

**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): March 30, 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
<b>Common Stock, \$0.01 par value per share</b>	<b>BLPH</b>	<b>The Nasdaq Capital Market</b>

☒ 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 March 30, 2020, to announces first patient treated with INOpulse® inhaled nitric oxide therapy for the expanded access treatment of COVID-19.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits:

Exhibit No.	Description
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press Release dated March 30, 2020</u></a>

## 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: March 30, 2020

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum

Title: Chief Executive Officer

**Bellerophon Therapeutics Announces First Patient Treated with INOpulse® Inhaled Nitric Oxide Therapy for COVID-19**

WARREN, N.J., Mar. 30, 2020 - Bellerophon Therapeutics, Inc. (Nasdaq: BLPH), a clinical-stage biotherapeutics company focused on developing treatments for cardiopulmonary diseases, today announced that expanded access treatment with the INOpulse® inhaled nitric oxide system (iNO) was initiated for the first time in a patient with a diagnosis of the novel coronavirus disease (COVID-19) at the University of Miami School of Medicine. The treatment follows the recent decision by the U.S. Food and Drug Administration (FDA) to grant emergency expanded access that allows INOpulse to immediately be used for the treatment of COVID-19 under the care and supervision of their physician.

“Based on previous studies that demonstrate the benefits of iNO in oxygenation and immune response, INOpulse has the potential to be used as a viable treatment option for COVID-19,” said the treating physician, Roger Alvarez, DO, MPH, Assistant Professor, University of Miami School of Medicine. “The cardiopulmonary benefit demonstrated by INOpulse in various indications provides the potential to prevent deterioration in patients with COVID-19, allowing ventilators to be preserved for the most critically ill. INOpulse’s ease of administration could significantly decrease the burden on therapists and nurses as they combat this pandemic with constrained resources.”

COVID-19 is caused by the SARS-CoV-2 virus, which is approximately 82% identical to the severe acute respiratory syndrome related coronavirus (SARS-CoV) that caused a global outbreak between 2003 and 2004<sup>1</sup>. Prior studies have shown that nitric oxide (NO) could provide benefit in treating SARS-CoV by preventing viral replication<sup>2</sup>, improving arterial oxygenation, reducing the need for ventilation support and preventing the proliferation of lung infiltrates<sup>3</sup>. Based on the genetic similarities between the two coronaviruses, the historical data in SARS-CoV support the potential for iNO to provide meaningful benefit for patients infected with COVID-19.

“We believe the first patient with COVID-19 to start treatment with INOpulse could be a critical step in the fight against this pandemic due to the therapy’s potential to halt disease progression and reduce the need for ventilation support,” said Fabian Tenenbaum, Chief Executive Officer of Bellerophon Therapeutics. “Moreover, INOpulse’s ability to treat patients in the outpatient setting could help alleviate the mounting impact on the capacity of hospitals and intensive care units. We will continue to collaborate with the FDA and will work diligently to make INOpulse available to more patients at more sites around the U.S. as expeditiously as possible.”

Bellerophon is currently developing INOpulse for multiple unmet cardiopulmonary indications. The Company recently announced positive top-line results from its Phase 2 studies for the treatment of pulmonary hypertension associated with pulmonary fibrosis (PH-PF) and plans to initiate a pivotal Phase 3 study in PH-PF. Bellerophon’s proprietary INOpulse delivery system is portable and designed to deliver NO in a targeted, pulsatile manner that ensures accurate drug delivery and allows for use in outpatient settings outside of the hospital.

## 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](http://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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1. L. Zhang *et al.*, *Science* 10.1126/science.abb3405 (2020).
2. Akerstrom S *et. Al.* Nitric oxide inhibits the Replication Cycle of Severe Acute Respiratory Syndrome Coronavirus. *J Virol* 2005; 79(3):1966-9.
3. Chen L. Inhalation of nitric oxide in the treatment of acute respiratory syndrome: a rescue trial in Beijing. *Clinical Infectious Diseases* 2004; 39(10):1531-5.