
**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, 2018

Global Blood Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-37539
(Commission File Number)

27-4825712
(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 2.02. Results of Operations and Financial Condition.

On November 6, 2018, Global Blood Therapeutics, Inc. reported recent business progress and announced its financial results for the third quarter ended September 30, 2018. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated November 6, 2018, furnished herewith.

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, 2018

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

EXHIBIT INDEX

Exhibit No.	Description
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99.1	Press release, dated November 6, 2018, furnished herewith.
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GBT Reports Recent Business Progress and Provides Third Quarter 2018 Financial Results

SOUTH SAN FRANCISCO, Calif., Nov. 06, 2018 (GLOBE NEWSWIRE) – Global Blood Therapeutics, Inc. (GBT) (NASDAQ: GBT) today reported business progress and financial results for the third quarter ended September 30, 2018.

“Voxelotor has the potential to be a transformative treatment for the sickle cell community. We remain in active discussions with the U.S. Food and Drug Administration regarding the potential for accelerated approval of voxelotor. We continue to believe that voxelotor meets the standard for accelerated approval based on the statistically significant and clinically meaningful increase in hemoglobin and reduction in hemolysis,” said Ted W. Love, M.D., president and chief executive officer of GBT. “Our guidance remains that we expect to provide a regulatory update by the end of this year. Additionally, we look forward to reporting an expanded data set from Part A of the HOPE Study and data from the 1500 mg cohort of the HOPE-KIDS 1 Study at the American Society of Hematology Annual Meeting later this year.”

Recent Business Progress

Sickle Cell Disease (SCD)

- Received acceptance of three oral presentations and one poster presentation at the upcoming 60th American Society of Hematology (ASH) Annual Meeting and Exposition, which will be held December 1-4 in San Diego.
- Presented three oral presentations during the 46th Annual National Sickle Cell Disease Association of America (SCDAA) Convention in Baltimore.
- Hosted two SCD-focused conferences: the inaugural Access to Care Summit, designed to bring together members of the SCD community to discuss solutions to improve access to SCD care, and the 7th Annual SCD Therapeutics Conference, which highlighted the latest medical advances and future trends in the treatment of patients with SCD.
- Participated in the FDA-ASH SCD Clinical Endpoints Workshop in Rockville, Maryland. GBT's Senior Vice President of Development Josh Lehrer, M.D., participated in the workshop's industry panel.

Corporate

- Announced an exclusive worldwide licensing agreement with F. Hoffmann-La Roche Ltd. for the development and commercialization of inclacumab, a novel fully human monoclonal antibody against P-selectin. GBT plans to develop inclacumab as a treatment for vaso-occlusive crises in patients with SCD.
- Expanded the management team with the appointment of Heidi L. Wagner as senior vice president, government affairs and policy. Ms. Wagner has more than 15 years of experience, joining GBT from Alexion Pharmaceuticals where she was senior vice president, global government affairs. Previously, she was at Genentech where she managed a broad portfolio of U.S. federal legislative and regulatory policy issues.

Financial Results for the Three Months Ended September 30, 2018

Cash, cash equivalents and marketable securities totaled \$482.1 million at September 30, 2018, compared with \$329.4 million at December 31, 2017.

Net loss for the three months ended September 30, 2018, was \$43.1 million compared with \$28.6 million for the same period in 2017. Basic and diluted net loss per share for the three months ended September 30, 2018, was \$0.83 compared with \$0.66 for the same period in 2017.

Research and development (R&D) expenses for the three months ended September 30, 2018, were \$33.0 million compared with \$21.0 million for the same period in 2017. The increase in R&D expenses is primarily attributable to increased expenses for the Phase 2a HOPE-KIDS 1 Study and the Phase 3 HOPE Study and the upfront payment under the licensing agreement with Roche for inclacumab. Total R&D non-cash stock compensation expense incurred for the three months ended September 30, 2018, was \$2.8 million compared with \$1.6 million for the same period in 2017.

General and administrative (G&A) expenses for the three months ended September 30, 2018, were \$12.5 million compared with \$8.2 million for the same period in 2017. 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 growth of the Company's operations. Total G&A non-cash stock compensation expense incurred in the three months ended September 30, 2018, was \$4.1 million, compared with \$2.1 million for the same period in 2017.

Operating expenses are expected to increase in Q4 2018 primarily due to manufacturing and pre-commercial activities.

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 the therapeutic potential and safety profile of voxelotor, 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, the availability of accelerated approval, our ability to generate and report data from our ongoing and potential future studies of voxelotor (including our ability to generate additional data from patients enrolled in our ongoing Phase 3 HOPE Study), our plan to report an expanded data set from the HOPE Study and the HOPE-KIDS 1 Study at the ASH Annual Meeting, the sufficiency of our data to support an application for regulatory approval, 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, including the sufficiency of our clinical data and of our primary and other key endpoints in our Phase 3 HOPE Study of voxelotor to support approval, or require additional studies or data to support approval or further clinical investigation of voxelotor, that drug-related adverse events may be observed in clinical development, that data and results may not meet regulatory requirements or otherwise be sufficient for further development, regulatory review or approval, and that we may need to devote additional time and resources to meet these regulatory requirements, 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.

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,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 33,026	\$ 20,952	\$ 94,543	\$ 56,513
General and administrative	12,450	8,228	36,115	20,817
Total operating expenses	<u>45,476</u>	<u>29,180</u>	<u>130,658</u>	<u>77,330</u>
Loss from operations	(45,476)	(29,180)	(130,658)	(77,330)
Other income (expense):				
Interest income, net	2,480	727	5,768	1,856
Other expenses, net	(72)	(104)	(101)	(298)
Total other income, net	<u>2,408</u>	<u>623</u>	<u>5,667</u>	<u>1,558</u>
Net loss	<u>\$ (43,068)</u>	<u>\$ (28,557)</u>	<u>\$ (124,991)</u>	<u>\$ (75,772)</u>
Basic and diluted net loss per common share	<u>\$ (0.83)</u>	<u>\$ (0.66)</u>	<u>\$ (2.47)</u>	<u>\$ (1.81)</u>
Weighted-average number of shares used in computing basic and diluted net loss per common share	<u>52,050,232</u>	<u>43,259,145</u>	<u>50,536,860</u>	<u>41,832,273</u>

GLOBAL BLOOD THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets (In thousands)

	September 30, 2018 (Unaudited)		December 31, 2017	
Assets				
Current assets:				
Cash and cash equivalents	\$	194,891	\$	198,332
Short-term marketable securities		188,337		116,493
Prepaid expenses and other current assets		8,951		9,487
Total current assets		<u>392,179</u>		<u>324,312</u>
Property and equipment, net		16,749		16,571
Long-term marketable securities		98,869		14,607

Other assets	2,614	1,230
Total assets	<u>\$ 510,411</u>	<u>\$ 356,720</u>
Liabilities and Stockholders' Equity		
Current liabilities	\$ 26,927	\$ 26,264
Other liabilities, noncurrent	11,283	11,652
Total liabilities	<u>38,210</u>	<u>37,916</u>
Total stockholders' equity	<u>472,201</u>	<u>318,804</u>
Total liabilities and stockholders' equity	<u>\$ 510,411</u>	<u>\$ 356,720</u>

Contact Information:

Myesha Lacy (investors)
 GBT
 650-351-4730
 investor@gbt.com

Julie Normart (media)
 W2O pure
 559-974-3245
 media@gbt.com