaluating the safety and efficacy of inclacumab, GBT’s P-selectin inhibitor, for the potential reduction of vaso-occlusive crisis (VOC) frequency and VOC-related hospital readmissions.
- In April, data from the Phase 2a HOPE-KIDS 1 study was published in *Pediatric Blood & Cancer*, an online peer-reviewed journal.
- GBT anticipates restarting in May the Phase 1 study of GBT021601 (GBT601), the company’s investigational next-generation sickle hemoglobin (HbS) polymerization inhibitor, to study a 150 mg daily dose, which is an increase over the 100 mg daily maintenance dose GBT previously studied. All six SCD patients that participated in the study in 2021 have expressed interest in participating in the restarted study. Upon completion, the company plans to submit this data for presentation at a medical meeting later this year. GBT is also planning to advance GBT601 into a Phase 2/3 trial, and anticipates initiating the Phase 2 portion by mid-2022.

- Results from the Oxbryta expanded access program for children (ages 4 to 11) with SCD will be presented in early May at the American Society of Pediatric Hematology/Oncology Conference, reinforcing the efficacy and safety of treatment with Oxbryta in these patients. In addition, the majority of patients had improved scores as measured by the patient and clinical global impressions of change scale.

Corporate

- Anticipates receiving marketing authorization for Oxbryta in Great Britain by mid-2022. There are approximately 15,000[1] SCD patients in Great Britain.
- Strengthened the company's research and development (R&D) team with the appointment of R. Clark Brown, M.D., Ph.D., a world-renowned pediatric hematologist-oncologist and SCD expert, as vice president of integrated science and clinical site excellence, starting in July 2022. In this new role, Dr. Brown will lead clinical research planning and implementation including initiatives to drive increased engagement at new and existing clinical trial sites. Previously, Dr. Brown served as the director of clinical research at the Aflac Cancer and Blood Disorders Center of Children's Healthcare of Atlanta, the largest comprehensive SCD program in the U.S.
- Published inaugural environmental, social and governance (ESG) report, demonstrating GBT's progress with its ESG priorities, which include improving access to affordable care; investing in GBT employees and communities; increasing environmental sustainability; and upholding GBT's ethics and values.

Financial Results for the First Quarter 2022
Total net product sales for the first quarter of 2022 were $55.2 million, resulting from sales of Oxbryta, compared to $39.0 million for the first quarter of 2021.

Cost of sales for the three months ended March 31, 2022, was $1.1 million, compared with $0.6 million for the same period in 2021. Manufacturing costs incurred prior to FDA approval of Oxbryta in November 2019 were previously recorded as R&D expense in the company's consolidated statement of operations. GBT expects the cost of Oxbryta sales as a percentage of revenue will increase in future periods as product manufactured prior to FDA approval, and therefore previously expensed, is completely utilized.

R&D expenses for the three months ended March 31, 2022, were $52.8 million, compared with $50.9 million for the same period in 2021. The increase in R&D expenses for the period was primarily due to an increase in external costs related to the GBT601 program, partially offset by a decrease in external costs related to Oxbryta. Total R&D non-cash stock compensation expense incurred for the three months ended March 31, 2022, was $5.5 million, compared with $4.9 million for the same period in 2021.

Sales, general, and administrative (SG&A) expenses for the three months ended March 31, 2022, were $74.5 million, compared with $59.0 million for the same period in 2021. The increase in SG&A expenses for the period was primarily attributable to increased professional and consulting services associated with the company's expanded commercial and medical affairs operations for Oxbryta, including supporting the pediatric launch in the U.S. and launch readiness in geographies outside of the U.S.; increased employee-related costs; and operational growth, partially offset by a decrease in non-cash stock compensation expense. Total SG&A non-cash stock compensation expense incurred in the three months ended March 31, 2022, was $13.6 million, compared with $15.1 million for the same period in 2021.

Net loss for the three months ended March 31, 2022, was $81.4 million, compared with $74.9 million for the same period in 2021. Basic and diluted net loss per share for the three months ended March 31, 2022, was $1.26, compared with $1.21 for the same period in 2021.

Cash, cash equivalents, and marketable securities totaled $662.1 million at March 31, 2022, compared with $734.8 million at December 31, 2021.

Conference Call Details
GBT will host a conference call today, Wednesday, May 4, 2022, at 4:30 p.m. ET to discuss the financial results for the first quarter 2022 and provide a business update. To participate in the conference call, please dial 877-407-3982 (domestic) or +1 201-493-6780 (international). A live audio webcast of the conference call can be accessed on GBT's website at www.gbt.com in the Investors section. An archived audio webcast will be available for one month following the event.

About Sickle Cell Disease
Sickle cell disease (SCD) affects more than 100,000 people in the United States,[2] an estimated 52,000 people in Europe,[3] and millions of people throughout the world, particularly among those whose ancestors are from sub-Saharan Africa.[4] It also affects people of Hispanic, South Asian, Southern European and Middle Eastern ancestry.[4] SCD is a lifelong inherited rare blood disorder that impacts hemoglobin, a protein carried by red blood cells that delivers oxygen to tissues and organs throughout the body.[5] Due to a genetic mutation, individuals with SCD form abnormal hemoglobin known as sickle hemoglobin. Through a process called hemoglobin polymerization, red blood cells become sickled – deoxygenated, crescent-shaped and rigid.[5,6,7] The sickling process causes hemolytic anemia (low hemoglobin due to red blood cell destruction) and blockages in capillaries and small blood vessels, which impede the flow of blood and oxygen delivery throughout the body. The diminished oxygen delivery to tissues and organs can lead to life-threatening complications, including stroke and irreversible organ damage.[6,7,8,9] Complications of SCD begin in early childhood and can include neurocognitive impairment, acute chest syndrome, and silent and overt stroke, among other serious issues.[10]

About Oxbryta® (voxelotor) Tablets and Tablets for Oral Suspension
Oxbryta (voxelotor) is an oral, once-daily therapy for patients with sickle cell disease (SCD). Oxbryta works by increasing hemoglobin's affinity for oxygen. Since oxygenated sickle hemoglobin does not polymerize, Oxbryta inhibits sickle hemoglobin polymerization and the resultant sickling and destruction of red blood cells leading to hemolysis and hemolytic anemia, which are primary pathologies faced by every single person living with SCD. Through addressing hemolytic anemia and improving oxygen delivery throughout the body, GBT believes that Oxbryta has the potential to modify the course of SCD.

In November 2019, the U.S. Food and Drug Administration (FDA) granted accelerated approval for Oxbryta tablets for the treatment of SCD in adults and children 12 years of age and older, and in December 2021, the FDA expanded the approved use of Oxbryta for the treatment of SCD in patients 4 years of age and older in the United States.[11] As a condition of accelerated approval for patients ages 4 and older in the United States, GBT will continue to study Oxbryta in the HOPE-KIDS 2 Study, a post-approval confirmatory study using transcranial Doppler (TCD) flow velocity to assess the ability of the therapy to decrease stroke risk in children 2 to 14 years of age.

In recognition of the critical need for new SCD treatments, the FDA granted Oxbryta Breakthrough Therapy, Fast Track, Orphan Drug, and Rare Pediatric Disease designations for the treatment of patients with SCD. Additionally, Oxbryta received the prestigious 2021 Prix Galien USA award for "Best Biotechnology Product" from The Galien Foundation.

Oxbryta has been granted Priority Medicines (PRIME) designation from the European Medicines Agency (EMA), Oxbryta was designated by the European Commission (EC) as an orphan medicinal product for the treatment of patients with SCD, and Oxbryta was granted Promising Innovative Medicine (PIM) designation in the United Kingdom from the Medicines and Healthcare products Regulatory Agency (MHRA). In February 2022, the European Commission (EC) granted Marketing Authorization for Oxbryta for the treatment of hemolytic anemia due to SCD in adult and pediatric patients 12 years of age and older as monotherapy or in combination with hydroxycarbamide (hydroxyurea). In addition, the Ministry of Health and Prevention (MOHAP) in the United Arab Emirates (UAE) has granted marketing authorization for Oxbryta for the treatment of SCD in adults and children 12 years of age and older.

Please click here for Important Safety Information and full Prescribing Information including Patient Information for Oxbryta in the U.S.

About Global Blood Therapeutics
Global Blood Therapeutics (GBT) is a biopharmaceutical company dedicated to the discovery, development and delivery of life-changing treatments that provide hope to underserved patient communities, starting with sickle cell disease (SCD). Founded in 2011, GBT is delivering on its goal to transform the treatment and care of SCD, a lifelong, devastating inherited blood disorder. The company has introduced Oxbryta® (voxelotor), the first FDA-approved medicine that directly inhibits sickle hemoglobin (HbS) polymerization, the root cause of red blood cell sickling in SCD. GBT is also advancing its pipeline program in SCD with inclacumab, a P-selectin inhibitor in Phase 3 development to address pain crises associated with the disease, and GBT021601 (GBT601), the company's next generation HbS polymerization inhibitor. In addition, GBT's drug discovery teams are working on new targets to develop the next wave of potential treatments for SCD. To learn more, please visit www.gbt.com and follow the company on Twitter @GBT_news.

Forward-Looking Statements
Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995, including statements containing the words "will," "anticipates," "plans," "believes," "forecast," "estimates," "expects," and "intends," or similar expressions. These forward-looking statements are based on GBT's current expectations and actual results could differ materially. Statements in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. GBT intends these forward-looking statements, including statements regarding GBT's priorities, commitment, dedication, focus, goals, mission, vision, and positioning; the safety, efficacy, and mechanism of action of Oxbryta, and other product characteristics; the commercialization, awareness, delivery, availability, use, and commercial and medical potential of Oxbryta, including the use, significance and potential of related initiatives; expanding patient access to Oxbryta; potential launch of Oxbryta in Europe, including strategy and timing; significance of the FDA's approval of regulatory submissions to expand the approved use of Oxbryta for more patients and in a pediatric formulation in the U.S. and the marketing authorization for Oxbryta by the EC, including with respect to patient access and use; payer coverage for Oxbryta, including coverage for patients aged 4 to less than 12 and establishing reimbursement in Europe; ongoing and planned studies, clinical trials and registries, and related protocols, activities, timing, and other expectations; future submission and presentation of data; GBT's financial position, outlook, guidance, and expectations; the COVID-19 pandemic and related expectations, including the potential impact on prescriptions; expanding the approved use of Oxbryta, including through the potential marketing authorization in Great Britain and related timing; Dr. Brown's potential impact, including driving engagement at clinical trial sites; GBT's ESG priorities and related progress; impacting the treatment, care, and course of SCD and mitigating related complications; safety, efficacy, mechanism of action, advancement and potential of GBT's drug candidates and pipeline; and working on new targets and discovering, developing, and delivering treatments, to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act, and GBT makes this statement for purposes of complying with those safe harbor provisions. These forward-looking statements reflect GBT's current views about its plans, intentions, expectations, strategies, and prospects, which are based on the information currently available to the company and on assumptions the company has made. GBT can give no assurance that the plans, intentions, expectations, or strategies will be attained or achieved, and, furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond GBT's

control, including, without limitation, risks and uncertainties relating to the COVID-19 pandemic, including the extent and duration of the impact on GBT's business, including commercialization activities, regulatory efforts, research and development, corporate development activities, and operating results, which will depend on future developments that are highly uncertain and cannot be accurately predicted, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing, and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat the disease; the risks that GBT is continuing to establish its commercialization capabilities and may not be able to successfully commercialize Oxbryta; risks associated with GBT's dependence on third parties for research, development, manufacture, distribution, and commercialization activities; government and third-party payer actions, including those relating to reimbursement and pricing; risks and uncertainties relating to competitive treatments and other changes that may limit demand for Oxbryta; the risks regulatory authorities may require additional studies or data to support continued commercialization of Oxbryta; the risks that drug-related adverse events may be observed during commercialization or clinical development; data and results may not meet regulatory requirements or otherwise be sufficient for further development, regulatory review, or approval; compliance with obligations under the Pharmakon loan; and the timing and progress of activities under GBT's collaboration, license and distribution agreements; along with those risks set forth in GBT's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the U.S. Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in GBT's subsequent filings with the U.S. Securities and Exchange Commission. Except as required by law, GBT assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events, or otherwise.

References

1. NHS England. https://www.england.nhs.uk/wp-content/uploads/2018/08/Specialised-services-for-haemoglobinopathy-care-all-ages.pdf. Last accessed April 2022.
2. Centers for Disease Control and Prevention website. Sickle Cell Disease Research. https://www.cdc.gov/ncbddd/hemoglobinopathies/scdc-understanding-sickle-cell-disease.html. Accessed February 23, 2022.
3. European Medicines Agency. https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu3182125 Accessed February 23, 2022.
4. Centers for Disease Control and Prevention website. Sickle Cell Disease (SCD). https://www.cdc.gov/ncbddd/sicklecell/data.html. Accessed February 23, 2022.
5. National Heart, Lung, and Blood Institute website. Sickle Cell Disease. https://www.nhlbi.nih.gov/health-topics/sickle-cell-disease. Accessed February 23, 2022.
6. Kato GJ, et al. *Nat Rev Dis Primers*. 2018;4:18010.
7. Rees DC, et al. *Lancet*. 2010;376(9757):2018-2031.
8. Kato GJ, et al. *J Clin Invest*. 2017;127(3):750-760.
9. Caboot JB, et al. *Paediatr Respir Rev*. 2014;15(1):17-23.
10. Kanter J, et al. *Blood Rev*. 2013 Nov;27(6):279-87.
11. Oxbryta (voxelotor) tablets and tablets for oral suspension prescribing information. South San Francisco, Calif. Global Blood Therapeutics, Inc.; December 2021.

GLOBAL BLOOD THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2022	**2021**
Product sales, net	$ 55,160	$ 39,043
Costs and operating expenses:		
Cost of sales	1,055	584
Research and development	52,833	50,857
Selling, general and administrative	74,533	58,966
Total costs and operating expenses	128,421	110,407
Loss from operations	(73,261)	(71,364)
Other income (expense):		
Interest income (expense), net	(7,705)	(3,360)
Other expenses, net	(286)	(83)
Total other expense, net	(7,991)	(3,443)
Loss before income taxes	(81,252)	(74,807)
Provision for income taxes	171	123
Net loss	(81,423)	(74,930)
Other comprehensive expense:		
Net unrealized loss on marketable securities, net of tax	(1,915)	(181)

Cumulative translation adjustment	(147)	—
Comprehensive loss	$ (83,485)	$ (75,111)
Basic and diluted net loss per common share	$ (1.26)	$ (1.21)
Weighted-average number of shares used in computing basic and diluted net loss per common share	64,842,086	62,101,070

GLOBAL BLOOD THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(In thousands)

	March 31, 2022	December 31, 2021
Assets	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 391,803	$ 684,717
Short-term marketable securities	161,614	—
Other current assets	122,231	117,253
Total current assets	675,648	801,970
Long-term marketable securities	108,667	50,057
Property and equipment, net	33,598	34,918
Operating lease right-of-use assets	47,271	48,015
Other assets, noncurrent	4,359	4,248
Total assets	$ 869,543	$ 939,208
Liabilities and Stockholders' Equity		
Current liabilities	79,305	87,998
Long-term debt, net	246,738	246,352
Convertible debt, net	334,451	334,089
Other liabilities, noncurrent	75,047	74,359
Total liabilities	735,541	742,798
Total stockholders' equity	134,002	196,410
Total liabilities and stockholders' equity	$ 869,543	$ 939,208

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