

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, 2018

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, 2018, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the quarter and nine months ended September 30, 2018. 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, 2018.



Bellerophon Provides Business Update and Reports Third Quarter 2018 Financial Results

WARREN, N.J., November 7, 2018 -- Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) (“Bellerophon” or the “Company”), a clinical-stage biotherapeutics company, today provided a business update and reported financial results for the third quarter ended September 30, 2018.

“We are pleased to have completed enrollment in the first cohort of our inhaled nitric oxide for pulmonary fibrosis (iNO-PF) Phase 2b study in pulmonary hypertension associated with interstitial lung disease (PH-ILD), and look forward to the results, which are expected in January 2019,” said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. “The additional cohorts are expected to begin enrolling later this year, with results anticipated in 2019. The additional cohorts will allow us to assess higher doses of inhaled nitric oxide (iNO), along with longer duration of treatment, enabling us to plan for a potential pivotal Phase 3 program. In addition, we expect to initiate a Phase 2a trial to evaluate the hemodynamic benefit of INOpulse in pulmonary hypertension associated with Sarcoidosis (PH-Sarcoidosis) by year-end 2018, with results expected in 2019. Moreover, we recently finalized the design of our Phase 2b study for INOpulse in pulmonary hypertension associated with chronic obstructive pulmonary disease (PH-COPD), and intend to initiate this trial in 2019. All three of our target indications, PH-ILD, PH-COPD and PH-Sarcoidosis, represent significant unmet medical needs with mean survival as low as two years from diagnosis. INOpulse’s unique targeted vasodilation differentiates it from current vasodilators and offers the potential for it to be the first approved therapy in these indications.”

“Although our INOvation-1 trial for INOpulse in pulmonary arterial hypertension (PAH) did not achieve its primary endpoint of six-minute walk distance (6MWD), we believe that the collective results of the trial support the cardio-pulmonary benefits of iNO,” continued Mr. Tenenbaum. “The results showed clinical benefit in hemodynamics and right ventricular function consistent with currently marketed PAH therapies. In addition, subjects not on prostanoids or multiple background therapies experienced an improvement in 6MWD. These results support the potential benefit that INOpulse can provide in PH-ILD, PH-COPD and PH-Sarcoidosis, where patients are not on any background PAH medications.”

Key Recent Highlights

- **PAH:** The Company announced interim results from its Phase 3 INOvation-1 trial, evaluating INOpulse for the treatment of PAH. Based on the recommendation of the Data Monitoring Committee, the trial was stopped due to the overall change in 6MWD being insufficient to meet its primary endpoint. However, INOpulse was well-tolerated with no safety concerns. Bellerophon believes that the analysis of the remaining interim results confirmed the INOpulse mechanism of action and supported its potential in treating PH-ILD, PH-COPD and PH-Sarcoidosis patients. In the Phase 3 trial, subjects on iNO demonstrated clinically meaningful improvements, as compared to placebo, that were consistent with currently marketed PAH drugs:
 - Pulmonary vascular resistance (PVR) improved 18% (186 dynes/sec/cm⁵)
 - Cardiac output (CO) improved 0.7 L/min
 - NT-ProBNP, a peptide biomarker for right ventricular failure, improved 68 pmol/L
 - 6MWD increased 23 meters for patients on mono-PAH background therapy
 - 6MWD increased 17 meters for patients without prostanoid background therapy
 - Clinically meaningful decline in 6MWD (>15%) was twice as high in the placebo arm as compared to INOpulse
- **PH-ILD:** Following positive results in its Phase 2a study in PH-IPF, Bellerophon is currently conducting a Phase 2b study to assess the safety and efficacy of pulsed iNO versus placebo in patients with PH-ILD.

Enrollment of the planned 40 subjects (iNO 30 versus placebo) has been completed, with top-line results for this cohort expected in January 2019. The study is evaluating multiple endpoints, including change in exercise capacity, oxygen saturation, right ventricular function, activity monitoring, patient reported outcomes, as well as several composite endpoints. In order to support a potential registration package, the Company has expanded the iNO-PF study to assess higher doses of iNO and increase the duration of treatment to 16 weeks, through the addition of Cohort 2 (iNO 45 versus placebo) and Cohort 3 (iNO 75 versus placebo). Enrollment in these additional cohorts is expected to begin later this year, with top-line data anticipated in 2019.

- **PH-COPD:** Following positive results from its Phase 2 study for INOpulse in PH-COPD, Bellerophon finalized the design of a Phase 2b study in PH-COPD. Agreement with the U.S. Food and Drug Administration (FDA) has been reached on the design of this trial, which will be a randomized, double-blind, placebo-controlled study, and will enroll approximately 90 subjects. The Company intends to initiate this study in 2019. The trial will evaluate multiple endpoints, including change in exercise capacity, right ventricular function and oxygen saturation, as well as other composite endpoints.
- **PH-Sarcoidosis:** Bellerophon is planning to initiate a Phase 2a study by year-end 2018 to assess the benefits of INOpulse on patients with PH-Sarcoidosis, with results expected in 2019. The dose escalation study design will allow the hemodynamic benefit of iNO to be assessed via right heart catheterization.
- **Bellerophon Leadership:** On October 24, 2018, Hunter Gillies, M.D., joined the Company as Acting Chief Medical Officer. Dr. Gillies has more than 20 years in the pharmaceutical industry working on early- and late-stage clinical programs in pulmonary hypertension. Prior to joining Bellerophon, he led the pulmonary vascular disease program at Gilead Sciences, including overseeing the Phase 3 AMBITION study in PAH. Dr. Gillies also worked on multiple PDE5 inhibitor programs, including sildenafil for PAH, at Pfizer.

Third quarter 2018 Financial Results

For the third quarter ended September 30, 2018, the Company reported a net income of \$11.1 million, or \$0.19 per share, compared to a net loss of \$7.6 million, or \$(0.22) per share, in the third quarter ended September 30, 2017. On a diluted basis, the Company reported a loss of \$(0.10) per share for the third quarter ended September 30, 2018, compared to a loss \$(0.22) per share, in the third quarter ended September 30, 2017.

Net income for the third quarter of 2018 included an adjustment of \$17.8 million due to a change in fair value of the Company's common stock warrant liability, as compared to an adjustment of \$(1.4) million in the third quarter of 2017.

Research and development expenses for the third quarter of 2018 were \$5.2 million, compared to \$4.4 million in the third quarter of 2017. The increase was primarily due to increased clinical trial activities and supply costs related to ongoing clinical programs.

General and administrative expenses for the third quarter of 2018 were \$1.6 million, compared to \$1.7 million in third quarter of 2017. The decrease was primarily due a reduction in stock-based compensation expenses.

Nine Months Ended September 30, 2018 Financial Results

For the nine months ended September 30, 2018, the Company's net income was \$3.7 million, compared to a net loss of \$30.7 million in the prior year period. Net income per share was \$0.06 in the nine months ended September 30, 2018, compared to a net loss of \$(0.92) in the prior year period. On a diluted basis, the Company reported a loss of \$(0.27) per share for the nine months ended September 30, 2018, compared to a loss of \$(0.92) per share in the prior year period.

Net income for the nine months ended September 30, 2018, included an adjustment of \$21.2 million in the fair value of the Company's common stock warrant liability, as compared to an adjustment of \$(13.5) million in the prior year period.

Research and development expenses for the nine months ended September 30, 2018, increased to \$17.4 million, as compared to \$12.5 million in the prior year period. The increase was primarily due to increased clinical trial activities and supply costs related to ongoing clinical programs.

General and administrative expenses for the nine months ended September 30, 2018, were \$5.8 million, as compared to \$4.8 million in the prior year period. The increase was primarily due to increased commercial, intellectual property and financial consulting expenses, and stock-based compensation expenses.

Balance Sheet

As of September 30, 2018, the Company had cash, cash equivalents and marketable securities of \$20.6 million, compared to cash, cash equivalents and marketable securities of \$31.8 million at December 31, 2017.

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 multiple product candidates under its INOpulse program, a proprietary pulsatile nitric oxide delivery system. 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 Annual Report on Form 10-K and in subsequent 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.

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Bellerophon Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands except share and per share data)

	As of September 30, 2018 (Unaudited)	As of December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 19,552	\$ 28,823
Restricted cash	255	402
Marketable securities	998	2,996
Prepaid expenses and other current assets	1,738	3,359
Total current assets	22,543	35,580
Restricted cash, non-current	300	150
Other non-current assets	44	54
Property and equipment, net	755	1,026
Total assets	\$ 23,642	\$ 36,810
Liabilities and Stockholders' Equity (Deficiency in Assets)		
Current liabilities:		
Accounts payable	\$ 4,371	\$ 3,853
Accrued research and development	3,823	1,785
Accrued expenses	880	1,441
Total current liabilities	9,074	7,079
Common stock warrant liability	10,641	32,325
Total liabilities	19,715	39,404
Commitments and contingencies		
Stockholders' equity (deficiency in assets):		
Common stock, \$0.01 par value per share; 200,000,000 and 125,000,000 shares authorized, 58,679,492 and 56,899,353 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively, 289,269 shares paid for and to be issued at December 31, 2017	587	569
Preferred stock, \$0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at September 30, 2018 and December 31, 2017	—	—
Additional paid-in capital	178,925	176,151
Accumulated other comprehensive loss	(1)	(4)
Accumulated deficit	(175,584)	(179,310)
Total stockholders' equity (deficiency in assets)	3,927	(2,594)
Total liabilities and stockholders' equity (deficiency in assets)	\$ 23,642	\$ 36,810

Bellerophon Therapeutics, Inc.

Condensed Consolidated Statement of Operations (Unaudited)

(in thousands except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 5,247	\$ 4,438	\$ 17,442	\$ 12,464
General and administrative	1,584	1,746	5,754	4,826
Total operating expenses	6,831	6,184	23,196	17,290
Loss from operations	(6,831)	(6,184)	(23,196)	(17,290)
Change in fair value of common stock warrant liability	17,840	(1,435)	21,201	(13,455)
Interest income and other, net	92	33	282	86
Pre-tax income (loss)	11,101	(7,586)	(1,713)	(30,659)
Income tax benefit	—	—	5,439	—
Net income (loss)	\$ 11,101	\$ (7,586)	\$ 3,726	\$ (30,659)
Weighted average shares outstanding:				
Basic	57,710,251	34,989,831	57,356,445	33,505,444
Diluted	64,544,504	34,989,831	65,854,903	33,505,444
Net income (loss) per share:				
Basic	\$ 0.19	\$ (0.22)	\$ 0.06	\$ (0.92)
Diluted	\$ (0.10)	\$ (0.22)	\$ (0.27)	\$ (0.92)