

**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 23, 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)

7059

(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 23, 2020, to announce the results of the interim analysis of the Company's phase 3 COViNOX Study of INOpulse® for the treatment of COVID-19.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 23, 2020

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 23, 2020

By: /s/ Fabian Tenenbaum
Name: Fabian Tenenbaum
Title: Chief Executive Officer

Bellerophon Therapeutics Announces Results of Interim Analysis of Phase 3 COViNOX Study of INOpulse® for the Treatment of COVID-19

WARREN, N.J., Nov. 23, 2020 – Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) (“Bellerophon” or the “Company”), a clinical-stage biotherapeutics company focused on developing treatments for cardiopulmonary and infectious diseases, today announced that the independent Data Monitoring Committee (DMC) has completed its pre-specified interim analysis from the first 100 patients randomized in the Phase 3 COViNOX study of INOpulse® for the treatment of COVID-19. The interim analysis, as requested by the U.S. Food and Drug Administration, was limited to the evaluation of safety and a single efficacy endpoint of respiratory failure or death (RFD).

“Based on the recommendation of the DMC, we have put the COViNOX study on clinical hold. To date, we have recruited close to 200 patients, of which 100 were included in the interim analysis. Of note, the interim analysis included 10 RFD events, representing a small sample size for evaluation of the RFD endpoint. We intend to complete the study procedures for the remaining patients and evaluate the full data set, which will include additional clinically important endpoints, such as change in clinical status and duration of hospitalization, in order to assess potential next steps in our COVID-19 program,” said Fabian Tenenbaum, Chief Executive Officer of Bellerophon Therapeutics.

“We continue to be enthusiastic about our lead program in fibrotic interstitial lung disease (fILD) and other pulmonary hypertension (PH) programs, which leverage years of experience with inhaled nitric oxide as a targeted and potent vasodilator to address the underlying vascular resistance and improve hemodynamics, ventilation/perfusion mismatch, quality of life, and exercise capacity in these patients. These indications represent significant unmet medical needs for which there are currently no approved therapies. Importantly, following the positive results from our Phase 2 studies, we expect to enroll the first patient in our Phase 3 REBUILD study in fILD shortly, and our ongoing Phase 2b trial in PH associated with sarcoidosis is progressing well, with top-line results anticipated around the end of 2020,” concluded Mr. Tenenbaum.

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 and infectious lung 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: risks and uncertainties relating to INOpulse® not proving to be an effective treatment for COVID-19 or approved for marketing by the FDA, 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.

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