
**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 7, 2019

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.)

**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 2.02. Results of Operations and Financial Condition.

On November 7, 2019, Global Blood Therapeutics, Inc. reported recent business progress and its financial results for the third quarter ended September 30, 2019. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1	Press Release, dated November 7, 2019, furnished herewith
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 7, 2019

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

GBT Reports Recent Business Progress and Third Quarter 2019 Financial Results

SOUTH SAN FRANCISCO, Calif., Nov. 07, 2019 (GLOBE NEWSWIRE) -- Global Blood Therapeutics, Inc. (GBT) (NASDAQ: GBT) today reported recent business progress and financial results for the third quarter ended September 30, 2019.

"With the recent FDA acceptance of our NDA filing for voxelotor, we are an important step closer to potentially transforming the treatment paradigm for sickle cell disease. We remain focused on our launch preparations, including the buildout of our commercial organization with the hiring of the entire field team, and steadfast in our mission to deliver to the sickle cell community a breakthrough therapy that has the potential to modify the course of this complex disease," said Ted W. Love, M.D., president and chief executive officer of GBT. "We remain on track to initiate our post-approval confirmatory study of voxelotor, which utilizes transcranial Doppler flow velocity as the primary endpoint, prior to year-end. We also look forward to sharing several post-hoc analyses of data from the HOPE Study, as well as other sickle cell disease research, at the upcoming ASH Annual Meeting."

Recent Business Progress

Sickle Cell Disease (SCD)

- Announced that the U.S. Food and Drug Administration (FDA) accepted for filing the company's New Drug Application (NDA) seeking accelerated approval for voxelotor for the treatment of SCD. The FDA granted the NDA Priority Review and assigned a Prescription Drug User Fee Act target action date of February 26, 2020.
- Hired 65 Sickle Cell Therapeutic Specialists, bringing the company's field team to approximately 75 members.
- Received acceptance of eight abstracts at the 61st American Society of Hematology (ASH) Annual Meeting & Exposition, which will be held December 7-10 in Orlando.
- Presented results of the first of several planned post-hoc analyses of data from the Phase 3 HOPE Study. The findings suggest that voxelotor resolved or reduced the severity of existing leg ulcers and decreased the incidence of new leg ulcers in patients with SCD. The exploratory post-hoc analysis was presented at the 13th Annual Academy for Sickle Cell and Thalassemia Conference in London.
- Presented four abstracts and sponsored a lunch symposium during the 47th Annual National Sickle Cell Disease Association of America Convention in Baltimore.
- Hosted two SCD-focused conferences:
 - The 2019 SCD Access to Care Summit in Washington, D.C., which brought together members of the SCD community to discuss solutions toward improving access to care; and
 - The 8th Annual SCD Therapeutics Conference, which highlighted the latest medical advances and future trends in the treatment of patients with SCD.

Corporate

- Appointed three members of the company's senior management team to the following positions:
 - Josh Lehrer, M.D., to chief medical officer. Dr. Lehrer has played a critical role in overseeing the clinical development of voxelotor since he joined the company in 2013.
 - Peter Radovich to executive vice president, operations. Mr. Radovich has led the manufacturing, quality assurance and project management functions for GBT since he joined the company in 2014 and has been integral to the development of voxelotor.
 - Jonathan Sorof, M.D., to senior vice president, head of medical affairs and program team leader, voxelotor. Dr. Sorof has made tremendous contributions in building the medical and regulatory affairs teams since he joined the company in 2017.

Financial Results for the Three Months Ended September 30, 2019

Cash, cash equivalents and marketable securities totaled \$683.1 million at September 30, 2019, compared with \$591.8 million at December 31, 2018.

Net loss for the three months ended September 30, 2019, was \$64.5 million compared with \$43.1 million for the same period in 2018. Basic and diluted net loss per share for the three months ended September 30, 2019, was \$1.07 compared with \$0.83 for the same period in 2018. Operating expenses increased from the second quarter to the third quarter of 2019. GBT continues to expect its net loss to significantly increase in the fourth quarter of 2019. The increase will be primarily driven by expenses related to the continued buildout of the company's commercial infrastructure as it prepares for the potential commercial launch of voxelotor, the expansion of its manufacturing efforts for voxelotor, the commencement of additional clinical studies of voxelotor in SCD, and the advancement of its pipeline programs, including its inclacumab program.

Research and development (R&D) expenses for the three months ended September 30, 2019, were \$39.1 million compared with \$33.0 million for the same period in 2018. The increase in R&D expenses is primarily attributable to increased employee-related costs, including non-cash stock compensation expense, and increased costs associated with NDA submission activities. Total R&D non-cash stock compensation expense incurred for the three months ended September 30, 2019, was \$5.1 million compared with \$2.8 million for the same period in 2018.

General and administrative (G&A) expenses for the three months ended September 30, 2019, were \$29.7 million compared with \$12.5 million for the same period in 2018. The increase in G&A expenses is primarily attributable to increased employee-related costs, including non-cash stock compensation expense, and increased professional and consulting services associated with the buildout of the company's commercial operations. Total G&A non-cash stock compensation expense incurred in the three months ended September 30, 2019, was \$7.3 million compared with \$4.1 million for the same period in 2018.

About Global Blood Therapeutics

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](https://twitter.com/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 delivering a breakthrough therapy that has the potential to modify the course of SCD, regulatory review and actions relating to voxelotor, including the availability of and sufficiency of data to support accelerated regulatory approval of voxelotor, the therapeutic potential and safety profile of voxelotor for SCD, including the potential to be a disease-modifying therapy, to transform the treatment paradigm and to become a new standard of care, implementing and completing clinical development plans for voxelotor, generating and reporting data and analyses from past, ongoing and potential future studies of voxelotor, the potential commercial launch of voxelotor, GBT’s commercial infrastructure and manufacturing efforts, GBT’s pipeline programs, GBT’s future financial results, 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 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.

GLOBAL BLOOD THERAPEUTICS, INC.

**Condensed Consolidated Statements of Operations
(Unaudited)**

(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 39,088	\$ 33,026	\$ 109,564	\$ 94,543
General and administrative	29,654	12,450	72,503	36,115
Total operating expenses	68,742	45,476	182,067	130,658
Loss from operations	(68,742)	(45,476)	(182,067)	(130,658)
Other income (expense):				
Interest income, net	4,226	2,480	11,422	5,768
Other expenses, net	(31)	(72)	(146)	(101)
Total other income, net	4,195	2,408	11,276	5,667
Net loss	\$ (64,547)	\$ (43,068)	\$ (170,791)	\$ (124,991)
Basic and diluted net loss per common share	\$ (1.07)	\$ (0.83)	\$ (2.96)	\$ (2.47)
Weighted-average number of shares used in computing basic and diluted net loss per common share	60,098,093	52,050,232	57,637,318	50,536,860

GLOBAL BLOOD THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(In thousands)

	September 30, 2019	December 31, 2018
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 267,604	\$ 275,357
Short-term marketable securities	335,500	202,177
Prepaid expenses and other current assets	12,699	8,246
Total current assets	615,803	485,780
Property and equipment, net	14,337	14,981
Long-term marketable securities	80,000	114,281

Operating lease right-of-use assets	13,845	—
Other assets	3,363	2,601
Total assets	<u>\$ 727,348</u>	<u>\$ 617,643</u>
Liabilities and Stockholders' Equity		
Current liabilities	\$ 41,193	\$ 33,773
Operating lease liabilities, noncurrent	23,691	—
Other liabilities, noncurrent	4,367	11,071
Total liabilities	<u>69,251</u>	<u>44,844</u>
Total stockholders' equity	658,097	572,799
Total liabilities and stockholders' equity	<u>\$ 727,348</u>	<u>\$ 617,643</u>

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