

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): August 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 August 7, 2017, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the quarter ended June 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 August 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: August 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 August 7, 2017 (furnished and not filed for purposes of Item 2.02)
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Bellerophon Reports Second Quarter 2017 Financial Results and Provides Business Update

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

“We continue to be encouraged with the progress of our Phase 3 clinical program in PAH, as well as Phase 2 programs in pulmonary hypertension associated with interstitial lung disease (PH-ILD) and chronic obstructive pulmonary disease (PH-COPD). In our INOvation-1 Phase 3 trial in PAH, we have now initiated 100 sites in 16 countries with around 50 patients already randomized,” stated Fabian Tenenbaum, Chief Executive Officer of Bellerophon Therapeutics. “We anticipate reporting top line results for this trial in 2018.”

“We are also encouraged by the results of our Phase 2a PH-IPF study which were presented at the 2017 American Thoracic Society International Conference in late May, and which showed a statistically significant increase in pulmonary blood vessel volume, correlating with the best ventilated areas of the lung. We have since received FDA acceptance of our IND and Phase 2b study and look forward to initiating the trial around the end of the year. There are currently no therapies to treat pulmonary hypertension in IPF and other ILDs and we believe that inhaled nitric oxide delivered by means of the INOpulse® delivery system is uniquely positioned to provide targeted delivery without the systemic concerns of other therapies. In COPD we also presented favorable interim results of our Phase 2 study in PH-COPD, which showed targeted vasodilation and a clinically relevant decrease in the pulmonary pressure. We expect to communicate top line results of this study in the near future,” added Mr. Tenenbaum.

Key Highlights for the Second Quarter of 2017 and Business Update:

- **Pulmonary Arterial Hypertension:** In the Company’s Phase 3 program for INOpulse® in the treatment of PAH, the first Phase 3 study, 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 initiated in 100 clinical sites in 16 countries and, to date, approximately 50 subjects have already been randomized. Both the interim analysis as well as top line results for the study are expected to be reported 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. This study has the benefit of eliminating the need for recruitment of new study subjects. The Company plans to initiate its second Phase 3 study in 2018 with top line results expected in 2019.

- **PH-ILD:** in Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD), the Company presented successful results from its Phase 2a study for INOpulse in the treatment of PH

associated with Idiopathic Pulmonary Fibrosis (PH-IPF) at the American Thoracic Society (ATS) International Conference on May 21st. The study met its primary endpoint, showing a 15.3% average increase in blood vessel volume ($p < 0.001$). Moreover, the treatment with INOpulse showed: a significant association between ventilation and vasodilation; a clinically meaningful reduction of 14% in systolic pulmonary arterial pressure (sPAP); and an average improvement of 75 meters in 6MWD.

A larger Phase 2b study in IPF as well as other pulmonary fibrotic diseases within ILD, called iNO-PF, is planned for 2018. The study will recruit approximately 40 subjects diagnosed with pulmonary fibrosis, half of which are at intermediate to high risk of pulmonary hypertension as determined via echocardiography. The study design has been reviewed and accepted by the U.S. Food and Drug Administration (FDA) and an IND for the planned study has been accepted by the Agency.

- **PH-COPD:** The Company presented favorable interim results from its Phase 2 study for INOpulse in the treatment of Pulmonary Hypertension associated with Chronic Obstructive Pulmonary Disease (PH-COPD) at ATS on May 21st. The study is designed to evaluate the acute and chronic effects of pulsed iNO on hemodynamics and exercise tolerance. The preliminary data showed a significant association between ventilation and vasodilation on acute treatment as well as a clinically meaningful reduction of 17.4% on sPAP on chronic treatment over 4 weeks. Top line results from this study are anticipated shortly.
- **Capital Raise:** On May 10, 2017, the Company announced a registered direct offering of common stock shares and warrants to a single healthcare institutional investor generating gross proceeds of \$3.0 million and net proceeds of \$2.7 million.

Second Quarter 2017 Financial Results

For the second quarter ended June 30, 2017, the Company's net loss reduced to \$3.9 million, compared to a \$5.1 million net loss reported in the second quarter 2016. Net loss per share was \$0.12 in the second quarter of 2017 compared to a loss of \$0.39 in the corresponding prior year period.

Research and development expenses for the second quarter of 2017 increased to \$4.7 million, from \$4.0 million in the same quarter last year. The increase was primarily due to increased supply manufacturing related to the PAH program.

General and administrative expenses (G&A) for the second quarter of 2017 increased to \$1.6 million from \$1.2 million in the prior year quarter primarily due to the reversal of a restructuring accrual in the three months ended June 30, 2016.

Net loss for the second quarter of 2017 included a decrease in the fair value of the Company's common stock warrant liability of \$2.4 million. There was no change in the fair value of common stock warrant liability for the second quarter of 2016 as the warrants were issued in November 2016 and May 2017.

First Half 2017 Financial Results

For the first six months ended June 30, 2017, the Company's net loss was \$23.1 million, compared to a \$12.2 million net loss reported in first half of 2016. Net loss per share was \$0.70 in first half of 2017 compared to a loss of \$0.93 in the prior year period.

Research and development expenses for the first half of 2017 decreased to \$8.0 million, from \$9.1 million in the first half of 2016. The decrease was primarily due to higher Phase 2 costs in the first half of 2016 offset in part by an increase in Phase 3 costs and increased supply manufacturing related to the PAH program in the first half of 2017.

General and administrative expenses (G&A) for the first half of 2017 were \$3.1 million as compared to \$3.2 million in the prior year period.

Net loss for the first half of 2017 included an increase in the fair value of the Company's common stock warrant liability of \$12.0 million. There was no such change in the fair value of common stock warrant liability for the first half of 2016 as the warrants were issued in November 2016 and May 2017.

Balance Sheet

At June 30, 2017, the Company had cash and cash equivalents, restricted cash and marketable securities of \$15.3 million compared to cash and cash equivalents, restricted cash and marketable securities of \$20.5 million at December 31, 2016.

As of June 30, 2017, the Company had \$4.7 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)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$10,968	\$14,453
Restricted cash	150	150
Marketable securities	3,901	5,571
Prepaid expenses and other current assets	5,362	6,331
Total current assets	20,381	26,505
Restricted cash, non-current	307	307
Other non-current assets	462	1,491
Property and equipment, net	1,207	1,399
Total assets	\$22,357	\$29,702
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$2,834	\$2,807
Accrued research and development	1,821	2,573
Accrued expenses	622	922
Due to Ikaria, Inc.	216	193
Total current liabilities	5,493	6,495
Common stock warrant liability	17,651	5,215
Total liabilities	23,144	11,710
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value per share; 125,000,000 shares authorized, 35,224,520 and 31,702,624 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	352	317
Preferred stock, \$0.01 par value per share; 5,000,000 share authorized, zero shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Additional paid-in capital	146,426	142,167
Accumulated other comprehensive income (loss)	—	—
Accumulated deficit	(147,565)	(124,492)
Total stockholders' equity	(787)	17,992
Total liabilities and stockholders' equity	\$22,357	\$29,702

Bellerophon Therapeutics, Inc.

Consolidated Statement of Operations

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

	Quarter Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	\$ 4,689	\$ 3,954	\$ 8,026	\$ 9,067
General and administrative	1,634	1,205	3,080	3,181
Total operating expenses	6,323	5,159	11,106	12,248
Loss from operations	(6,323)	(5,159)	(11,106)	(12,248)
Change in fair value of common stock warrant liability	2,367	—	(12,020)	—
Interest income	26	22	53	52
Loss before taxes	(3,930)	(5,137)	(23,073)	(12,196)
Income tax benefit	—	—	—	—
Net loss	<u>\$ (3,930)</u>	<u>\$ (5,137)</u>	<u>\$ (23,073)</u>	<u>\$ (12,196)</u>
Weighted average shares outstanding:				
Basic and diluted	<u>33,558,669</u>	<u>13,093,176</u>	<u>32,750,949</u>	<u>13,073,202</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.39)</u>	<u>\$ (0.70)</u>	<u>\$ (0.93)</u>