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 8.01. Other Events.

On November 4, 2021, Global Blood Therapeutics, Inc. issued a press release titled "GBT Announces Six Data Presentations on Sickle Cell Disease at Upcoming 63rd American Society of Hematology (ASH) Annual Meeting & Exposition." A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release dated November 4, 2021
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 Announces Six Data Presentations on Sickle Cell Disease at Upcoming 63rd American Society of Hematology (ASH) Annual Meeting & Exposition

Accepted Abstracts Include Real-World Experience with Oxbryta® (voxelotor) and Phase 1 Data on GBT021601 and Inclacumab

SOUTH SAN FRANCISCO, Calif., Nov. 04, 2021 (GLOBE NEWSWIRE) -- Global Blood Therapeutics, Inc. (GBT) (NASDAQ: GBT) today announced that six abstracts related to its sickle cell disease (SCD) programs, including data from the growing body of real-world evidence on Oxbryta® (voxelotor) tablets and new data on GBT's pipeline, will be presented at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition. The meeting is taking place online and in person at the Georgia World Congress Center in Atlanta, Georgia from December 11-14, 2021.

"Our data presentations at ASH 2021 include three new analyses from the growing body of data on Oxbryta that reinforce our belief in the benefits of this innovative and potentially disease-modifying treatment for sickle cell disease," said Kim Smith-Whitley, M.D., executive vice president and head of research and development at GBT. "Additionally, we're very excited to present new Phase 1 data from our pipeline relating to GBT601 and inclacumab – both of which we believe have the potential to be best-in-class therapies – as we work on behalf of patients to achieve our goal of transforming sickle cell disease into a well-managed chronic condition."

The three Oxbryta analyses provide greater insight into its efficacy and safety in both the real-world and long-term clinical trial settings:

- An analysis of nearly 2,700 patients ages 12 years or older from the Symphony Health claims database who initiated Oxbryta treatment between November 2019 and March 2021 demonstrated that, in real-world practice, Oxbryta increased hemoglobin (Hb), consistent with the results of the Phase 3 HOPE Study. These data show statistically significant reductions in transfusions, vaso-occlusive crises (VOCs), and all-cause and VOC-related hospitalizations after Oxbryta use.

- An evaluation of data from an open-label extension of the Phase 3 HOPE Study demonstrated that long-term use of Oxbryta is safe, well tolerated, and has a durable effect in reducing anemia and hemolysis in patients with SCD.

- Data from the Retrospective Study to Evaluate Outcomes in Patients with Sickle Cell Disease Treated with Oxbryta (RETRO), the first multicenter, retrospective study to examine the real-world effectiveness of Oxbryta, showed the treatment was associated with increased Hb levels and decreased hemolytic markers. The safety data are consistent with those from the Phase 3 HOPE Study of SCD patients ages 12 years and older.

Data presented from two key Phase 1 studies from GBT's R&D pipeline in SCD include:

- An analysis of a Phase 1 study of GBT021601 (GBT601), GBT's next-generation sickle hemoglobin polymerization inhibitor, will highlight data in both healthy volunteers and a cohort of six adults with SCD. Single ascending doses in healthy volunteers and single doses of GBT601 in patients with SCD were well tolerated in healthy volunteers and patients with SCD. In addition, multiple-dose data will be presented and will help to evaluate GBT601's potential as a best-in-class, oral, disease-modifying therapy. GBT believes GBT601 has the capacity to achieve a targeted Hb occupancy and attain the desired hematological effect at low doses, therefore reducing pill burden and improving clinical outcomes for individuals living with SCD.

- An analysis of a Phase 1 study of inclacumab, GBT's fully human P-selectin monoclonal antibody in development for the reduction of VOCs in SCD patients, displayed a well-tolerated safety profile for up to 29 weeks following a single dose of 20 or 40 mg/kg in healthy subjects. Durable inhibition of platelet-leukocyte aggregate (PLA) formation was observed through at least 12 weeks, consistent with prior observations. The results support a dose of 30 mg/kg every 12 weeks in patients with SCD-related VOCs being studied in GBT's two Phase 3 THRIVE (**TH**erapy for **R**eduction with **I**nclacumab of **V**OC **E**pisodes) trials (NCT04935879 and NCT04927247), which the company initiated in June 2021.

An additional abstract features data from a natural history cohort of pediatric patients with SCD:

- An analysis of a natural history cohort of pediatric SCD patients showed an inverse relationship between Hb level and transcranial Doppler (TCD) velocity in patients with SCD, supporting the beneficial effect of higher Hb levels in SCD patients. TCD is a validated screening tool to identify pediatric SCD patients at risk of cerebrovascular events.

All of these abstracts are now available at www.hematology.org. Details of the GBT presentations, which will be available in the poster hall and via the virtual event platform, are as follows:

Saturday, Dec. 11, 5:30 p.m. to 7:30 p.m. ET
Poster Session: Preliminary Results of a Phase 1 Study in Healthy Subjects Administered Inclacumab, a Fully Human IgG4 Anti-P-Selectin Monoclonal Antibody in Development for Treatment of Sickle Cell Disease
Abstract #977
Presenter: Christina Mayer, PharmD, Semivida Research, Dallas, TX, (formerly with GBT)

Sunday, Dec. 12, 6:00 p.m. to 8:00 p.m. ET
Poster Session: Real-World Experience of Voxelotor for the Management of Complications in Sickle Cell Disease
Abstract #2052
Presenter: Nirmish Shah, M.D., Duke University School of Medicine, Durham, NC

Monday, Dec. 13, 6:00 p.m. to 8:00 p.m. ET
Poster Session: Real-World Experience of Patients with Sickle Cell Disease Treated with Voxelotor: A Multicenter, Retrospective Study
Abstract #3100
Presenter: Biree Andemariam, M.D., New England Sickle Cell Institute, University of Connecticut Health, Farmington, CT

Poster Session: Long-Term Safety and Efficacy of Voxelotor for Patients with Sickle Cell Disease: Results from an Open-Label Extension of the Phase 3 HOPE Trial
Abstract #3114
Presenter: Maureen M. Achebe, M.D., MPH, Brigham and Women's Hospital, Harvard Medical School, Boston, MA

Poster Session: The Role of Hemoglobin and Hemolysis on Transcranial Doppler Velocities in Children with Sickle Cell Disease: Data from a Natural History Cohort
Abstract #3092
Presenter: Raffaella Colombatti, M.D., Ph.D., Clinic of Pediatric Hematology Oncology, Department of Women's and Child's Health, Azienda Ospedale – Università di Padova, Padua, Italy

Poster Session: GBT021601, a Next Generation HbS Polymerization Inhibitor: Results of Safety, Tolerability, Pharmacokinetics and Pharmacodynamics in Adults Living with Sickle Cell Disease and Healthy Volunteers
Abstract #3099
Presenter: Clark Brown, M.D., Ph.D., Aflac Cancer and Blood Disorders Center of Children's Healthcare of Atlanta and Department of Pediatrics, Emory School of Medicine, Atlanta, GA

About Sickle Cell Disease
Sickle cell disease (SCD) affects an estimated 100,000 people in the United States,[1] 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.[1] It also affects people of Hispanic, South Asian, Southern European and Middle Eastern ancestry.[1] 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.[3] 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.[3-5] 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.[4-7]

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, Oxbryta inhibits sickle hemoglobin polymerization and the resultant sickling and destruction of red blood cells, 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. 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.[8]

As a condition of accelerated approval, GBT is studying 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 was 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 Europe 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 health care 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 health care 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 health care 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 two weeks after the last dose.

Patients should tell their health care 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 the 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, 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, dedication, commitment, focus, goals, mission and vision; safety, efficacy and mechanism of action of Oxbryta and other product characteristics; potential of Oxbryta, including in being a disease-modifying treatment; significance of reducing sickling and hemolysis and raising hemoglobin; commercialization, delivery, availability, use and commercial and medical potential of Oxbryta; the content, timing and significance of data and abstracts to be presented at ASH; ongoing and planned studies, clinical trials and registries, and related protocols, 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; altering the treatment, course and care of SCD and mitigating related complications; safety, efficacy, mechanism of action, potential and advancement 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, 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. Centers for Disease Control and Prevention website. Sickle Cell Disease (SCD). https://www.cdc.gov/ncbddd/sicklecell/data.html. Accessed June 3, 2019.
2. European Medicines Agency. https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu3182125. Accessed June 12, 2020.
3. National Heart, Lung, and Blood Institute website. Sickle Cell Disease. https://www.nhlbi.nih.gov/health-topics/sickle-cell-disease. Accessed August 5, 2019.
4. Rees DC, et al. *Lancet*. 2010;376(9757):2018-2031.
5. Kato GJ, et al. *Nat Rev Dis Primers*. 2018;4:18010.
6. Kato GJ, et al. *J Clin Invest*. 2017;127(3):750-760.
7. Caboot JB, et al. *Paediatr Respir Rev*. 2014;15(1):17-23.
8. Oxbryta (voxelotor) tablets prescribing information. South San Francisco, Calif. Global Blood Therapeutics, Inc.; November 2019.

Contact:

Steven Immergut (media)
+1.650.410.3258
simmergut@gbt.com

Courtney Roberts (investors)
+1.650.351.7881
croberts@gbt.com