

**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, 2020

GLOBAL BLOOD THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-37539
(Commission File Number)

27-4825712
(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, 2020, Global Blood Therapeutics, Inc. issued a press release titled "GBT Announces Upcoming Virtual Data Presentations at 62nd 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 No. **Description**

[99.1](#) [Press Release, dated November 4, 2020](#)
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, 2020

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

GBT Announces Upcoming Virtual Data Presentations at 62nd American Society of Hematology (ASH) Annual Meeting & Exposition

Abstracts Include 72-Week Analysis of Phase 3 HOPE Study Supporting Long-Term Use of Oxbryta® (voxelotor)

Preclinical Data Highlights Promise of GBT's Sickle Cell Disease Pipeline

GBT to Host Virtual Analyst & Investor Day Event on Monday, Dec. 7, 2020

SOUTH SAN FRANCISCO, Calif., Nov. 04, 2020 (GLOBE NEWSWIRE) -- Global Blood Therapeutics, Inc. (GBT) (NASDAQ: GBT), today announced that nine abstracts related to its sickle cell disease (SCD) programs will be presented at the 62nd American Society of Hematology (ASH) Annual Meeting & Exposition, taking place online Dec. 5-8, 2020. The studies to be presented include the 72-week analysis of the Phase 3 HOPE Study of Oxbryta® (voxelotor) tablets and new research from GBT's pipeline.

"Nearly one year after the FDA approval of Oxbryta, we are pleased to share new clinical data supporting both the long-term use of this first-in-class therapy to reduce anemia and hemolysis in people with sickle cell disease and its effectiveness in the real-world setting," said Ted W. Love, M.D., president and chief executive officer of GBT. "As part of our strategy to be the leader in sickle cell disease and our deep commitment to this community, we are also excited to unveil new preclinical data from our SCD pipeline programs, including our novel fully human monoclonal antibody that has the potential to be a best-in-class P-selectin inhibitor, and our next generation hemoglobin S polymerization inhibitor."

Highlights of the data to be presented at ASH include:

Oxbryta

- An analysis of the Phase 3 HOPE Study showed that Oxbryta (1,500 mg) treatment demonstrated sustained improvements in hemoglobin (Hb) levels and markers of hemolysis over 72 weeks, consistent with previously published 24-week analyses. These results support durability of Oxbryta longer-term use to reduce anemia and hemolysis and potentially mitigate the associated morbidity and mortality of SCD.
- Consistent with the 24-week results analysis, patients in the Phase 3 HOPE Study who achieved the greatest average Hb levels over 72 weeks with Oxbryta experienced numerically fewer vaso-occlusive crises (VOCs), with a stepwise reduction in VOC rate with each increase in Hb stratum (up to 12 to \leq 13.3 g/dL).
- In the Phase 3 HOPE Study, the Clinical Global Impression of Change (CGI-C) outcome measure showed that treatment with Oxbryta compared to placebo resulted in a significantly higher rating of improved overall patient health status after 72 weeks of treatment, regardless of baseline Hb and hemolysis markers. CGI provides an overall clinician-determined summary measure that takes into account available information, including knowledge of the patient's history, psychosocial circumstances, symptoms and behavior, and the impact of the symptoms on the patient's ability to function.
- An analysis of Symphony Health claims data from a subset of 1,275 patients treated with Oxbryta showed that the increase in Hb levels observed in a real-world setting was consistent with published results from the Phase 3 HOPE Study. The data further demonstrated favorable trends in decreasing transfusion and annualized rates of VOCs after the initiation of Oxbryta therapy.
- An analysis of data from Clinical and Patient Global Impression of Improvement scales (CGI-I and PGI-I) collected from 27 patients treated with Oxbryta at The University of Texas Comprehensive Sickle Cell Center demonstrated that the majority of patients reported substantial improvement in overall clinical status after treatment with Oxbryta, which correlated with the clinician impression of their status.

Pipeline

- An *in vitro* study of inclacumab, a novel P-selectin inhibitor in development to reduce VOCs in SCD, demonstrated the potential for a substantially longer duration of exposure and more convenient dosing compared to crizanlizumab.
- A preclinical analysis demonstrated that GBT021601, GBT's next generation HbS polymerization inhibitor, tested at lower doses than Oxbryta, was highly effective in reducing hemolysis, increasing hemoglobin levels, prolonging red blood cell (RBC) half-life and improving RBC health as well as potentially improving organ function in SCD transgenic mice.

The ASH abstracts are now available at www.hematology.org. Details of the GBT presentations are as follows:

Saturday, Dec. 5, available virtually from 7 a.m. to 3:30 p.m. P.T.

Poster Session: 114. Hemoglobinopathies, Excluding Thalassemia—Clinical: Poster I
Abstract #795: Higher Hemoglobin Levels Achieved with Voxelotor Are Associated with Lower Vaso-occlusive Crisis Incidence: 72-Week Analysis from the HOPE Study
Presenter: Elliott Vichinsky, M.D., UCSF Benioff Children's Hospital Oakland

Poster Session: 114. Hemoglobinopathies, Excluding Thalassemia—Clinical: Poster I
Abstract #802: Improvement in the Clinical Global Impression of Change with Voxelotor in Patients with Sickle Cell Disease in the Phase 3 HOPE Trial
Presenter: Wally Smith, M.D., Virginia Commonwealth University

Sunday, Dec. 6, available virtually from 7 a.m. to 3:30 p.m. P.T.

Poster Session: 114. Hemoglobinopathies, Excluding Thalassemia—Clinical: Poster II
Abstract #1716: Efficacy and Safety of Voxelotor in Adolescents and Adults with Sickle Cell Disease: HOPE Trial 72-Week Analysis
Presenter: Jo Howard, MB BChir, MRCP, FRCPath, Guy's and St. Thomas' NHS Foundation Trust and King's College London

Poster Session: 114. Hemoglobinopathies, Excluding Thalassemia—Clinical: Poster II
Abstract #1723: Patient Perception of Oxbryta Treatment Benefit
Presenter: Modupe Idowu, M.D., McGovern Medical School at The University of Texas Health Science Center at Houston

Poster Session: 113. Hemoglobinopathies, Excluding Thalassemia—Basic and Translational Science: Poster II
Abstract #1704: GBT021601 Inhibits HbS Polymerization, Prevents RBC Sickling and Improves the Pathophysiology of Sickle Cell Disease in a Murine Model
Presenter: Kobina Dufu, Ph.D., GBT

Poster Session: 113. Hemoglobinopathies, Excluding Thalassemia—Basic and Translational Science: Poster II
Abstract #1707: Inclacumab, a Fully Human Anti-P-selectin Antibody, Directly Binds to PSGL-1 Binding Region and Demonstrates Robust and Durable Inhibition of Cell Adhesion
Presenter: Xin Geng, Ph.D., GBT

Poster Session: 113. Hemoglobinopathies, Excluding Thalassemia—Basic and Translational Science: Poster II
Abstract #1706: Rheological Impact of GBT1118 Cessation in a Sickle Mouse Model
Presenters: Danitza Nebor, Ph.D., Baylor College of Medicine
Vivian Sheehan, M.D., Ph.D., Baylor College of Medicine

Poster Session: 114. Hemoglobinopathies, Excluding Thalassemia—Clinical: Poster II
Abstract #1724: The Impact of Hemoglobin Level on Risk of End-Organ Damage Among Patients with Sickle Cell Disease – A Large-Scale, Longitudinal Analysis
Presenter: William Ershler, M.D., Inova Schar Cancer Institute

Monday, Dec. 7, available virtually from 7 a.m. to 3 p.m. P.T.

Poster Session: 113. Hemoglobinopathies, Excluding Thalassemia—Basic and Translational Science: Poster III
Abstract #2627: Real-World Effectiveness of Voxelotor for Treating Sickle Cell Disease in the U.S.
Presenter: Ahmar Zaidi, M.D., Children's Hospital of Michigan, Central Michigan University, College of Medicine

GBT Analyst & Investor Day Webcast Details

GBT will host a virtual Analyst & Investor Day event on Monday, Dec. 7, at 4 p.m. P.T. to review data being presented at the 2020 ASH Annual Meeting. The event will also provide an overview of the company's SCD development pipeline, including inclacumab and GBT021601. The webcast can also be accessed directly at <http://www.gbtinvestorday.virtualeventsite.com/>. Participants are requested to register in advance. A replay will be available for three months following the event on GBT's investor webpage at www.gbt.com.

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 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, people 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. 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 Nov. 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 will continue to study voxelotor in the HOPE-KIDS 2 Study, a post-approval confirmatory study using transcranial Doppler (TCD) flow velocity to assess the ability of Oxbryta 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. The European Medicines Agency (EMA) has included Oxbryta in its Priority Medicines (PRIME) program, and the European Commission (E.C.) has designated Oxbryta as an orphan medicinal product for the treatment of patients with SCD.

GBT plans to seek regulatory approvals to expand the potential use of Oxbryta in the United States for the treatment of SCD in children age 4 to 11 years and to treat hemolytic anemia in SCD in people age 12 years and older in Europe.

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), 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 development to address pain crises associated with the disease, and GBT021601, 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 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, strategy, focus, goals and vision; the safety, efficacy and mechanism of action of Oxbryta and other product characteristics; the commercialization, delivery, availability, use, and commercial and medical potential of Oxbryta; ongoing and planned studies of Oxbryta and related protocols, activities and expectations; the potential expansion of the approved use of Oxbryta for more patients in the U.S., and potential regulatory approval for Oxbryta to treat patients in Europe; impacting the treatment, care, course and outcome of SCD; future presentations and the significance of related results; the potential of GBT's pipeline, including inclacumab and other product candidates; and advancing GBT's 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 has only recently established its commercialization capabilities and may not be able to successfully commercialize Oxbryta; risks associated with GBT's dependence on third parties for development, manufacture and commercialization activities related to Oxbryta; government and third-party payor actions, including those relating to reimbursement and pricing; risks and uncertainties relating to competitive products 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 the funding and other obligations under the Pharmakon loan; and the timing and progress of GBT's and Syros' research and development activities under their collaboration; along with those risks set forth in GBT's Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2019, 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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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.
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5. Kato GJ, et al. *Nat Rev Dis Primers*. 2018;4:18010.
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