

**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 6, 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))

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>

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).

- 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 2.02. Results of Operations and Financial Condition.**

On April 6, 2020, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the quarter and year ended December 31, 2019. 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:

<b>Exhibit No.</b>	<b>Description</b>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press Release date April 6, 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: April 6, 2020

By: /s/ Assaf Korner  
Name: Assaf Korner  
Title: Chief Financial Officer



## Bellerophon Provides Clinical Program Update and Reports Fourth Quarter and Full-Year 2019 Financial Results

WARREN, N.J., April 6, 2020 - Bellerophon Therapeutics, Inc. (Nasdaq: BLPH), a clinical-stage biotherapeutics company focused on developing treatments for cardiopulmonary diseases, today provided a clinical program update and reported financial results for the fourth quarter and year ended December 31, 2019.

“We are extremely pleased with the significant progress achieved with our clinical program for INOpulse® to address multiple unmet cardiopulmonary diseases. Most notably, we reported positive top-line results from Phase 2 of our ongoing Phase 2/3 clinical study (iNO-PF) of INOpulse for the treatment of PH-PF, completed our End-of-Phase 2 meetings with the U.S. Food and Drug Administration (FDA), and reached alignment on key parameters for our upcoming pivotal Phase 3 trial for the treatment of pulmonary hypertension associated with pulmonary fibrosis (PH-PF). In addition, in order to address the COVID-19 pandemic, we announced the first patient treated with INOpulse following a recent decision by the U.S. Food and Drug Administration (FDA) to grant emergency expanded access,” said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. “Importantly, our promising INOpulse development program is well-supported by a strong balance sheet. We recently closed a \$15.3 million registered direct offering of our common stock and, as such, we are well-capitalized to progress our development plan for the continued advancement of INOpulse.”

### Clinical Program Highlights:

#### PH-PF

- **Planned Pivotal Phase 3 Study:** Bellerophon Therapeutics 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. The Company intends to dose the first patient in the Phase 3 study shortly. 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 Therapeutics 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 Therapeutics reported positive top-line data from PHPF-002, a recently completed 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 Therapeutics 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.

### COVID-19 (Coronavirus)

- **FDA Granted Emergency Expanded Access Program:** Expanded access treatment with INOpulse was successfully used for the first time in a patient with a diagnosis of COVID-19 at the University of Miami School of Medicine and the patient was subsequently discharged from the hospital. Published *in vitro* data have demonstrated that nitric oxide reduces viral load and prevents viral replication in SARS Coronavirus (SARS-CoV)<sup>1</sup>, and a clinical study in patients infected with SARS-CoV revealed that treatment with inhaled nitric oxide can improve arterial oxygenation, reduce the need for ventilation support and reduce pneumonia infiltration<sup>2</sup>. The genetic similarities between the two coronaviruses and the historical data support INOpulse's potential to provide meaningful benefit for patients infected with COVID-19.

### **Corporate Finance Updates:**

- **Registered Direct Offering of Common Stock:** 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.
- **Convertible Financing Facility:** In December 2019, the Company entered into a \$10 million convertible financing facility led by existing institutional shareholders.

### **Fourth Quarter Financial Results:**

For the fourth quarter ended December 31, 2019, the Company reported a net loss of \$4.1 million, or \$(0.89) per share, compared to a net loss of \$0.9 million, or \$(0.24) per share in the fourth quarter ended December 31, 2018.

Net income for the three months ended December 31, 2018 included a gain of \$3.7 million due to a change in fair value of the Company's common stock warrant liability, as compared to \$0.2 million in the fourth quarter of 2019. On a diluted basis, the Company reported a loss of \$(0.89) per share for the fourth quarter ended December 31, 2019, compared to a loss of \$(1.15) per share in the fourth quarter ended December 31, 2018.

Research and development expenses for the fourth quarter ended December 31, 2019 were \$2.8 million, essentially flat as compared to the prior year period.

General and administrative expenses for the fourth quarter ended December 31, 2019 were \$1.4 million, compared to \$1.9 million in the prior year period. The decrease was primarily due to a decrease in stock-based compensation expenses.

### **2019 Year End Financial Results:**

For the year ended December 31, 2019, the Company reported a net loss of \$13.3 million, or \$(2.95) per share, compared to net income of \$2.8 million, or \$0.73 per share, in the year ended December 31, 2018.

Net income for the year ended December 31, 2018 included a gain of \$24.9 million due to a change in fair value of the Company's common stock warrant liability, as compared to only \$2.7 million in the year ended December 31, 2019. On a diluted basis, the Company reported a loss of \$(2.95) for the year ended December 31, 2019, compared to a loss of \$(5.07) per share in the year ended December 31, 2018.

Research and development expenses for the year ended of December 31, 2019 were \$11.0 million, compared to \$20.3 million in the year ended December 31, 2018. The decrease was primarily due to the conclusion of the INOvation-1 PAH trial, which was partially offset by increased activity in the PH-PF Phase 2/3 program.

General and administrative expenses for the year ended December 31, 2019, were \$6.4 million, compared to \$7.6 million for the year ended December 31, 2018. The decrease was primarily due to lower consulting expenses, as well as a decrease in stock-based compensation expenses.

### **Balance Sheet**

As of December 31, 2019, the Company had cash and cash equivalents of \$9.9 million, compared to cash, cash equivalents and marketable securities of \$16.6 million at December 31, 2018. 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.

### **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.

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1. Akerstrom S et. Al. Nitric oxide inhibits the Replication Cycle of Severe Acute Respiratory Syndrome Coronavirus. *J Virol* 2005; 79(3):1966-9.
2. 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.

**Bellerophon Therapeutics, Inc.**  
**Condensed Consolidated Balance Sheets**  
(in thousands except share and per share data)

	As of December 31, 2019	As of December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 9,874	\$ 16,645
Restricted cash	103	101
Prepaid expenses and other current assets	405	650
Total current assets	10,382	17,396
Restricted cash, non-current	300	300
Right of use asset, net	2,110	—
Property and equipment, net	316	664
Total assets	<u>\$ 13,108</u>	<u>\$ 18,360</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,106	\$ 2,755
Accrued research and development	2,117	3,771
Accrued expenses	1,703	1,013
Current portion of operating lease liabilities	658	—
Total current liabilities	7,584	7,539
Long-term operating lease liabilities	1,659	—
Common stock warrant liability	274	6,965
Total liabilities	9,517	14,504
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, \$0.01 par value per share; 200,000,000 shares authorized, 4,580,127 and 3,911,857 shares issued and outstanding at December 31, 2019 and 2018, respectively	46	39
Preferred stock, \$0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at June 30, 2019 and December 31, 2018	—	—
Additional paid-in capital	193,308	180,313
Accumulated deficit	(189,763)	(176,496)
Total stockholders' equity	3,591	3,856
<b>Total liabilities and stockholders' equity</b>	<u>\$ 13,108</u>	<u>\$ 18,360</u>



**Bellerophon Therapeutics, Inc.**

**Condensed Consolidated Statement of Operations**

(Amounts in thousands except share and per share data)

	<b>Year Ended</b>		
	<b>2019</b>	<b>2018</b>	<b>2017</b>
Operating expenses:			
Research and development	\$ 11,032	\$ 20,258	\$ 17,854
General and administrative	6,441	7,621	6,745
Total operating expenses	<u>17,473</u>	<u>27,880</u>	<u>24,599</u>
Loss from operations	(17,473)	(27,880)	(24,599)
Change in fair value of common stock warrant liability	2,682	24,877	(30,403)
Warrant amendment charge	(674)	—	—
Interest income and other, net	397	378	184
Pre-tax loss	(15,068)	(2,625)	(54,818)
Income tax benefit	(1,801)	(5,439)	—
Net (loss) income	<u>\$ (13,267)</u>	<u>\$ 2,814</u>	<u>\$ (54,818)</u>
Weighted average shares outstanding:			
Basic	4,503,375	3,829,769	2,596,729
Diluted	4,503,375	4,336,593	2,596,729
Net (loss) income per share:			
Basic	\$ (2.95)	\$ 0.73	\$ (21.11)
Diluted	\$ (2.95)	\$ (5.07)	\$ (21.11)