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): May 10, 2018

Bellerophon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter) 001-36845

(Commission

File Number)

(State or Other Jurisdiction of Incorporation)

Delaware

184 Liberty Corner Road, Suite 302

Warren, New Jersey

(Address of Principal Executive Offices)

07059

(Zip Code)

47-3116175

(IRS Employer

Identification No.)

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):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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).

- x Emerging growth company
- x 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 May 10, 2018, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the quarter ended March 31, 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 May 10, 2018.

EXHIBIT INDEX

Exhibit

No.

<u>99.1</u>

Description

Press Release dated May 10, 2018 (furnished and not filed for purposes of Item 2.02)

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: 5/10/2018

By: /s/ Assaf Korner

Name: Assaf Korner Title: Chief Financial Officer



Bellerophon Provides Business Update and Reports First Quarter 2018 Financial Results

Warren, NJ, May 10, 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 first quarter ended March 31, 2018.

"We continue to achieve significant progress in our clinical trials and expect multiple important and potentially value enhancing catalysts for our INOpulse® programs throughout the course of 2018," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "We intend to conduct an interim analysis in mid-2018 for our most advanced program, INOvation-1, a Phase 3 study in pulmonary arterial hypertension (PAH), with top-line data for the complete study anticipated around the end of the year. In addition, we expect top-line results from our Phase 2b study evaluating INOpulse in pulmonary hypertension associated with interstitial lung disease (PH-ILD) including idiopathic pulmonary fibrosis (PH-IPF) around the end of 2018. In pulmonary hypertension associated with chronic obstructive pulmonary disease (PH-COPD), we recently reached agreement with the U.S. Food and Drug Administration (FDA) on the design of our planned Phase 2b study in this large unmet medical need."

"Finally, we recently amended our license agreement with Ikaria to expand beyond IPF to a broader category of ILD. This amended agreement supports our clinical strategy within the broader ILD category and will allow us to develop our INOpulse therapy in a significantly larger patient population for which there are currently no approved therapies to treat the devastating implications of pulmonary hypertension associated with these diseases," concluded Mr. Tenenbaum.

Key Recent Highlights

- **PAH**: Enrollment continues to progress well in our Phase 3 INOvation-1 study evaluating INOpulse® in patients with PAH. As previously agreed with the FDA, an interim analysis of this study will be performed by the Data Monitoring Committee when approximately half of the subjects complete the 16-week blinded treatment phase. The interim analysis will determine if the study should be stopped early for efficacy or futility, continued as planned, or if the study size should be increased. The Company continues to expect the readout of the interim analysis in mid-2018.
- **PH-ILD**: Following positive results in its Phase 2a study in PH-IPF, Bellerophon is currently enrolling patients in a Phase 2b study evaluating INOpulse to assess the safety and efficacy of pulsed, inhaled nitric oxide (iNO) versus placebo in patients with PH-ILD. A total of 40 subjects will be randomized in the double-blind, placebo-controlled clinical study, including patients with idiopathic pulmonary fibrosis. The primary endpoint of the study is the change in 6 Minute Walk Distance (6MWD) and the study includes several additional endpoints, including improvement in right ventricular function. The Company continues to anticipate top-line results from this study around the end of 2018.
- **PH-COPD**: Following positive results from its Phase 2 study for INOpulse in PH-COPD, Bellerophon, in conjunction with its steering committee, finalized the design of a Phase 2b study in PH-COPD. Agreement with the FDA has been reached on the design of this trial, which will be a

double-blind, placebo-controlled study, which will enroll approximately 90 subjects. The primary endpoint is change in 6MWD, with several additional secondary endpoints including improvement in right ventricular function.

• **Amended License Agreement with Ikaria, Inc.**: Bellerophon recently amended its license agreement with Ikaria to expand the scope from IPF to a broader category of ILDs, which includes IPF as well as other fibrotic lung diseases. Broadening of the license has the potential to significantly expand the market opportunities for the Company's INOpulse technology.

First Quarter 2018 Financial Results

For the first quarter ended March 31, 2018, Bellerophon reported net income of \$4.1 million, or \$0.07 per share, compared to a net loss of \$19.1 million, or \$0.60 per share, in the first quarter ended March 31, 2017. On a diluted basis, Bellerophon reported a loss of \$0.04 per share for the first quarter ended March 31, 2018, compared to a loss \$0.60 per share, in the first quarter ended March 31, 2017.

Net income for the first quarter of 2018 included a positive adjustment of \$7.1 million to the fair value of the Company's common stock warrant liability, as compared to a negative adjustment of \$(14.4) million in the first quarter of 2017. Net income for the first quarter of 2018 also included an income tax benefit of \$5.4 million, compared to zero for the first quarter of 2017. The benefit in the first quarter of 2018 was due to the sale of \$61.5 million of State Net Operating Losses and \$0.2 million of research and development credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program for net cash proceeds of \$5.3 million.

Research and development expenses for the first quarter of 2018 were \$6.4 million, compared to \$3.3 million in the first quarter of 2017. The increase was primarily due to increased trial supply costs related to ongoing clinical programs.

General and administrative expenses for the first quarter of 2018 were \$2.1 million, compared to \$1.4 million in the first quarter of 2017. The increase was primarily due to increased commercial, intellectual property and financial consulting costs, and stock-based compensation expenses.

Balance Sheet

As of March 31, 2018, the Company had cash, cash equivalents and marketable securities of \$31.3 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 three product candidates under its INOpulse program, a proprietary pulsatile nitric oxide delivery system. The first is for the treatment of 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 <u>www.bellerophon.com</u>.

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

At Bellerophon: Fabian Tenenbaum, Chief Executive Officer (908) 574-4767 At LifeSci Advisors: Brian Ritchie (212) 915-2578 britchie@lifesciadvisors.com

Bellerophon Therapeutics, Inc.

Condensed Consolidated Balance Sheet

(in thousands except share and per share data)

	 March 31, 2018		December 31, 2017	
	(Unaudited)			
Assets				
Current assets:				
Cash and cash equivalents	\$ 28,350	\$	28,823	
Restricted cash	403		402	
Marketable securities	2,994		2,996	
Prepaid expenses and other current assets	3,016		3,359	
Total current assets	 34,763		35,580	
Restricted cash, non-current	150		150	
Other non-current assets	40		54	
Property and equipment, net	935		1,026	
Total assets	\$ 35,888	\$	36,810	
Liabilities and Stockholders' Equity		_		
Current liabilities:				
Accounts payable	\$ 4,593	\$	3,853	
Accrued research and development	2,987		1,785	
Accrued expenses	816		1,441	
Total current liabilities	 8,396		7,079	
Common stock warrant liability	25,275		32,325	
Total liabilities	33,671		39,404	
Commitments and contingencies		_		
Stockholders' equity (Deficiency in assets):				
Common stock, \$0.01 par value per share; 125,000,000 shares authorized, 57,369,165 and 56,899,353 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively, 289,269 shares paid for and to be issued at December 31, 2017	574		569	
Preferred stock, \$0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at March 31, 2018 and December 31, 2017	_		_	
Additional paid-in capital	176,862		176,151	
Accumulated other comprehensive loss	(5)		(4)	
Accumulated deficit	(175,214)		(179,310)	
Total stockholders' equity	2,217		(2,594)	
Total liabilities and stockholders' equity	\$ 35,888	\$	36,810	

BELLEROPHON THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

(in thousands except share and per share data)

	Quarter Ended March 31,			
	2018		2017	
Operating expenses:				
Research and development	\$ 6,380	\$	3,337	
General and administrative	2,112		1,446	
Total operating expenses	8,492		4,783	
Loss from operations	(8,492)		(4,783)	
Change in fair value of common stock warrant liability	7,050		(14,387)	
Interest income	99		27	
Loss before taxes	(1,343)		(19,143)	
Income tax benefit	5,439			
Net loss	\$ 4,096	\$	(19,143)	
Weighted average shares outstanding:				
Basic	57,059,686		31,934,253	
Diluted	72,100,690		31,934,253	
Net loss per share:				
Basic	\$ 0.07	\$	(0.60)	
Diluted	\$ (0.04)	\$	(0.60)	