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 6, 2019

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.)

171 Oyster Point Blvd., Suite 300
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 6, 2019, Global Blood Therapeutics, Inc. issued a press release titled “GBT Announces Upcoming Data Presentations at 61st American Society of Hematology 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 6, 2019
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 6, 2019

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

EXHIBIT 99.1

GBT Announces Upcoming Data Presentations at 61st American Society of Hematology Annual Meeting & Exposition

Abstracts Include Three Post-hoc Analyses of Phase 3 HOPE Study Clinical Data

Data Further Support the Safety and Efficacy of Voxelotor for Sickle Cell Disease (SCD)

Examination of Real-world Evidence Further Establishes Relationship Between Higher Levels of Hemoglobin and Decreased Risk of Stroke

SOUTH SAN FRANCISCO, Calif., Nov. 06, 2019 (GLOBE NEWSWIRE) -- Global Blood Therapeutics, Inc. (GBT) (NASDAQ: GBT) today announced that eight abstracts related to its sickle cell disease (SCD) research programs, including multiple abstracts related to the safety and efficacy of voxelotor, have been accepted for presentation during the 61st American Society of Hematology (ASH) Annual Meeting & Exposition, taking place December 7-10 at the Orange County Convention Center in Orlando, Florida.

“Our data presentations at ASH 2019, including three post-hoc analyses of the HOPE Study, reinforce the safety and efficacy of voxelotor as a potential disease-modifying treatment for SCD. In addition, the analysis of real-world evidence demonstrating the relationship between increased hemoglobin and decreased risk of stroke, as measured by transcranial Doppler flow velocity, provides further confidence in achieving a favorable result from our planned post-approval confirmatory study, which is designed to demonstrate that an improvement in hemolytic anemia translates into important clinical benefit,” said Josh Lehrer, M.D., chief medical officer of GBT. “We look forward to continuing our exploration of the HOPE Study data to generate additional insights into the potential benefits of addressing anemia and hemolysis in SCD.”

The three post-hoc analyses of the Phase 3 HOPE Study provide greater insight into the safety and efficacy of voxelotor for targeting anemia and hemolysis:

- An analysis of the association between absolute hemoglobin achieved with voxelotor treatment and the incidence of vaso-occlusive crises (VOC) showed that patients with hemoglobin values of ≥10 g/dL (n=46) and ≥12 g/dL (n=7) had the lowest observed rates of VOC. This inverse relationship suggests that voxelotor treatment can safely raise hemoglobin without causing a viscosity-related increased risk of VOC. The analysis also examined VOC rates within 28 days of treatment discontinuation and found no evidence of an increased risk of VOC with voxelotor withdrawal compared with placebo.
- An analysis of the association between hemoglobin response and markers of hemolysis in voxelotor-treated patients found that those who achieved an increase in hemoglobin of >1 g/dL had the greatest reductions in markers of hemolysis. Additionally, patients with an increase in hemoglobin of >1 g/dL who received voxelotor 1500 mg had greater reductions in hemolysis than those who received voxelotor 900 mg, suggesting that exposure to a higher dose of voxelotor results in overall better efficacy in treating anemia and hemolysis.
- An analysis of the effects of concomitant hydroxyurea use in the voxelotor treatment arms showed that hemoglobin increases for study participants on stable-dose hydroxyurea were equivalent to those observed in participants not taking hydroxyurea. The lack of observed changes in two red blood cell parameters, mean corpuscular volume and absolute neutrophil count, were consistent with stable hydroxyurea exposure throughout the treatment period, which provides reassurance that changes in voxelotor efficacy parameters were not confounded by changes in compliance with hydroxyurea.

In addition, a study quantifying the impact of raising hemoglobin on transcranial Doppler (TCD) flow velocity levels in a real-world setting provides increased confidence in the probability of success of GBT’s planned post-approval confirmatory study of voxelotor. The study analyzed data from children with SCD receiving treatment with hydroxyurea who participated in the Sickle Cell Clinical Research and Intervention Program (SCCRIP), a longitudinal lifetime cohort study. Over an observation period of up to four years, results showed that a therapeutic rise in hemoglobin was significantly associated with a reduction in TCD levels. Specifically, a 1 g/dL increase in hemoglobin was associated with a 14 cm/sec reduction in TCD level.

Additional abstracts accepted for presentation at ASH 2019 highlight:

- Voxelotor administered to pediatric patients at the targeted therapeutic dose improved red blood cell functionality;
- A voxelotor analog with comparable effects on hemoglobin oxygen affinity showed reduced brain hypoxic injury in an SCD mouse model;
- An association between low hemoglobin and renal disease based on data from the Globin Research Network for Data and Discovery (GRNDaD) sickle cell registry; and
- The economic burden of end organ damage among patients with SCD in the United States.

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

Saturday, December 7

Poster Session: 114. Hemoglobinopathies, Excluding Thalassemia—Clinical: Poster I
Abstract #130767: Concomitant Hydroxyurea and Voxelotor: Results from the HOPE Study
Presenter: Russell Ware, M.D., Ph.D., Cincinnati Children’s Hospital Medical Center
Time: 5:30-7:30 p.m. ET
Location: Hall B

Poster Session: 114. Hemoglobinopathies, Excluding Thalassemia—Clinical: Poster I
Abstract #130802: Correlation of Voxelotor Exposure with Hemoglobin Response and Measures of Hemolysis in Patients from the HOPE Study
Presenter: Jo Howard, MB BChir, MRCP, FRCPath, Guy’s and St. Thomas’ NHS Foundation Trust and King’s College London
Time: 5:30-7:30 p.m. ET
Location: Hall B

Poster Session: 114. Hemoglobinopathies, Excluding Thalassemia—Clinical: Poster I
Abstract #131177: Transcranial Doppler Velocities Conversion Rate Based on Increasing Hemoglobin Concentration: Analysis from the SCCRIP Cohort Study
Presenter: Jeremie Estepp, M.D., St. Jude Children’s Research Hospital

Time: 5:30-7:30 p.m. ET
Location: Hall B

Sunday, December 8

Poster Session: 114. Hemoglobinopathies, Excluding Thalassemia—Clinical: Poster II
Abstract #124933: Chronic Kidney Disease is Under-Screened in SCD and Mild Albuminuria is Associated with a Drop in Hemoglobin: A Report from the GRNDaD Sickle Cell Registry
Presenter: Elizabeth Williams, B.A., Johns Hopkins School of Medicine
Time: 6-8 p.m. ET
Location: Hall B

Poster Session: 114. Hemoglobinopathies, Excluding Thalassemia—Clinical: Poster II
Abstract #129026: Incidence of Vaso-occlusive Crisis Does Not Increase with Achieving Higher Hemoglobin Levels on Voxelotor Treatment or After Discontinuation: Analyses of the HOPE Study
Presenter: Elliott Vichinsky, M.D., UCSF Benioff Children's Hospital Oakland
Time: 6-8 p.m. ET
Location: Hall B

Poster Session: 114. Hemoglobinopathies, Excluding Thalassemia—Clinical: Poster II
Abstract #129351: Improvement in Red Blood Cell Physiology in Children with Sickle Cell Anemia Receiving Voxelotor
Presenter: Satheesh Chonat, M.D., Aflac Center & Blood Disorders Center of Children's Healthcare of Atlanta and the Department of Pediatrics, Emory University
Time: 6-8 p.m. ET
Location: Hall B

Poster Session: 901. Health Services Research—Non-Malignant Conditions: Poster II
Abstract #127173: Economic Burden of End Organ Damage Among Patients with Sickle Cell Disease in the US
Presenter: Xue Song, IBM Watson Health
Time: 6-8 p.m. ET
Location: Hall B

Monday, December 9

Poster Session: 113. Hemoglobinopathies, Excluding Thalassemia—Basic and Translational Science: Poster III
Abstract #129282: Pharmacological Increase of Hb-O2 Affinity with a Voxelotor Analog Does Not Decrease Brain Tissue pO_2 or Limit O_2 Extraction in Brain Tissues of Sickle Cell Mice
Presenter: Kobina Dufu, Ph.D., GBT
Time: 6-8 p.m. ET
Location: Hall B

About Sickle Cell Disease
SCD is a lifelong inherited blood disorder caused by a genetic mutation in the beta-chain of hemoglobin, which leads to the formation of abnormal hemoglobin known as sickle hemoglobin (HbS). In its deoxygenated state, HbS has a propensity to polymerize, or bind together, forming long, rigid rods within a red blood cell (RBC). The polymer rods deform RBCs to assume a sickled shape and to become inflexible, which causes hemolytic anemia (the destruction of RBCs) that can lead to multi-organ damage and early death. This sickling process also causes blockage in capillaries and small blood vessels. Beginning in childhood, SCD patients typically suffer unpredictable and recurrent episodes or crises of severe pain due to blocked blood flow to organs, which often lead to psychosocial and physical disabilities.

About Voxelotor in Sickle Cell Disease
Voxelotor (previously called GBT440) is being developed as an oral, once-daily therapy for patients with SCD. Voxelotor works by increasing hemoglobin's affinity for oxygen. Since oxygenated sickle hemoglobin does not polymerize, GBT believes voxelotor blocks polymerization and the resultant sickling of red blood cells. With the potential to improve hemolytic anemia and oxygen delivery, GBT believes that voxelotor may potentially modify the course of SCD. In recognition of the critical need for new SCD treatments, the U.S. Food and Drug Administration (FDA) has granted voxelotor 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 voxelotor in its Priority Medicines (PRIME) program, and the European Commission (EC) has designated voxelotor as an orphan medicinal product for the treatment of patients with SCD.

GBT is currently evaluating voxelotor in the HOPE (Hemoglobin Oxygen Affinity Modulation to Inhibit HbS PolymErization) Study, a Phase 3 clinical study in patients age 12 and older with SCD. Additionally, voxelotor is being studied in the ongoing Phase 2a HOPE-KIDS 1 Study, an open-label, single- and multiple-dose study in pediatric patients (age 4 to 17) with SCD. HOPE-KIDS 1 is assessing the safety, tolerability, pharmacokinetics and exploratory treatment effect of voxelotor.

About GBT
GBT is a clinical-stage biopharmaceutical company determined to discover, develop and deliver innovative treatments that provide hope to underserved patient communities. GBT is developing two therapies for the potential treatment of sickle cell disease, including its late-stage product candidate, voxelotor, as an oral, once-daily therapy. 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 about GBT's development plans for voxelotor and the potential benefits of voxelotor for SCD patients and other statements containing the words "anticipate," "planned," "believe," "forecast," "estimated," "expected," and "intend," among others. 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 the availability of, and sufficiency of data to support, accelerated regulatory approval, the therapeutic potential and safety profile of voxelotor, including the potential to be a disease-modifying therapy for SCD, the potential for voxelotor to be approved and to become a new standard of care for treating adolescents

and adults with SCD, the ability to implement and complete clinical development plans for voxelotor, the ability to generate and report data from our past, ongoing and potential future studies of voxelotor, regulatory review and actions relating to voxelotor, the potential commercial launch of voxelotor, possible results from a planned post-approval confirmatory study, and the timing of these events, 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 GBT's 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, the risks that GBT's clinical and preclinical development activities may be delayed or terminated for a variety of reasons, that results of clinical trials may be subject to differing interpretations, that regulatory authorities may disagree with GBT's clinical development plans or require additional studies or data to support further clinical investigation of GBT's product candidates, that drug-related adverse events may be observed in clinical development, and that data and results may not meet regulatory requirements or otherwise be sufficient for further development, regulatory review or approval, along with those risks set forth in GBT's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, and in GBT's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, 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.

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