

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): February 18, 2020

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 February 18, 2020, to announce Positive Top-Line Data from an Ancillary Acute Hemodynamic Study of INOpulse® for Treatment of Pulmonary Hypertension Associated with Pulmonary Fibrosis. 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
<u>99.1</u>	<u>Press Release dated February 18, 2020</u>

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: February 18, 2020

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum

Title: Chief Executive Officer

Bellerophon Reports Positive Top-Line Data from an Ancillary Acute Hemodynamic Study of INOpulse® for Treatment of Pulmonary Hypertension Associated with Pulmonary Fibrosis

WARREN, N.J., February 18, 2020 -- Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company, today announced positive top-line data from a recently completed acute, intra-patient, dose escalation, hemodynamics study (PHPF-002) of INOpulse® for the treatment of Pulmonary Hypertension associated with Pulmonary Fibrosis (PH-PF).

The top-line results from PHPF-002 demonstrated that acute treatment with INOpulse provided statistically and clinically significant improvements in hemodynamic parameters, including:

- Pulmonary vascular resistance reduced by 21%, with increased benefit ($p < 0.01$) on dose escalation from iNO30 (30 mcg/kg IBW/hr) to iNO45 (45 mcg/kg IBW/hr).
- Mean pulmonary arterial pressure reduced by 12%.
- iNO was well-tolerated with no safety concerns across the doses.

The acute hemodynamic improvements observed on iNO, along with the increased benefit demonstrated on iNO45 versus iNO30, correlate with the chronic benefit of iNO recently reported in Phase 2 of the Company's ongoing Phase 2/3 iNO-PF study.

In Phase 2 of iNO-PF, subjects on iNO30 and iNO45 maintained their level of moderate to vigorous physical activity (MVPA), defined as walking, climbing stairs, yard work, and similar activities, while subjects on placebo deteriorated. The improvements in MVPA were supported by benefits in other key parameters, with subjects on iNO45 demonstrating placebo corrected improvements in:

- MVPA: Improved by 14 minutes per day, representing 20% ($p = 0.02$).
- St. George Respiratory Questionnaire (SGRQ): Clinically meaningful benefit of 5 points (Activity domain), 6 points (Impacts domain), and 3 points (Total Score).
- University of California, San Diego Shortness of Breath Questionnaire: Clinically meaningful benefit of 5 points.

"The benefits demonstrated in our multiple Phase 2 studies support INOpulse's potential to become a transformative therapy for PH-PF patients," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "The hemodynamic dose response data generated in PHPF-002 validate the pulmonary vasodilatory capability of INOpulse, confirming the therapeutic benefit of iNO30 and supporting further benefit on iNO45. These findings are consistent with the compelling results from Phase 2 of our iNO-PF chronic study, in which all iNO doses demonstrated meaningful benefits in activity parameters and in which iNO45 also provided important benefits in patient reported outcomes, indicating that subjects were both functioning better and feeling better. We look forward to further assessing the benefit of INOpulse in our upcoming pivotal Phase 3 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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