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): June 29, 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 8.01. Other Events.

On June 29, 2022, Global Blood Therapeutics, Inc. issued a press release titled "GBT Initiates Phase 2/3 Clinical Trial of GBT601 in Patients with Sickle Cell Disease." 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 June 29, 2022
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: June 29, 2022

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

GBT Initiates Phase 2/3 Clinical Trial of GBT601 in Patients with Sickle Cell Disease

Phase 2 portion designed to identify the optimal dose for the pivotal Phase 3 portion of the trial

SOUTH SAN FRANCISCO, Calif., June 29, 2022 (GLOBE NEWSWIRE) -- Global Blood Therapeutics, Inc. (GBT) (NASDAQ: GBT) today announced that it initiated the Phase 2 portion of a planned Phase 2/3 trial of GBT021601 (GBT601), the company's investigational next-generation sickle hemoglobin (HbS) polymerization inhibitor. The study (NCT05431088) is a randomized, multicenter Phase 2/3 clinical trial evaluating the safety, tolerability, efficacy, pharmacokinetics (PK) and pharmacodynamics (PD) of GBT601.

"Based on compelling preclinical and clinical data, we believe GBT601 has the potential to be a best-in-class therapy for patients with sickle cell disease," said Kim Smith-Whitley, M.D., executive vice president and head of research and development of GBT. "Specifically, it has the potential to improve on the clinical results achieved with Oxbryta® at a lower daily dose. The initiation of our Phase 2/3 trial is an important milestone in our efforts to bring GBT601 to patients. We anticipate that initial data from this trial as well as data from the continuation of our GBT601 Phase 1 study will be available before the end of the year."

The study is planned to include sites in Africa, Europe, the Middle East, South America, and the United States, including several sites that are expected to begin enrolling patients in the near term. The Phase 2 portion of the study will evaluate the safety, tolerability, and efficacy of GBT601 and enroll up to 60 patients with SCD who are 18 to 65 years of age. Patients with hemoglobin (Hb) levels between 5.5 g/dL and 10.5 g/dL and 10 or fewer vaso-occlusive crises in the prior year are eligible for enrollment. Patients will be randomized 1:1:1 to a daily maintenance dose of GBT601 of 100, 150 or up to 200 mg. The primary outcome measure is the number of participants with a change from baseline in Hb through Week 12. Secondary outcomes measures include assessments of PK and PD, as well as an assessment of the relationship between GBT601 and measures of anemia and hemolysis.

Following the selection of the optimal safe and effective dose of GBT601 from the Phase 2 portion of the study, the Phase 3 portion will assess the efficacy and safety of the selected optimal dose compared to placebo in adult and pediatric SCD patients for 48 weeks. In addition, a third arm of the study will evaluate the PK and safety of single and multiple doses of GBT601 in an open-label single arm study with pediatric participants.

About Sickle Cell Disease

Sickle cell disease (SCD) affects more than 100,000 people in the United States,[1] an estimated 52,000 people in Europe,[2] up to 100,000 people in Brazil,[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.[5] SCD is a lifelong, devastating inherited 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. When sickle hemoglobin becomes deoxygenated, it polymerizes to form rods, which deforms the red blood cells into sickled – crescent-shaped, rigid – cells. [3,5,6] The recurrent sickling process causes destruction of the red blood cells, hemolysis and anemia (low hemoglobin due to red blood cell destruction) which drives vascular inflammation contributing to blockages in capillaries and small blood vessels (vaso-occlusion) that impede the flow of blood and oxygen delivery throughout the body. Episodes of painful vascular occlusions are commonly referred to as vaso-occlusive crises (VOCs). The diminished oxygen delivery to tissues and organs can lead to life-threatening complications, including stroke and irreversible organ damage. [3,6,7,8] Complications of SCD can begin in early childhood and can include neurocognitive impairment, acute chest syndrome, and silent and overt stroke, among other serious issues.[9] Early intervention and treatment of SCD have shown potential to modify the course of this disease, reduce symptoms and events, prevent long-term organ damage, and extend life expectancy.[10]

About GBT601

Discovered and designed by GBT's research and development team, GBT021601 (GBT601) has the same mechanism of action as Oxbryta (voxelotor), with the potential for improved clinical results by achieving higher hemoglobin levels and occupancy at a lower dose. GBT601 is being studied in a Phase 1 clinical trial and Phase 2 portion of a Phase 2/3 clinical trial.

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 generation of 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, dedication, commitment, focus, goals, mission, vision and positioning; safety, efficacy and mechanism of action of Oxbryta and other product characteristics; commercialization, delivery, availability, use and commercial and medical potential of Oxbryta; significance of the initiation of the Phase 2/3 trial of GBT601 and bringing GBT601 to patients; clinical trials of GBT601 and other ongoing and planned studies, clinical trials and registries, including related protocols, enrollment and other activities, timing, data availability and other expectations; significance of preclinical and clinical data of GBT601, including with respect to the potential of GBT601; safety, efficacy, mechanism of action, advancement and potential of GBT601, inclacumab and GBT’s other drug candidates and its pipeline; impacting the treatment, course and care of SCD; 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, 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

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