

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 12, 2019

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).

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	BLPH	The Nasdaq Capital Market

☒ 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 November 12, 2019, to announce positive initial data from acute hemodynamic dose escalation study of INOpulse® for treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease. 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 November 12, 2019

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 12, 2019

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum

Title: Chief Executive Officer

Bellerophon Announces Positive Initial Data from Acute Hemodynamic Dose Escalation Study of INOpulse® for Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease

WARREN, N.J., November 12, 2019 -- Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company, today announced positive initial data from an acute, dose escalation, clinical study (PHPF-002) of INOpulse® for the treatment of Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD). PHPF-002 is an ancillary study to the Company's ongoing double-blind, placebo-controlled, randomized, Phase 2/3 iNO-PF study of INOpulse for the treatment of PH-ILD, for which the Company expects to report top line results for Cohort 2 by the end of the year.

The results to date from PHPF-002 have demonstrated clinically meaningful improvements in multiple pre-specified pulmonary hemodynamic parameters, starting with the lowest dose of 30 mcg/kg IBW/hr (iNO30). Dose escalation showed:

- Pulmonary vascular resistance (PVR) improved by 29% (baseline PVR was 584 dynes \times sec \times cm⁻⁵)
- Cardiac Output (CO) improved by 16% (baseline CO was 3.5 L/min)
- Mean Pulmonary Arterial Pressure (mPAP) improved by 10% across doses (baseline mPAP was 34.3 mmHg)
- Oxygen saturation remained stable across doses
- iNO was well-tolerated with no safety concerns across doses

"PH-ILD results in severe functional impairment and significantly reduced life expectancy. These patients suffer from constriction of the pulmonary arteries that decreases cardiac output and causes right ventricular dysfunction," said Roger Alvarez, DO, MPH, Assistant Professor University of Miami School of Medicine, and Principal Investigator in the PHPF-002 study. "The hemodynamic improvements demonstrated by INOpulse's targeted vasodilation are compelling and provide the potential to meaningfully increase physical activity in PH-ILD patients who have limited ability to perform even the most basic daily tasks."

"We believe the acute hemodynamic benefit demonstrated in the PHPF-002 study is responsible for the chronic improvement in physical activity observed in Cohort 1 of our ongoing Phase 2/3 iNO-PF study," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "These hemodynamic improvements confirm the therapeutic benefit of iNO30 and support the potential for further benefit on iNO45. We look forward to reporting top-line results from Cohort 2 of iNO-PF, which is evaluating iNO45 in 44 subjects, by the end of the year."

PHPF-002 is designed to assess the acute hemodynamic benefit of escalating iNO doses in PH-ILD. The first four PHPF-002 study subjects were each treated sequentially, beginning with a dose of iNO30, followed by dose escalation to iNO45 and iNO75. Pulmonary hemodynamics were measured via right heart catheterization and collected at baseline, as well as following each sequential iNO dose. The Company intends to enroll up to four additional PH-ILD subjects in this study.

About Bellerophon

Bellerophon Therapeutics is a clinical-stage biotherapeutics company focused on developing innovative therapies 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,” “contemplate,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “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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