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 14, 2019

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. [ ]

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

Item 8.01. Other Events.

On June 14, 2019, Global Blood Therapeutics, Inc. (GBT) announced new results from its Phase 3 HOPE (Hemoglobin Oxygen Affinity Modulation to Inhibit HbS PolymErization) Study of voxelotor in patients ages 12 and older with sickle cell disease (SCD). The findings from 274 adolescents and adults treated with voxelotor showed the HOPE Study met its primary endpoint of an improvement in hemoglobin greater than 1 g/dL at 24 weeks with voxelotor 1500 mg compared with placebo, with a favorable safety and tolerability profile. In the study, voxelotor provided a rapid, statistically significant and sustained improvement in hemoglobin levels and reduced the incidence of worsening anemia and hemolysis.

The new results from the HOPE Study include 24-week efficacy data from 274 patients ages 12 and older with SCD enrolled in the study from 60 institutions across 12 countries. The data showed that patients treated with once-daily oral voxelotor demonstrated rapid, robust and sustained improvements in anemia, as measured by the increase in hemoglobin from baseline to 24 weeks compared to placebo (see Table 1). The mean increase in hemoglobin levels with voxelotor compared to placebo was similar with or without concurrent hydroxyurea treatment.

These results from the HOPE Study are reported using both intention-to-treat (ITT) and per-protocol (PP) analyses. The PP analysis is based on patients who completed the primary endpoint visit of 24 weeks, whereas the more conservative ITT analysis defines all patients with missing data at 24 weeks as non-responders. Previously, GBT had reported HOPE Study results as assessed only in the PP population. As discussed with the U.S. Food and Drug Administration (FDA), the HOPE Study primary endpoint – hemoglobin response at 24 weeks – is to be assessed in an ITT population for the New Drug Application (NDA). The benefit of voxelotor is highly statistically significant irrespective of ITT or PP analysis, and both analyses are presented below.

Table 1

	Intention-To-Treat (ITT) Analysis			**Per-Protocol (PP) Analysis**		
	N	*% with >1 g/dL Increase in Hb*	*Mean* Change in Hb from Baseline to 24 Weeks*	N	*% with >1 g/dL Increase in Hb*	*Mean Change in Hb from Baseline to 24 Weeks*
1500 mg voxelotor	90	51.1% (p<0.001)	1.1 g/dL (p<0.001)	74	59.5% (p<0.001)	1.3 g/dL (p<0.001)
900 mg voxelotor	92	32.6% (p<0.001)	0.6 g/dL (p<0.001)	79	38.0% (p<0.001)	0.7 g/dL (p<0.001)
Placebo	92	6.5%	-0.1 g/dL	76	9.2%	0 g/dL

*Adjusted for baseline stratification factors.
P-value is for comparison versus placebo; not adjusted for multiplicity.

The ITT analysis of all 274 patients at 24 weeks showed:

- Hemoglobin improved rapidly from baseline to the earliest timepoint measured (2 weeks) with voxelotor 1500 mg and was sustained through 24 weeks ($p<0.001$ vs. placebo). The improvement in hemoglobin was similar in patients with or without background use of hydroxyurea.
- Voxelotor 1500 mg increased hemoglobin levels to a mean of 9.8 g/dL at 24 weeks from a baseline of 8.6 g/dL, consistent with a clinically meaningful improvement in anemia.
- Improvements from baseline in hemoglobin, percent reticulocytes and indirect bilirubin occurred with both voxelotor doses, further demonstrating an improvement in hemolysis consistent with a dose-related inhibition of hemoglobin polymerization.
- There were numerically fewer vaso-occlusive crises (VOCs) and a lower annualized incidence rate (per person-year) of VOCs in both voxelotor dose groups than in the placebo group, despite the significant increases in hemoglobin with voxelotor treatment.
- Voxelotor was generally safe and well tolerated, with both doses having similar safety profiles. Treatment discontinuation rates did not differ substantially among the three trial groups. There was no evidence of impairment of tissue oxygenation at either dose of voxelotor.

Additional data further support GBT's voxelotor program in SCD:

- Clinical data from an investigator-initiated ancillary study of three adolescents with SCD enrolled 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, showed that all participants had unchanged or lower cerebral blood flow as measured by functional MRI with angiography while receiving voxelotor, suggesting that cerebral blood flow was maintained or improved with administration of voxelotor. Lower cerebral blood flow with rising hemoglobin levels suggests improved oxygen delivery to the brain.
- An *in vitro* study of the mechanism of voxelotor showed that oxygen is released from voxelotor-modified hemoglobin under deoxygenated conditions and that normal physiological compensatory mechanisms to enhance oxygen delivery are not disrupted. This finding suggests that treatment with voxelotor maintains oxygen delivery to tissues and supports the safety of this investigational treatment.

Forward-Looking Statements

Certain statements in this Form 8-K 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 we make in this Form 8-K 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 regulatory 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 to be a disease-modifying therapy for SCD, our plan to initiate a TCD confirmatory study, the potential for TCD flow velocity to serve as an acceptable primary endpoint in a confirmatory study, the potential for voxelotor to become a new standard of care for treating adolescents and adults with SCD, our ability to implement and complete our clinical development plans for voxelotor, 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 data from patients enrolled in our Phase 3 HOPE Study, and data from our ongoing Phase 2a HOPE-KIDS 1 Study), regulatory review and actions relating to voxelotor, our potential commercial launch of 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, 2018, and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, 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.

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 14, 2019

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