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): April 8, 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**	**07059**
(Address of Principal Executive Offices)	(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o 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**

x Emerging growth company

x 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 April 8, 2020, to announce the submission of an Investigational New Drug Application to the U.S. Food and Drug Administration to study INOpulse® Inhaled Nitric Oxide therapy for the treatment of patients infected with COVID-19.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated April 8, 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: April 8, 2020

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum
Title: Chief Executive Officer

Exhibit 99.1

Bellerophon Therapeutics Submits Investigational New Drug Application to Study INOpulse® Inhaled Nitric Oxide Therapy for the Treatment of COVID-19

IND Submission Follows Completed Treatment of Several COVID-19 Patients with INOpulse Under FDA Authorized Emergency Expanded Access Program

WARREN, N.J., April 8, 2020 - Bellerophon Therapeutics, Inc. (Nasdaq: BLPH), a clinical-stage biotherapeutics company focused on developing treatments for cardiopulmonary diseases, today announced the submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) to study the INOpulse® inhaled nitric oxide system (iNO) for the treatment of patients infected with COVID-19. INOpulse is the only therapy to deliver targeted nitric oxide by autonomously adjusting to the patient's breathing pattern to ensure accurate and consistent drug delivery into the airways.

The proposed randomized, open-label study, called PULSE-CVD19-001, will evaluate the efficacy and safety of INOpulse in patients with COVID-19 who require supplemental oxygen. The PULSE-CVD19-001 protocol utilizes an adaptive design and aims to enroll up to 500 patients with COVID-19 who will be treated with INOpulse or standard of care. In parallel, the company has applied for federal funding, through BARDA (Biomedical Advanced Research and Development Authority) and NIH (National Institutes of Health), to support the proposed IND study.

"As the U.S. continues to face a public health crisis related to COVID-19, it's important that we progress our research efforts to expand INOpulse treatment to more patients and gather the necessary data through a formal IND study," said Hunter Gillies, M.D., Chief Medical Officer at Bellerophon Therapeutics. "INOpulse is the only technology able to deliver consistent and accurate doses of nitric oxide to the lung based specifically on each patient's real-time breathing patterns, and we believe our IND submission represents a significant step forward as we aim to improve clinical outcomes and reduce the number of patients requiring assisted ventilation."

The IND submission follows agreement by the FDA to allow treatment with INOpulse for COVID-19 patients under an emergency expanded access program. To date, three COVID-19 patients have completed treatment with INOpulse, with several additional patients currently on the INOpulse therapy.

"We are pleased to report that the three COVID-19 patients that completed INOpulse treatment to date have already demonstrated improved oxygenation that allowed them to avoid the need for mechanical ventilation and two of the patients have already been discharged. We continue to collaborate closely with the FDA and medical centers around the country to make INOpulse available to as many patients as possible as quickly as we can," continued Dr. Gillies.

COVID-19 is caused by the SARS-CoV-2 coronavirus, which is approximately 82% identical to the severe acute respiratory syndrome related coronavirus (SARS-CoV) that caused a global outbreak between 2003 and 2004[1]. Prior studies have shown that nitric oxide (NO) could provide benefit in treating SARS-CoV by preventing viral replication[2], improving arterial oxygenation, reducing the need for ventilation support and preventing the proliferation of pneumonia lung infiltrates[3]. 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.

Nitric oxide is a naturally produced molecule as part of the immune response to pathogens and plays a key role in preventing viral replication. The proprietary INOpulse delivery system from Bellerophon Therapeutics is an investigational system that is portable and designed to deliver nitric oxide 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.

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.

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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.