

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, 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 8.01 Other events

Bellerophon Therapeutics, Inc. (the "Company") issued a press release on August 7, 2018, to announce the results of the interim analysis of its phase 3 INOvation-1 study evaluating INOpulse® for treatment of pulmonary arterial hypertension.

A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated August 7, 2018

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, 2018

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum

Title: Chief Executive Officer



Bellerophon Announces Results of Interim Analysis of Phase 3 INOvation-1 Study Evaluating INOpulse® for Treatment of Pulmonary Arterial Hypertension

Warren, NJ, August 7, 2018 - Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) (“Bellerophon” or the “Company”), a clinical-stage biotherapeutics company, today announced that the Data Monitoring Committee (DMC) has completed its pre-specified interim analysis from the first 75 enrolled subjects completing 16-weeks of treatment in the Phase 3 INOvation-1 study evaluating INOpulse® for the treatment of pulmonary arterial hypertension (PAH).

The DMC has recommended that the trial be stopped for futility. INOpulse® was well-tolerated and there were no safety concerns that led the DMC to recommend concluding the trial. The data showed improvement in pulmonary vascular resistance, however, the DMC deemed the overall change in 6 minute walk distance, the primary endpoint of the trial, insufficient to support the continuation of the study.

As previously agreed upon with the U.S. Food and Drug Administration (FDA), the pre-specified interim analysis was conducted by the DMC after half of the planned subjects completed 16-weeks of blinded treatment. The DMC considered four potential recommendations relative to its review of the data: stopping the trial early for efficacy, continuing to enroll the study as planned, increasing the targeted enrollment size if the original design was slightly underpowered, and stopping the study for futility or safety concerns.

“While we are disappointed in the overall efficacy results of this study, we are encouraged by the positive data in hemodynamics and pleased with the safety and tolerability profile of INOpulse®. Over the next few weeks, we intend to further analyze the full data set available to us from this interim analysis in order to determine the next steps in our PAH program. On behalf of everyone at Bellerophon, I would like to thank all of the patients and physicians who participated in the INOvation-1 study,” said Fabian Tenenbaum, Chief Executive Officer of Bellerophon Therapeutics.

“Based on the results of our Phase 2 studies in pulmonary hypertension associated with interstitial lung disease (PH-ILD) and pulmonary hypertension associated with chronic obstructive pulmonary disease (PH-COPD), we remain positive regarding the potential of our other INOpulse® programs. Unlike PAH, patients with PH-ILD and PH-COPD have underlying lung disease for whom systemic vasodilators have been ineffective and there are currently no approved therapies. Our ongoing Phase 2b trial in PH-ILD is progressing well, with top-line results expected around the end of 2018. PH-ILD is a significant unmet medical need which we believe represents a substantial potential market opportunity,” concluded Mr. Tenenbaum.

Bellerophon has sufficient resources to support its currently planned activities into the first half of 2019.

About Pulmonary Arterial Hypertension

Pulmonary arterial hypertension is one form of a broader condition known as pulmonary hypertension, which means high blood pressure in the lungs. PAH occurs when the very small arteries throughout the lungs narrow in diameter, which increases the resistance to blood flow through the lungs. Over time, the

increased blood pressure can damage the heart. A number of diseases and conditions can cause PAH, and symptoms are similar to the symptoms often seen in more common diseases, such as asthma, chronic obstructive pulmonary disease (COPD), and heart failure.

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 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.

Contacts

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