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): December 3, 2018

Global Blood Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-37539**	**27-4825712**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

171 Oyster Point Blvd., Suite 300, South San Francisco, CA 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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 December 3, 2018, Global Blood Therapeutics, Inc. issued a press release titled "GBT Announces Positive 24-week Results from Phase 3 HOPE Study Demonstrating Clinically and Statistically Significant Improvements in Hemoglobin and Clinical Measures of Hemolysis and a Favorable Safety Profile" (the "Press Release"). A copy of the Press Release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated December 3, 2018

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: December 3, 2018

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated December 3, 2018

EXHIBIT 99.1

GBT Announces Positive 24-week Results from Phase 3 HOPE Study Demonstrating Clinically and Statistically Significant Improvements in Hemoglobin and Clinical Measures of Hemolysis and a Favorable Safety Profile

Interim Analysis of Data from 1500 mg Cohort of HOPE-KIDS 1 Study Consistent with Phase 3 HOPE- Results in Demonstrating Improvement in Hemoglobin and Clinical Measures of Hemolysis and Favorable Safety in Pediatric Patients

Company to Host Investor Webcast Today, Monday, December 3, at 12:00 p.m. PT/3:00 p.m. ET, to Discuss Data

SOUTH SAN FRANCISCO, Calif., Dec. 03, 2018 (GLOBE NEWSWIRE) -- Global Blood Therapeutics, Inc. (GBT) (Nasdaq: GBT) today announced updated efficacy and safety results from Part A of its Phase 3 HOPE Study of voxelotor in patients age 12 and older with sickle cell disease (SCD). Preliminary results from 154 adolescents and adults with SCD treated with voxelotor for 24 weeks demonstrated rapid, robust and sustained improvements in hemoglobin levels and measures of hemolysis with a favorable safety and tolerability profile. The findings will be presented in an oral session today at the 60th American Society of Hematology (ASH) Annual Meeting & Exposition in San Diego, Calif.

“These longer-term efficacy and safety data from more than 150 patients enrolled in the HOPE Study continue to support the potential of voxelotor to be a disease-modifying treatment for SCD. These major improvements in anemia and hemolysis have the potential to prevent the chronic organ damage that is the leading cause of death in patients with SCD in the United States,” said Elliott Vichinsky, M.D., lead investigator of the HOPE Study and Director of Hematology/Oncology at UCSF Benioff Children’s Hospital in Oakland, Calif. “In addition to the large improvements in hemolytic anemia, I am greatly encouraged in seeing a very good safety profile.”

“These data from the Phase 3 HOPE Study, including the clinically meaningful and statistically significant increase in hemoglobin, have been a key element in the discussions with the FDA which led to the agency’s agreement with GBT’s proposal for voxelotor under the subpart H accelerated approval pathway,” said Ted W. Love, M.D., president and chief executive officer of GBT. “To further support our NDA submission, we are continuing to generate efficacy and safety data on an additional 118 patients in the HOPE Study.”

Results from Part A of the Hemoglobin Oxygen Affinity Modulation to Inhibit HbS Polymerization (HOPE) Trial (GBT440-031) at 24-weeks, a Placebo-Controlled Randomized Study Evaluating Voxelotor (GBT440) in Adults and Adolescents with Sickle Cell Disease (abstract #118508)
GBT previously reported top-line results from the global Phase 3 HOPE Study showing the trial achieved its primary endpoint of an improvement in hemoglobin greater than 1 g/dL with voxelotor 1500 mg compared with placebo at 12 weeks. An updated efficacy and safety analysis of the 154 patients in Part A at 24 weeks will be presented in an oral session at ASH 2018. Key findings include the following:

- 65 percent of patients taking voxelotor 1500 mg ($p<0.0001$) and 33 percent of patients taking voxelotor 900 mg ($p=0.0159$) achieved a greater than 1 g/dL increase in hemoglobin at 24 weeks versus 10 percent of patients taking placebo.
- Hemoglobin improved rapidly at the earliest timepoint measured (2 weeks) and was sustained through 24 weeks.
- Voxelotor 1500 mg increased hemoglobin to a mean of 10 g/dL at 24 weeks from a baseline of 8.6 g/dL, consistent with a clinically meaningful improvement in anemia.
- The improvement in hemoglobin was similar in patients with or without background use of hydroxyurea. Approximately 64 percent of patients enrolled in Part A were receiving hydroxyurea at study entry and throughout the study.
- Improvements in hemoglobin, reticulocytes and bilirubin occurred with both voxelotor doses, further demonstrating an improvement in hemolysis consistent with inhibition of Hb polymerization.
- There were fewer vaso-occlusive crises (VOC) despite substantial increases in hemoglobin. Specifically, there were numerically fewer VOC episodes and a lower VOC incidence rate (per person-year) in both voxelotor doses than in the placebo group.
- Voxelotor was generally safe and well tolerated with similar safety profiles between the two doses. There was no evidence of impairment of tissue oxygenation at either dose.

Efficacy and Safety of 1500mg Voxelotor in a Phase 2a Study (GBT440-007) in Adolescents with Sickle Cell Disease (abstract #117510)
The HOPE-KIDS 1 Study (GBT440-007), an ongoing open-label, single- and multiple-dose Phase 2a study is evaluating the safety, tolerability, pharmacokinetics and exploratory treatment effect of voxelotor in adolescents ages 4 to 17 with SCD. Part A of the study evaluated a single 600 mg dose of voxelotor in 13 patients ages 6 to 17 years, while Part B was designed to explore voxelotor at doses of 900 mg and 1500 mg per day administered to 36 patients ages 12 to 17 for 24 weeks. Part C of the study is currently enrolling and will evaluate a single 1500 mg dose (or weight-based equivalent) in up to 50 patients ages 4 to 17 years for up to 48 weeks. We plan to present data from Part C at a future scientific conference.

The Part B results being presented in an oral session at ASH 2018 are an interim analysis of data from patients treated with voxelotor 1500 mg. This presentation includes safety data for 15 patients and efficacy data for 11 patients (who had completed 16 weeks of treatment). Key findings include the following for voxelotor 1500 mg:

- Increased hemoglobin levels and improved clinical measures of hemolysis, as evaluated by changes from baseline in hemoglobin, percent of reticulocytes, and percent of unconjugated bilirubin.

- 55 percent of patients (6 of 11) achieved a hemoglobin response >1 g/dL at week 16 with a median hemoglobin change from baseline of 1.1 g/dL.

- 12 patients had normal transcranial doppler (TCD) velocity at baseline, and all patients remained normal when assessed at week 12. One patient with a conditional TCD velocity at baseline normalized at week 24 of treatment, corresponding to a decrease in stroke risk category, with concordant improvements in hemoglobin and reticulocytes observed.

- Favorable safety and tolerability profile in adolescents, consistent with results in adults. There were no drug-related discontinuations due to adverse events. There was no evidence of impairment of tissue oxygenation.

Additional data presented at ASH 2018 support GBT’s sickle cell disease program:

- Results of a systematic literature review and meta-analysis of the consequences of low hemoglobin were presented in an oral session on Saturday, December 1 (abstract #117261). Results showed a statistically significant relationship between chronic anemia and negative clinical outcomes in SCD patients. Specifically, low hemoglobin levels increased the risk of stroke, kidney disease, elevated estimated pulmonary artery systolic pressure and premature death. Hemoglobin was significantly lower by approximately 0.4 to 1.0 g/dL among patients experiencing negative outcomes. Further modeling of these data predicted that an increase in hemoglobin of 1 g/dL or greater might reduce the risk of stroke by 41 percent and of mortality by 64 percent.

- A meta-analysis of data on the societal costs of SCD in the United States will be presented in a poster session later today (abstract #119420). Results showed that individuals with SCD experience markedly reduced life expectancy, diminished quality-adjusted life expectancy, and lower lifetime earnings than individuals without SCD. Specifically, the study found that people with SCD are estimated to live two decades less than those without SCD, and this reduced life expectancy translates into approximately $700,000 in lost lifetime earnings.

Investor Webcast Details
GBT will host an investor event webcast today, Monday, December 3, 2018, at 12:00 p.m. PT/3:00 p.m. ET to review the data being presented at the 2018 ASH Annual Meeting. The event will be webcast live and available for replay from GBT's website at www.gbt.com in the Investors section.

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. The HOPE-KIDS 1 Study 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
Statements we make 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. We intend these forward-looking statements, including statements regarding our plan to submit an NDA for voxelotor under an accelerated approval pathway, the availability of, and sufficiency of our data to support, accelerated regulatory approval, the therapeutic potential and safety profile of voxelotor, including the potential for voxelotor to be a disease-modifying treatment for SCD, the potential for voxelotor to raise hemoglobin and prevent organ damage in SCD patients, our ability to implement and complete our clinical development plans for voxelotor, our ability to engage in continued discussions with the FDA and the outcome of our discussions with the FDA, the potential for an increase in hemoglobin of 1 g/dL or greater to reduce the risk of stroke and mortality in patients with SCD, our ability to generate and report data from our ongoing and potential future studies of voxelotor (including additional data from patients enrolled in our ongoing Phase 3 HOPE Study, and data in our ongoing Phase 2a HOPE-KIDS 1 Study), , regulatory review and actions relating to voxelotor, 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 are making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. We 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 our control including, without limitation, the risks that our 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 our clinical development plans or require additional studies or data to support further clinical investigation of our 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, as well as discussions of potential risks, uncertainties and other important factors in our subsequent filings with the U.S. Securities and Exchange Commission. Except as required by law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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