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 7.01. Regulation FD Disclosure.

On December 3, 2018, Global Blood Therapeutics, Inc. issued a press release titled "GBT Announces U.S. FDA Agrees with its Proposal Relating to Accelerated Approval Pathway for Voxelotor for the Treatment of Sickle Cell Disease and GBT Plans to Submit New Drug Application (NDA)" (the "Press Release"). A copy of the Press Release is furnished as Exhibit 99.1 to this report on Form 8-K.

The information in this Item 7.01 and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

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 U.S. FDA Agrees with its Proposal Relating to Accelerated Approval Pathway for Voxelotor for the Treatment of Sickle Cell Disease and GBT Plans to Submit New Drug Application (NDA)

Pre-NDA Meeting to be Requested for First Quarter of 2019

Company to Host Conference Call and Webcast Today, Monday, December 3,
at 5:30 a.m. PT/8:30 a.m. ET

SOUTH SAN FRANCISCO, Calif., Dec. 03, 2018 (GLOBE NEWSWIRE) -- Global Blood Therapeutics, Inc. (GBT) (Nasdaq: GBT) today announced that the U.S. Food and Drug Administration (FDA) has informed GBT through discussions and written correspondence that the agency agrees with the Company's proposal relating to use of an accelerated approval pathway for voxelotor for the treatment of sickle cell disease (SCD). GBT plans to submit an NDA for voxelotor for the treatment of SCD under this pathway. GBT proposed that by raising hemoglobin, voxelotor is reasonably likely to reduce strokes in SCD patients. As part of these discussions, the FDA agreed that transcranial doppler (TCD) flow velocity would be an acceptable primary endpoint in a post-approval confirmatory study to demonstrate stroke risk reduction.

GBT plans to request a pre-NDA meeting for the first quarter of 2019 and intends to provide further details regarding its plans and timing for an NDA submission as well as additional specifics on the TCD confirmatory study following this meeting.

"Gaining U.S. regulatory alignment for voxelotor under the accelerated approval pathway is a significant achievement for SCD patients and their families. The FDA has been innovative in considering new endpoints and accelerated approvals to bring desperately needed new therapies to other serious rare diseases. The FDA's openness to now apply this same approach to SCD is well founded based upon the compelling evidence that more severe hemolytic anemia is associated with higher morbidity and mortality," said Ted W. Love, M.D., president and chief executive officer of GBT. "We commend the FDA, and the broader SCD community, for its continuous commitment toward understanding the critical need for new clinical endpoints that support the development of much needed new therapies to treat this devastating disease."

"Acute and chronic brain injury that frequently manifests as cognitive disorders and includes severe complications such as stroke has a major impact on a patient's quality of life and future productivity. Our current approach to mitigating these risks via chronic transfusions has significant downsides and associated lifelong complications," said Kim Smith-Whitley, M.D., clinical director of the Division of Hematology and professor of pediatrics at the Perelman School of Medicine at the University of Pennsylvania, and director of the Comprehensive Sickle Cell Center at the Children's Hospital of Philadelphia. "A once-daily, oral therapy that has the potential to safely improve the anemia of SCD and thereby preserve brain function would be a major breakthrough. I am encouraged by the FDA's acknowledgement of the urgent need for new treatment options for the SCD community."

"Despite the complex nature of the disease, SCD patients have had limited treatment options for decades, and it is critical that we continue to advance the development of new medicines that address not only the symptoms, but also the underlying cause and the chronic and cumulative damage to organs," said Alexis Thompson, M.D., president of the American Society of Hematology. "The recent workshop we held in partnership with the FDA emphasized the need for new clinical endpoints beyond measuring pain and pain crisis and is an important step towards allowing us to better evaluate the impact of new innovative therapies for SCD."

Investor Conference Call and Webcast Details
GBT will host an investor conference call and webcast today, Monday, December 3, at 5:30 a.m. PT/8:30 a.m. ET, to provide information about the voxelotor regulatory update. To participate in the conference call, please dial (844) 471-0808 (domestic) or (480) 696-7309 (international) and refer to conference ID 9327146. The webcast will be available live and for replay on GBT's website at www.gbt.com in the Investors section. A replay of the webcast will be archived and available for replay for one month following the event.

About Accelerated Approval
The FDA grants accelerated approval under subpart H for new drugs that address serious or life-threatening illnesses and appear to provide meaningful therapeutic benefit to patients over existing treatments on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. Drugs approved under subpart H are subject to preapproval of promotional materials and are required to be further evaluated in post-marketing studies to confirm clinical benefit and are subject to expedited withdrawal if post-marketing studies fail to confirm such benefit.

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 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 raise hemoglobin and thereby reduce stroke risk in SCD patients, the potential for TCD flow velocity to serve as an acceptable primary endpoint in a confirmatory study, our plan to request a pre-NDA meeting, the FDA's innovation and openness in considering new endpoints and accelerated approval for new SCD therapies and the potential impact thereof, the potential impact of an SCD therapy that safely improves the anemia of SCD and thereby preserves brain function, 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 those discussions, 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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