

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): October 23, 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 October 23, 2019, to publish new positive data from Cohort 1 of the ongoing phase 2/3 study of INOpulse® for treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease at the American College of Chest Physicians (CHEST) 2019 Annual Meeting. 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 October 23, 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: October 23, 2019

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum

Title: Chief Executive Officer

Bellerophon Presents New Positive Data from Cohort 1 of Ongoing Phase 2/3 Study of INOpulse® for Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease at CHEST 2019 Annual Meeting

*Results Presented in Late-Breaking Abstract as an Oral Presentation
Presentation Will Also be Published in the Highlights from CHEST Special Edition*

WARREN, N.J., October 23, 2019 -- Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) (“Bellerophon” or the “Company”), a clinical-stage biotherapeutics company, presented additional new data from Cohort 1 of its ongoing Phase 2/3 randomized, double-blind, placebo-controlled clinical study (iNO-PF) of INOpulse® for the treatment of Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD) as a late-breaking oral presentation at the American College of Chest Physicians (CHEST) 2019 Annual Meeting in New Orleans. The data were presented by Steven D. Nathan, M.D., F.C.C.P., Medical Director of the Advanced Lung Disease and Lung Transplant Program at Inova Fairfax Hospital and Chair of Bellerophon’s Steering Committee.

“The collective data generated to date from Cohort 1 in the iNO-PF study are exciting,” said Dr. Nathan. “The newly presented responder analysis results are especially gratifying, with subjects on INOpulse showing benefit in moderate to vigorous physical activity, or MVPA, overall activity and non-sedentary activity, as compared to consistent and significant deterioration in the placebo group. In addition, subjects saw a reversal from deterioration to maintenance when switching from placebo during blinded treatment to INOpulse during open-label extension (OLE). The durability of the efficacy signal, with subjects maintaining their activity levels on open-label INOpulse through six months on average, is especially remarkable in a patient population that has a median life expectancy of only 18 months. I am excited for the potential prospects of this promising therapy and look forward to the availability of additional clinical data in the near future.”

“The overall results from Cohort 1 of the iNO-PF study continue to enhance our confidence in the potential of INOpulse to offer the first treatment option for PH-ILD patients,” said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. “We have completed recruitment in Cohort 2 of our iNO-PF study, which will assess a higher dose, as well as a longer duration of treatment, and expect to report top-line results by year-end 2019. The data from Cohorts 1 and 2 will be used to determine the optimal dose between iNO30 and iNO45 to progress into the pivotal Phase 3 study, for which we already have agreement with the U.S. Food and Drug Administration on the use of MVPA as the primary endpoint. We anticipate initiating the Phase 3 study in the first quarter of 2020.”

Bellerophon previously presented positive top-line data from Cohort 1 of its ongoing iNO-PF trial. Cohort 1, the first of 3 cohorts, included 41 subjects randomized 1:1 to either iNO 30 (30 mcg/kg IBW/hr) or placebo, for a period of 8 weeks of blinded treatment. Data highlights included:

- MVPA (walking, stairs, yardwork, etc.) improved by 34% (8% increase on iNO vs. 26% decrease on placebo; p=0.04)
 - 23% of subjects on INOpulse had a clinically significant improvement in MVPA, compared to 0% of subjects on placebo (placebo corrected difference of 23%)
 - 39% of subjects on INOpulse had a clinically significant decline in MVPA, compared to 71% of subjects on placebo (placebo corrected difference of 32%)
 - Proportion of awake time spent in MVPA improved by 38% (16% increase on iNOpulse vs. 22% decrease on placebo; p=0.04)
- Overall activity improved by 12% (stable on iNOpulse vs. 12% decrease on placebo; p=0.05)

The CHEST presentation included additional responder analysis data, as well as new long-term results for subjects on OLE. Presentation highlights included:

- Responder analysis:
 - 85% of subjects on placebo declined in MVPA, overall activity and non-sedentary activity
 - 46% of subjects on INOpulse improved in MVPA, 62% in overall activity and 39% in non-sedentary activity (compared to only 15% of subjects on placebo in each category)
- OLE:
 - Collectively, subjects (with an average of 27 weeks of OLE data) demonstrated maintenance of MVPA, overall activity and non-sedentary activity
 - Subjects randomized to active treatment in the blinded portion of the trial continued to maintain their activity levels when transitioning to OLE over 27 weeks of open-label treatment
 - Subjects randomized to placebo in the blinded portion of the trial transitioned from a decline during blinded treatment to stabilization of activity levels (MVPA, overall activity and non-sedentary activity) over 27 weeks of open-label treatment

The CHEST presentation and poster can be found at investors.bellerophon.com. At the conference's request, Dr. Nathan recorded an abridged version of the presentation for the Highlights from CHEST, a program highlighting key topics from the meeting. The presentation will be published as a special edition following the annual meeting.

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

At Bellerophon:

Fabian Tenenbaum, Chief Executive Office
(908) 574-4767

At LifeSci Advisors:

Brian Ritchie
(212) 915-2578
britchie@lifesciadvisors.com