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): May 11, 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))

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**

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).

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 2.02. Results of Operations and Financial Condition.

On May 11, 2020, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the three months ended March 31, 2020. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

99.1 Press Release dated May 11, 2020.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated May 11, 2020 (furnished and not filed for purposes of Item 2.02)

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: May 11, 2020

By: /s/ Assaf Korner

Name: Assaf Korner
Title: Chief Financial Officer

Bellerophon Provides Clinical Program Update and Reports First Quarter 2020 Financial Results

WARREN, N.J., May 11, 2020 - Bellerophon Therapeutics, Inc. (Nasdaq: BLPH), ("Bellerophon" or the "Company") a clinical-stage biotherapeutics company focused on developing treatments for cardiopulmonary and infectious lung diseases, today provided a clinical program update and reported financial results for the first quarter ended March 31, 2020.

"Bellerophon continues to advance its robust clinical program for INOpulse® to address multiple cardiopulmonary and infectious lung diseases," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "We are excited that we have received clearance from the U.S. Food and Drug Administration (FDA) to initiate a Phase 3 study of INOpulse in patients diagnosed with COVID-19. This study will provide the required clinical data for potential regulatory approval and builds upon the experience we have gained through emergency access, which has enabled more than 50 COVID-19 patients in the U.S. to receive INOpulse therapy. We have applied for federal funding, through the Biomedical Advanced Research and Development Authority (BARDA) and the National Institutes of Health (NIH), to support this Phase 3 clinical study."

"In addition, we have completed our End-of-Phase 2 meetings with the FDA, and reached alignment with the agency on the key parameters of our upcoming pivotal Phase 3 trial of INOpulse for the treatment of pulmonary hypertension associated with pulmonary fibrosis (PH-PF). We previously reported positive top-line results from our Phase 2 study and have agreement with the FDA to use the same endpoint in the pivotal Phase 3 study," concluded Mr. Tenenbaum.

Clinical Program Highlights:

COVID-19 (Coronavirus)

- **Emergency Expanded Access:** To date, over 50 patients at 12 hospitals across the U.S. have received treatment with INOpulse for COVID-19 under emergency expanded access granted by the FDA. The program allows INOpulse to be used for the treatment of specific patients with COVID-19 under the care and supervision of their physician. The investigational INOpulse therapy is the only system designed to deliver precise doses of nitric oxide by autonomously adjusting to the patient's breathing pattern to ensure accurate and consistent drug delivery into the airways. Nitric oxide is a naturally produced molecule that is both a powerful vasodilator, improving oxygenation in the bloodstream, and an immune response to pathogens, playing a key role in preventing viral replication.

- **PULSE-CVD19-001 Phase 3 Study:** Bellerophon announced FDA acceptance of its Investigational New Drug (IND) application, allowing the Company to initiate its Phase 3 study of INOpulse inhaled nitric oxide (iNO) therapy in up to 500 patients infected with COVID-19. The Phase 3 randomized, placebo-controlled study, called PULSE-CVD19-001, will evaluate the efficacy and safety of INOpulse in patients diagnosed with COVID-19 who require supplemental oxygen before the disease progresses to necessitate mechanical ventilation support. 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 either INOpulse or placebo. The primary endpoint will assess the proportion of subjects that had respiratory failure or mortality, which should allow the trial to serve as a registrational study for approval. In parallel, the Company has applied for federal funding, through BARDA and NIH, to support the clinical study.

PH-PF

- **Planned Pivotal Phase 3 Study**: Bellerophon successfully completed its End-of-Phase 2 meetings with the FDA and finalized key elements of its planned pivotal Phase 3 study of INOpulse for the treatment of PH-PF. If approved, INOpulse would become the first therapy to treat a broad PH-PF population that includes patients at low, intermediate- and high-risk of pulmonary hypertension.

- **iNO-PF Phase 2 Study:** Bellerophon reported positive top-line results from Phase 2 of its ongoing Phase 2/3 randomized, double-blind, placebo-controlled clinical study (iNO-PF) of INOpulse for the treatment of PH-PF. Subjects treated with INOpulse (iNO30 or iNO45) maintained their activity levels, including moderate to vigorous physical activity (MVPA), while subjects on placebo deteriorated. Subjects treated with the higher dose of iNO45 chronically over four months demonstrated statistically significant improvement in MVPA of 14 minutes per day, representing a 20% improvement ($p=0.02$). Improvements in MVPA were supported by benefits in other activity parameters, as well as two patient reported questionnaires. The University of California, San Diego Shortness of Breath Questionnaire improved by 5 points and the St. George's Respiratory Questionnaire total score improved by 3 points, with the Activity and Impacts domains improving by 5 and 6 points, respectively.

- **PHPF-002 (ancillary study to iNO-PF):** Bellerophon reported positive top-line data from PHPF-002, an ancillary dose escalation study assessing the acute hemodynamic effect of INOpulse in PH-PF via right heart catheterization. The study demonstrated that acute treatment with INOpulse provided statistically and clinically significant improvements in pre-

specified hemodynamic parameters, including a 21% reduction in pulmonary vascular resistance, with increased benefit ($p<0.01$) on dose escalation from iNO30 to iNO45, and a 12% reduction in mean pulmonary arterial pressure. The acute hemodynamic benefits underpin the chronic benefit in exercise capacity demonstrated in the iNO-PF study and support utilizing the dose of iNO45 in the planned Phase 3 trial.

Pulmonary Hypertension-Sarcoidosis (PH-Sarc)

- **Phase 2 Clinical Study:** Bellerophon is conducting a Phase 2 dose escalation study in PH-Sarc. The safety and efficacy study is assessing the acute hemodynamic benefit of INOpulse via right heart catheterization. PH-Sarc is an unmet medical need with a median survival of approximately five years after diagnosis. Similar to PH-PF and PH-ILD, PH-Sarc cannot be treated with currently available systemic vasodilators.

Corporate Finance Update:

- In April 2020, the Company closed a registered direct offering of 1,275,000 shares of its common stock at a purchase price of $12.00 per share for total gross proceeds of $15.3 million, before deducting placement agent fees and offering expenses. In May 2020, the Company received $2.0 million from the sale of its New Jersey state 2018 net operating losses (NOLs) and research and development credits.

First Quarter Ended March 31, 2020 Financial Results

For the three months ended March 31, 2020, the Company reported an operating loss of $4.1 million, compared to $4.3 million in the three months ended March 31, 2019.

For the three months ended March 31, 2020, the Company reported a net loss of $5.0 million, or $(1.08) per share, compared to a net loss of $0.8 million, or $(0.18) per share, for the three months ended March 31, 2019.

Net loss for the three months ended March 31, 2020 included an expense of $0.9 million due to a change in fair value of common stock warrant liability, as compared to an income of $1.6 million for the three months ended March 31, 2019. Net income for the first quarter of 2019 also included $1.8 million of tax income from the sale of the New Jersey state 2017 NOLs. The proceeds from the sale of the New Jersey state 2018 NOLs were received in the second quarter of 2020.

Research and development expenses for the three months ended March 31, 2020 were $2.2 million, compared to $2.3 million in the prior year period. The decrease was primarily due to decreased research and development infrastructure cost.

General and administrative expenses for the three months ended March 31, 2020 were $1.9 million, compared to $2.0 million in the prior year period. The decrease was primarily due to lower stock-based compensation.

Balance Sheet

As of March 31, 2020, the Company had cash and cash equivalents of $8.6 million, compared to $9.9 million at December 31, 2019. In April 2020, Bellerophon closed a registered direct offering of 1,275,000 shares of its common stock at a purchase price of $12.00 per share for total gross proceeds of $15.3 million. In May 2020, Bellerophon received an additional $2.0 million in cash from the sale of the Company's 2018 New Jersey state NOLs and R&D tax credits.

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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Bellerophon Therapeutics, Inc.

Condensed Consolidated Balance Sheets

(in thousands except share and per share data)

	As of March 31, 2020 (Unaudited)	As of December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 8,595	$ 9,874
Restricted cash	103	103
Prepaid expenses and other current assets	349	405
Total current assets	9,047	10,382
Restricted cash, non-current	300	300
Right of use asset, net	1,961	2,110
Property and equipment, net	270	316
Total assets	$ 11,578	$ 13,108
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,220	$ 3,106
Accrued research and development	1,785	2,117
Accrued expenses	2,101	1,703
Current portion of operating lease liability	669	658
Total current liabilities	6,775	7,584
Long-term operating lease liability	1,489	1,659
Common stock warrant liability	1,168	274
Total liabilities	9,432	9,517
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value per share; 200,000,000 shares authorized, 4,857,393 and 4,580,127 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	49	46
Preferred stock, $0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at March 31, 2020 and December 31, 2019	—	—
Additional paid-in capital	196,830	193,308
Accumulated deficit	(194,733)	(189,763)
Total stockholders' equity	2,146	3,591
Total liabilities and stockholders' equity	$ 11,578	$ 13,108

Bellerophon Therapeutics, Inc.

Condensed Consolidated Statement of Operations (Unaudited)

(in thousands except share and per share data)

	Three Months Ended March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 2,238	$ 2,305
General and administrative	1,872	2,037
Total operating expenses	4,110	4,342
Loss from operations	(4,110)	(4,342)
Change in fair value of common stock warrant liability	(894)	1,616
Interest income and other, net	34	130
Pre-tax loss	(4,970)	(2,596)
Income tax benefit	—	1,801
Net loss	$ (4,970)	$ (795)
Weighted average shares outstanding:		
Basic	4,615,046	4,346,109
Diluted	4,615,046	4,346,109
Net loss per share:		
Basic	$ (1.08)	$ (0.18)
Diluted	$ (1.08)	$ (0.18)