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): November 4, 2021

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. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 4, 2021, Global Blood Therapeutics, Inc. reported financial results for the third quarter ended September 30, 2021 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 No.	**Description**
99.1	Press Release, dated November 4, 2021, 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: November 4, 2021

By: /s/ Jeffrey Farrow
Jeffrey Farrow
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 99.1

GBT Reports Third Quarter 2021 Financial Results

Achieved Oxbryta® (voxelotor) net revenues of $52.1 million, a 41% increase year over year

Oxbryta sNDA and NDA for pediatric label expansion accepted by FDA for priority review; PDUFA target action date of December 25, 2021

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

SOUTH SAN FRANCISCO, Calif., Nov. 04, 2021 (GLOBE NEWSWIRE) -- Global Blood Therapeutics, Inc. (GBT) (NASDAQ: GBT) today reported financial results for the third quarter ended September 30, 2021 and recent business progress.

"Our third quarter results reflect progress with our ongoing initiatives to drive Oxbryta awareness, adoption and access, and like others in our industry, this was partially offset by the impact of the Delta variant causing a surge in COVID-19 cases in key states. Importantly, we continued to grow the net number of patients on Oxbryta, and the fundamentals of our launch remain strong," said Ted W. Love, M.D., president and chief executive officer of GBT. "Going forward, we have the opportunity to significantly expand the number of patients that potentially may benefit from Oxbryta, including approximately 16,000[1] patients ages 4 to 11 years by end of year if our pediatric label expansion in the U.S. receives approval, and approximately 52,000[2] patients via a potential marketing authorization in Europe in the first half of 2022."

"We are also advancing a robust R&D pipeline. At the ASH Annual Meeting in December, we will present initial results from our Phase 1 study of GBT601, our next-generation sickle hemoglobin polymerization inhibitor, in both healthy volunteers and sickle cell patients – adding to our confidence in GBT601's potential. We will also report new Phase 1 data on inclacumab at ASH that we believe supports its best-in-class potential as a well-tolerated, quarterly dosed P-selectin inhibitor," added Dr. Love.

Recent Business Progress

Commercial

- Achieved Oxbryta® (voxelotor) net sales of $52.1 million in the third quarter, an increase of 41% year over year. On a sequential basis, sales increased 9.5%, primarily driven by patient demand.
- Recorded approximately 850 new prescriptions for Oxbryta in the third quarter.
- The net number of patients taking Oxbryta increased compared to the prior quarter and has increased each quarter since launch.
- Results in the third quarter reflect headwinds from the spike in new COVID-19 cases in August and September. GBT continues to believe that when the pandemic subsides, the number of new Oxbryta prescriptions will improve incrementally. GBT anticipates that in future periods new prescriptions will eventually surpass pre-COVID-19 levels.
- Oxbryta continues to have broad payer coverage, with more than 90% of covered lives having access through their healthcare plans.
- Launched the first branded direct-to-consumer television advertising campaign in sickle cell disease (SCD) to educate and empower patients, which exceeded its targeted audience reach in the initial months of the campaign. The commercial can be viewed on Oxbryta.com.
- Furthered GBT's education and brand commitment efforts, including the launch of a video titled "Mechanism of Sickle Cell Disease" on SickleCellSpeaks.com, to help people learn about SCD and how it affects the body.
- Continued preparations for the potential approval of Oxbryta in the U.S. for children ages 4-11 years, including enrolling patients in GBT's pediatric expanded access protocol (EAP), engaging in medical and scientific education with pediatric hematologists, and educating payers.

Clinical

- Received acceptance of six abstracts on GBT's SCD programs to be presented at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition, which will be held from December 11-14. The presentations will include additional real-world experience with Oxbryta, long-term data from the open-label extension of the Phase 3 HOPE trial, initial data from the Phase 1 trial of GBT021601 (GBT601) in healthy volunteers and SCD patients, and an analysis of data from the Phase 1 trial of inclacumab in healthy volunteers.
- Presented a poster demonstrating that pediatric patients (aged 4-11 years) experience improvements in health-related quality of life after initiating therapy with Oxbryta at The Foundation For Sickle Cell Disease Research's (FSCDR) Inaugural Nursing in Sickle Cell Disease Symposium, which was held on October 1, 2021.

Corporate

- Announced that the U.S. Food and Drug Administration (FDA) has accepted for filing and Priority Review of the company's supplemental New Drug Application (sNDA) seeking accelerated approval for Oxbryta for the treatment of SCD in children ages 4 to 11 years and its New Drug Application (NDA) seeking approval for a new age-appropriate dispersible tablet dosage form of Oxbryta suitable for pediatric patients. The FDA assigned a Prescription Drug User Fee Act (PDUFA) target action date for both applications of December 25, 2021.

- Granted marketing authorization for Oxbryta by the Ministry of Health and Prevention (MOHAP) in the United Arab Emirates (UAE) for the treatment of SCD in adults and children 12 years of age and older. The UAE is the first country outside of the U.S. where Oxbryta has been approved.
- Continued progress toward potential Oxbryta marketing authorization application approval by the European Medicines Agency in the first half of 2022.
- Hosted the 10th Annual SCD Therapeutics Conference, which highlighted the latest advancements and future trends for treating patients with SCD. The event featured sessions on a variety of critical topics, including the impact of the novel COVID-19 vaccines and the experiences of the SCD community with these vaccines.
- Supported the Sickle Cell Disease Association of America's (SCDAA) 49th Annual National Convention as the Diamond sponsor, to help address the multifactorial aspects of SCD and foster the exchange of the latest scientific and clinical information.
- Launched The GBT Foundation, a 501(c)(3) organization and source of charitable giving that will work to improve the health and well-being of underserved patient communities around the world. It will fund programs that will support people within the SCD community and beyond through education, empowerment, improved healthcare access and enhanced health equity.
- GBT and Oxbryta received the prestigious 2021 Prix Galien USA award for "Best Biotechnology Product" from The Galien Foundation. Oxbryta was selected among 19 nominees by a committee of 12 leaders from the biotech industry and academia, including five Nobel Laureates.

Financial Results for the Third Quarter 2021
Total net product sales for the third quarter of 2021 were $52.1 million, resulting from sales of Oxbryta, compared to $36.9 million for the third quarter of 2020.

Cost of sales for the three months ended September 30, 2021, was $0.8 million, compared with $0.5 million for the same period in 2020. Manufacturing costs incurred prior to FDA approval of Oxbryta in November 2019 were previously recorded as research and development 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 fully expensed, is completely utilized.

Research and development (R&D) expenses for the three months ended September 30, 2021, were $50.5 million, compared with $40.2 million for the same period in 2020. The increase was primarily due to an increase in external costs related to the company's preclinical programs and Oxbryta and inclacumab programs. Total R&D non-cash stock compensation expense incurred for the three months ended September 30, 2021, was $4.6 million, compared with $4.2 million for the same period in 2020.

Sales, general, and administrative (SG&A) expenses for the three months ended September 30, 2021, were $68.0 million, compared with $54.5 million for the same period in 2020. The increase in SG&A expense was primarily attributable to increased professional and consulting services associated with the company's commercial operations for Oxbryta and employee-related costs, including non-cash stock compensation expense. Total SG&A non-cash stock compensation expense incurred in the three months ended September 30, 2021, was $13.5 million, compared with $14.9 million for the same period in 2020.

Net loss for the three months ended September 30, 2021, was $71.0 million, compared with $59.9 million for the same period in 2020. Basic and diluted net loss per share for the three months ended September 30, 2021, was $1.13, compared with $0.97 for the same period in 2020.

Cash, cash equivalents, and marketable securities totaled $416.8 million at September 30, 2021, compared with $560.9 million at December 31, 2020.

Conference Call Details
GBT will host a conference call today, Thursday, November 4, 2021, at 4:30 p.m. ET to discuss the financial results for the third quarter 2021 and provide a general business update. To participate in the conference call, please dial 855-327-6838 (domestic) or +1 604-235-2082 (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.

GBT R&D Day Details
GBT will host its R&D Day on Thursday, November 11, 2021, in New York City from 9:00 a.m. to 12:00 p.m. ET. The company will provide an update to the investment community on Oxbryta, including the growing body of real-world experience with the product, and its R&D pipeline, including inclacumab and GBT601. A live video webcast can be accessed on GBT's website at www.gbt.com in the Investors section. The archived video webcast will be available for three months following the event.

About Sickle Cell Disease
Sickle cell disease (SCD) affects an estimated 100,000 people in the United States,[3] an estimated 52,000 people in Europe,[2] and millions of people throughout the world, particularly among those whose ancestors are from sub-Saharan Africa.[3] It also affects people of Hispanic, South Asian, Southern European, and Middle Eastern ancestry.[3] 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.[4] 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.[4-6] 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 throughout the body. The diminished oxygen delivery to tissues and organs can lead to life-threatening complications, including stroke and irreversible organ damage.[5-8]

About Oxbryta® (voxelotor) tablets
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, GBT believes Oxbryta blocks polymerization and the resultant sickling and destruction of red blood cells, which are primary pathologies faced by every single person living with SCD. With the potential to improve hemolytic anemia and oxygen delivery, GBT believes that Oxbryta has the potential to modify the course of SCD. On November 25, 2019, Oxbryta received U.S. Food and Drug Administration (FDA) accelerated approval for the treatment of SCD in adults and children 12 years of age and older.[9]

As a condition of accelerated approval, 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 15 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 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).

The EMA has accepted for review GBT's Marketing Authorization Application (MAA) seeking full marketing authorization of Oxbryta in the European Union to treat hemolytic anemia in SCD patients ages 12 years and older. GBT is also seeking regulatory approval to expand the potential use of Oxbryta in the United States for the treatment of SCD in children as young as 4 years old.

Important Safety Information
Oxbryta should not be taken if the patient has had an allergic reaction to voxelotor or any of the ingredients in Oxbryta. See the end of the patient leaflet for a list of the ingredients in Oxbryta. Oxbryta can cause serious side effects, including serious allergic reactions. Patients should tell their healthcare provider or get emergency medical help right away if they get rash, hives, shortness of breath, or swelling of the face.

Patients receiving exchange transfusions should talk to their healthcare provider about possible difficulties with the interpretation of certain blood tests when taking Oxbryta.

The most common side effects of Oxbryta include headache, diarrhea, stomach (abdominal) pain, nausea, tiredness, rash, and fever. These are not all the possible side effects of Oxbryta.

Before taking Oxbryta, patients should tell their healthcare provider about all medical conditions, including if they have liver problems; if they are pregnant or plan to become pregnant as it is not known if Oxbryta can harm an unborn baby; or if they are breastfeeding or plan to breastfeed as it is not known if Oxbryta can pass into breastmilk or if it can harm a baby. Patients should not breastfeed during treatment with Oxbryta and for at least 2 weeks after the last dose.

Patients should tell their healthcare provider about all the medicines they take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines may affect how Oxbryta works. Oxbryta may also affect how other medicines work.

Patients are advised to call their doctor for medical advice about side effects. Side effects can be reported to FDA at 1-800-FDA-1088. Side effects can also be reported to Global Blood Therapeutics at 1-833-428-4968 (1-833-GBT-4YOU).

Full Prescribing Information for Oxbryta is available at Oxbryta.com.

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. Founded in 2011, GBT is delivering on its goal to transform the treatment and care of sickle cell disease (SCD), a lifelong, devastating inherited blood disorder. The company has introduced Oxbryta® (voxelotor) tablets, the first FDA-approved treatment that directly inhibits sickle hemoglobin 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 hemoglobin S 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; the content, timing and significance of data and abstracts to be presented at ASH; payer coverage for Oxbryta; the EAP for Oxbryta and other initiatives to provide early access, including the availability, enrollment, use and impact; ongoing and planned studies, clinical trials and registries, and related protocols, activities, timing, and other expectations; GBT's financial position, outlook, guidance, and expectations; the COVID-19 pandemic and related expectations, including the potential impact on prescriptions as the pandemic subsides; expanding access to Oxbryta, including related strategies, activities and expectations; regulatory submissions to potentially expand the approved use of Oxbryta for more patients and in a pediatric formulation in the U.S. and to treat patients in Europe and other territories, including potential review, timing and approval; the GBT Foundation, including the related activities and expectations; impacting the treatment, care, and course of SCD and mitigating related complications; safety, efficacy, mechanism of action, potential and advancement of GBT's drug candidates and pipeline; 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, 2020, and in GBT's most recent Quarterly Report on Form 10-Q 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. Symphony Health Claims Data, May 2021.
2. European Medicines Agency. https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu3182125. Accessed February 24, 2021.
3. Centers for Disease Control and Prevention website. Sickle Cell Disease (SCD). https://www.cdc.gov/ncbddd/sicklecell/data.html. Accessed February 24, 2021.
4. National Heart, Lung, and Blood Institute website. Sickle Cell Disease. https://www.nhlbi.nih.gov/health-topics/sickle-cell-disease. Accessed August 5, 2019.
5. Rees DC, et al. *Lancet*. 2010;376(9757):2018-2031.
6. Kato GJ, et al. *Nat Rev Dis Primers*. 2018;4:18010.
7. Kato GJ, et al. *J Clin Invest*. 2017;127(3):750-760.
8. Caboot JB, et al. *Paediatr Respir Rev*. 2014;15(1):17-23.
9. Oxbryta (voxelotor) tablets prescribing information. South San Francisco, Calif. Global Blood Therapeutics, Inc.; November 2019.

GLOBAL BLOOD THERAPEUTICS, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Product sales, net	$ 52,052	$ 36,889	$ 138,650	$ 82,508

Costs and operating expenses:				
Cost of sales	830	513	2,162	1,025
Research and development	50,529	40,196	153,170	114,054
Selling, general and administrative	67,987	54,491	188,046	151,227
Total costs and operating expenses	119,346	95,200	343,378	266,306
Loss from operations	(67,294)	(58,311)	(204,728)	(183,798)
Other income (expense):				
Interest income	85	881	578	5,251
Interest expense	(3,709)	(2,291)	(11,075)	(6,887)
Other expenses, net	(70)	(160)	(285)	(313)
Total other income (expense), net	(3,694)	(1,570)	(10,782)	(1,949)
Net loss	(70,988)	(59,881)	(215,510)	(185,747)
Other comprehensive loss:				
Net unrealized gain on marketable securities, net of tax	(42)	(507)	(301)	(35)
Cumulative translation adjustment	(39)	—	220	—
Comprehensive loss	$ (71,069)	$ (60,388)	$ (215,591)	$ (185,782)
Basic and diluted net loss per common share	$ (1.13)	$ (0.97)	$ (3.45)	$ (3.04)
Weighted-average number of shares used in computing basic and diluted net loss per common share	62,925,081	61,573,877	62,449,207	61,160,984

GLOBAL BLOOD THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(In thousands)

	September 30, 2021	**December 31, 2020**
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 382,869	$ 494,766
Short-term marketable securities	3,205	66,126
Other current assets	102,790	71,271
Total current assets	488,864	632,163
Long-term marketable securities	30,692	—
Property and equipment, net	35,415	37,882
Operating lease right-of-use assets	48,732	50,722
Other assets	3,975	3,235
Total assets	$ 607,678	$ 724,002
Liabilities and Stockholders' Equity		
Current liabilities	$ 74,058	$ 79,032
Long-term debt	149,508	148,815
Operating lease liabilities, noncurrent	74,990	79,176
Other noncurrent liabilities	822	822
Total liabilities	299,378	307,845
Total stockholders' equity	308,300	416,157
Total liabilities and stockholders' equity	$ 607,678	$ 724,002

Contact:
Steven Immergut (media)
650-410-3258
simmergut@gbt.com

Courtney Roberts (investors)
650-351-7881
croberts@gbt.com