

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, 2017

Bellerophon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

001-36845

47-3116175

(State or Other Jurisdiction of Incorporation)

(Commission
File Number)

(IRS Employer
Identification No.)

184 Liberty Corner Road, Suite 302

Warren, New Jersey

(Address of Principal Executive Offices)

07059

(Zip Code)

Registrant's telephone number, including area code: **(908) 574-4770**

(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 (*see* General Instruction A.2. below):

- ☐ 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 (§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, 2017, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the quarter ended September 30, 2017. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on 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 (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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

99.1 Press Release dated November 7, 2017.

SIGNATURES

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.

BELLEROPHON THERAPEUTICS, INC.

Date: November 7, 2017

By: /s/ Megan Schoeps

Name: Megan Schoeps

Title: Controller and Principal Financial Officer

EXHIBIT INDEX

Exhibit

No.

Description

[99.1](#)

[Press Release dated November 7, 2017 \(furnished and not filed for purposes of Item 2.02\).](#)



Bellerophon Provides Business Update and Reports Third Quarter 2017 Financial Results

Warren, NJ, November 7, 2017 - Bellerophon Therapeutics, Inc. (Nasdaq: BLPH), a clinical-stage biotherapeutics company, today provided a business update and reported financial results for the third quarter ended September 30, 2017.

“We continue to achieve important progress in all three of our INOpulse® clinical development programs,” said Fabian Tenenbaum, Chief Executive Officer of Bellerophon Therapeutics. “In our INOvation-1 Phase 3 trial for Pulmonary Arterial Hypertension (PAH), we now have over 100 sites activated in 17 countries and patient enrollment is progressing as planned. We expect to review both an interim analysis and top-line results from this trial in 2018.”

“We are especially encouraged with the recently announced positive top-line Phase 2 data in patients with Pulmonary Hypertension Associated with Chronic Obstructive Pulmonary Disease (PH-COPD). These results further support the potentially unique role that INOpulse’s targeted vasodilation could have in becoming the first therapy approved for patients suffering from pulmonary hypertension associated with lung diseases, such as PH-COPD and pulmonary hypertension associated with Interstitial Lung Disease (PH-ILD). In order to support the continued development of our robust pipeline, we recently completed a private placement that raised aggregate gross proceeds of approximately \$23.4 million, which will allow the Company to reach multiple key clinical milestones in our ongoing and planned clinical trials,” concluded Mr. Tenenbaum.

Key Recent Highlights

- **Pulmonary Arterial Hypertension:** In the Company’s Phase 3 program for INOpulse® in the treatment of PAH, INOvation-1 will read-out after all subjects have completed 16 weeks of blinded treatment. An interim read-out of the trial is planned when 16-week data is available on approximately 75 subjects. The INOvation-1 study has now been activated in over 100 clinical sites in 17 countries. Enrollment is progressing as planned and both the interim analysis and the top-line results for the study are expected to be available in 2018.

The second Phase 3 study in PAH, INOvation-RW, is a randomized withdrawal study that will recruit approximately 40 subjects directly from INOvation-1, eliminating the need for the recruitment of new study subjects. Bellerophon intends to initiate INOvation-RW in the second half of 2018, with top-line results anticipated in 2019.

- **PH-COPD:** The Company announced positive results from its Phase 2 study for INOpulse in PH-COPD in the third quarter. The study was designed to assess the acute effect of pulsed inhaled nitric oxide (iNO) on targeted vasodilation and the chronic effect (4 weeks) of iNO on hemodynamics and exercise capacity using a dose of 30 mcg/kg IBW/hr (iNO 30). The acute results showed a statistically significant increase (4.2%) in blood vessel volume and a statistically significant correlation in ventilation-vasodilation. The chronic results demonstrated a statistically significant improvement in six-minute walking distance (6MWD) (50.7 meters, $p=0.04$) and a statistically significant reduction in systolic pulmonary arterial pressure (19.9%, $p=0.02$). Bellerophon is currently developing the next

Phase 2b study in PH-COPD in conjunction with its newly formed steering committee, which is chaired by Dr. Raymond Benza of the Cardiovascular Institute at Allegheny General Hospital in Pittsburgh, PA.

- **PH-ILD:** The Company presented positive results from its Phase 2a study for INOpulse for the treatment of PH associated with Idiopathic Pulmonary Fibrosis (PH-IPF) at the American Thoracic Society International Conference in May 2017. The study met its primary endpoint, demonstrating a 15.3% average increase in blood vessel volume ($p < 0.001$) and a significant association between ventilation and vasodilation. In addition, clinically meaningful improvements were seen in systolic pulmonary arterial pressure (14% reduction) and 6MWD (75 meter increase).

A larger Phase 2b study in IPF, as well as other pulmonary fibrotic diseases within ILD, called iNO-PF, is planned to initiate in early 2018, with readout expected by the end of 2018. The study will recruit approximately 40 subjects diagnosed with pulmonary fibrosis, who are either at low or high risk of pulmonary hypertension as determined via echocardiography. Bellerophon has opened a new Investigational New Drug application to conduct this study, and its design has been reviewed and accepted by the U.S. Food and Drug Administration.

- **Capital Raise:** In the third quarter, Bellerophon raised aggregate gross proceeds of approximately \$23.4 million with new and existing investors through a private placement of its common stock and warrants. The financing was led by Puissance Capital Management and Venrock Healthcare Capital Partners, and was supported by certain of the Company's existing investors, including New Mountain Capital and Linde North America, Inc. Bellerophon expects its strengthened cash position to primarily support ongoing development activities, including the completion of the INOVation-1 Phase 3 PAH trial, as well as the planned iNO-PF Phase 2b study in PH-ILD.

Third Quarter 2017 Financial Results

For the third quarter ended September 30, 2017, the Company reported a net loss of \$7.6 million, or \$0.22 per share, compared to a net loss of \$4.2 million, or \$0.30 per share, in the third quarter ended September 30, 2016.

Net loss for the third quarter of 2017 included an increase in the fair value of the Company's common stock warrant liability of \$1.4 million. There was no change in the fair value of common stock warrant liability for the third quarter of 2016, as the warrants were issued in November 2016 and May 2017.

Research and development expenses for the third quarter of 2017 were \$4.4 million, compared to \$2.5 million in the third quarter of 2016. The increase was primarily due to increased spending on the PAH Phase 3 trial.

General and administrative expenses for the third quarter of 2017 were \$1.7 million, essentially flat as compared to the corresponding period of 2016.

Nine-Months Ended September 30, 2017, Financial Results

For the nine-months ended September 30, 2017, the Company reported a net loss of \$30.7 million, or \$0.92 per share, compared to a net loss of \$16.4 million, or \$1.23 per share, in the same nine-month period in 2016.

Net loss for the first nine months of 2017 included an increase in the fair value of the Company's common stock warrant liability of \$13.5 million. There was no change in the fair value of common stock warrant liability for the first nine months of 2016, as the warrants were issued in November 2016 and May 2017.

Research and development expenses for the first nine months of 2017 were \$12.5 million, compared to \$11.5 million in the prior year period. The increase was primarily due to increased trial supply costs related to ongoing clinical programs.

General and administrative expenses for the nine-month period ended September 30, 2017, were \$4.8 million, as compared to \$4.9 million in the prior year period.

Balance Sheet

As of September 30, 2017, the Company had cash, cash equivalents and marketable securities of \$35.5 million, compared to cash, cash equivalents and marketable securities of \$20.0 million at December 31, 2016.

As of September 30, 2017, the Company had \$3.2 million in prepayments of research and development expenses related to its drug supply agreement with Ikaria and its clinical research service agreement with WCT for the INOvation-1 study. The corresponding prepayments balance as of December 31, 2016, was \$7.2 million.

About Bellerophon

Bellerophon Therapeutics is a clinical-stage biotherapeutics company focused on developing innovative therapies at the intersection of drugs and devices that address significant unmet medical needs in the treatment of cardiopulmonary diseases. The Company is currently developing three product candidates under its INOpulse program, a proprietary pulsatile nitric oxide delivery system. The first is for the treatment of pulmonary arterial hypertension (PAH), for which the Company has commenced Phase 3 clinical trials. The second is for the treatment of pulmonary hypertension associated with chronic obstructive pulmonary disease (PH-COPD) and the third candidate is for the treatment of pulmonary hypertension associated with Interstitial Lung Disease (PH-ILD), both of which are in Phase 2 development. For more information, please visit www.bellerophon.com.

Forward-looking Statements

Any statements in this press release about Bellerophon's future expectations, plans and prospects, including statements about the clinical development of its product candidates, regulatory actions with respect to the Company's clinical trials and expectations regarding the sufficiency of the Company's cash balance to fund clinical trials, operating expenses and capital expenditures, and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary or interim results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials will be indicative of the results of later clinical trials, expectations for regulatory approvals, the FDA's substantial discretion in the approval process, availability of funding sufficient for our foreseeable and unforeseeable operating expenses and capital expenditure requirements

and other factors discussed in the “Risk Factors” section of the Company’s most recent filings with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release represent Bellerophon’s views only as of the date of this release and should not be relied upon as representing the Company’s views as of any subsequent date. The Company specifically disclaims any obligation to update any forward-looking statements included in this press release.

Contacts

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Bellerophon Therapeutics, Inc.

Consolidated Balance Sheet

(unaudited, in thousands except share and per share data)

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 32,283	\$ 14,453
Restricted cash	—	150
Marketable securities	3,178	5,571
Prepaid expenses and other current assets	3,934	6,331
Total current assets	39,395	26,505
Restricted cash, non-current	300	307
Other non-current assets	59	1,491
Property and equipment, net	1,116	1,399
Total assets	\$ 40,870	\$ 29,702
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,755	\$ 2,807
Accrued research and development	1,873	2,573
Accrued expenses	1,784	1,115
Total current liabilities	6,412	6,495
Common stock warrant liability	18,784	5,215
Total liabilities	25,196	11,710
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value per share; 125,000,000 shares authorized, 54,960,068 and 31,702,624 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	550	317
Preferred stock, \$0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at September 30, 2017 and December 31, 2016	—	—
Additional paid-in capital	170,275	142,167
Accumulated other comprehensive income (loss)	—	—
Accumulated deficit	(155,151)	(124,492)
Total stockholders' equity	15,674	17,992
Total liabilities and stockholders' equity	\$ 40,870	\$ 29,702

Bellerophon Therapeutics, Inc.

Consolidated Statement of Operations

(unaudited, in thousands except share and per share data)

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	\$ 4,438	\$ 2,472	\$ 12,464	\$ 11,539
General and administrative	1,746	1,745	4,826	4,926
Total operating expenses	6,184	4,217	17,290	16,465
Loss from operations	(6,184)	(4,217)	(17,290)	(16,465)
Change in fair value of common stock warrant liability	(1,435)	—	(13,455)	—
Interest income and other, net	33	22	86	74
Loss before taxes	(7,586)	(4,195)	(30,659)	(16,391)
Income tax benefit	—	—	—	—
Net loss	\$ (7,586)	\$ (4,195)	\$ (30,659)	\$ (16,391)
Weighted average shares outstanding:				
Basic and diluted	34,989,831	13,854,188	33,505,444	13,335,358
Net loss per share:				
Basic and diluted	\$ (0.22)	\$ (0.30)	\$ (0.92)	\$ (1.23)