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): August 5, 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):

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 August 5, 2020, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the three and six months ended June 30, 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 August 5, 2020.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated August 5, 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: August 5, 2020

By: /s/ Assaf Korner

Name: Assaf Korner
Title: Chief Financial Officer

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

WARREN, N.J., August 5, 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 provided a clinical program update and reported financial results for the second quarter ended June 30, 2020.

"Bellerophon has achieved significant clinical and regulatory progress advancing our development program for the INOpulse® inhaled nitric oxide therapy," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "We are pleased to have treated the first patient with INOpulse in our COViNOX Phase 3 clinical trial for the treatment of COVID-19 and are excited to work with leading hospitals across the U.S. to enroll patients as expeditiously as possible. The trial initiation follows highly encouraging preliminary data generated from 180 hospitalized COVID-19 patients treated under our recently completed Emergency Expanded Access Program (EAP)."

"Turning to our Pulmonary Fibrosis program, we have recently completed our End-of-Phase 2 meetings with the U.S. Food and Drug Administration (FDA) to align on study design and endpoints and look forward to initiating our pivotal Phase 3 REBUILD trial of INOpulse in Pulmonary Hypertension associated with Pulmonary Fibrosis (PH-PF)," continued Mr. Tenenbaum. "Importantly, results from Cohort 1 of the Phase 2 Study were published in the August 2020 edition of the peer-reviewed *CHEST* journal and the results from Cohort 2 are being presented at the upcoming American Thoracic Society (ATS) virtual conference."

"Our strong balance sheet, enhanced by our recently closed $59.0 million from public and registered direct offerings, provides us with the resources necessary to efficiently advance our INOpulse development program and achieve our planned clinical milestones," concluded Mr. Tenenbaum.

Clinical Program Highlights:

COVID-19 (Coronavirus)

- **COViNOX Phase 3 Study:** Bellerophon announced that the first patient has been treated in the Company's Phase 3 clinical study of INOpulse inhaled nitric oxide (iNO) therapy for the treatment of COVID-19. The Phase 3 randomized, placebo-controlled COViNOX study will evaluate the efficacy and safety of the investigational INOpulse therapy in patients diagnosed with COVID-19 who require supplemental oxygen. The COViNOX 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 at major U.S. hospitals. 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 potential approval. Bellerophon has also applied for federal funding, through the Biomedical Advanced Research and Development Authority and the National Institutes of Health, to support the clinical study.

- **Emergency Expanded Access:** Under the recently completed EAP, 180 patients at 18 hospitals across the U.S. received treatment with INOpulse for COVID-19 under emergency expanded access granted by the FDA. The program allowed INOpulse to be used for the treatment of

specific patients with COVID-19 under the care and supervision of their physician. Preliminary data demonstrated a 73.0% recovery rate and 6.3% mortality rate at day 14 from treatment initiation. Importantly, INOpulse was well-tolerated with no safety concerns related to the therapy observed by the treating physicians.

PH-PF

- **REBUILD Phase 3 Study**: Bellerophon successfully completed its End-of-Phase 2 meetings with the FDA and finalized key elements of its Phase 3 REBUILD registrational study (iNO-PF Cohort 3) of INOpulse for the treatment of PH-PF. The REBUILD study will enroll 300 PH-PF patients who will be treated with either INOpulse or placebo. The primary endpoint is change in moderate to vigorous physical activity (MVPA). The Company expects to initiate the REBUILD study in the second half of 2020. 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 its Phase 2 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 MVPA, while subjects on placebo deteriorated. Subjects treated with the higher dose of iNO45 chronically over four months demonstrated clinically and 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 (SGRQ) total score improved by 3 points, with the Activity and Impacts domains improving by 5 and 6 points, respectively. An anchoring analysis between MVPA and the SGRQ Activity domain established a minimally important difference for MVPA of 4.8 minutes per day.

  The results from Cohort 1 of the iNO-PF study were published in the August 2020 edition of the peer-reviewed *CHEST* journal. These results established the safety of the iNO30 dose and confirmed the potential for INOpulse to provide clinically meaningful benefits in levels of daily activity in this patient population.

  The results from Cohort 2 of the iNO-PF study are being presented as an e-Poster, available from August 5, 2020 to November 10, 2020, at the 2020 ATS virtual conference. These results demonstrated the safety and efficacy of the iNO45 dose and established the dose and endpoints for the pivotal REBUILD Phase 3 study.

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 Update:

- In April 2020, the Company closed a registered direct offering for total gross proceeds of approximately $15.3 million, before deducting placement agent fees and offering expenses.
- In May 2020, the Company closed a public offering of common stock and a concurrent registered direct offering for total gross proceeds of approximately $43.7 million, before deducting placement agent fees and offering expenses.
- In June 2020, the Company was added to the Russell 3000® and Microcap® Indexes.

Second Quarter Ended June 30, 2020 Financial Results

For the three months ended June 30, 2020, the Company reported an operating loss of $5.8 million, compared to $4.2 million in the three months ended June 30, 2019.

For the three months ended June 30, 2020, the Company reported a net loss of $3.8 million, or $(0.51) per basic and diluted share, compared to a net loss of $4.1 million, or $(0.90) per basic and diluted share, for the three months ended June 30, 2019.

Net loss for the three months ended June 30, 2020 included $2.1 million of tax income from the sale of the New Jersey state 2018 net operating losses and an expense of $0.2 million due to a change in fair value of common stock warrant liability, as compared to an income of $0.7 million for the three months ended June 30, 2019.

Research and development expenses for the three months ended June 30, 2020 were $3.5 million, compared to $2.6 million in the prior year period. The increase was primarily due to increased activities related to the development of INOpulse.

General and administrative expenses for the three months ended June 30, 2020 were $2.3 million, compared to $1.6 million in the prior year period. The increase was primarily due to higher consulting fees.

Six Months Ended June 30, 2020 Financial Results

For the six months ended June 30, 2020, the Company reported an operating loss of $9.9 million, compared to $8.6 million in the six months ended June 30, 2019.

For the six months ended June 30, 2020, the Company reported a net loss of $8.8 million, or $(1.44) per basic and diluted share, compared to a net loss of $4.9 million, or $(1.10) per basic and diluted share, in the six months ended June 30, 2019.

Net loss for the six months ended June 30, 2020 included an expense of $1.1 million due to a change in fair value of the Company’s common stock warrant liability, as compared to an income of $2.3 million for the six months ended June 30, 2019.

Research and development expenses for the six months ended June 30, 2020 were $5.7 million, compared to $4.9 million in the prior year period. The increase was primarily due to increased activities related to the development of INOpulse.

General and administrative expenses for the six months ended June 30, 2020 were $4.2 million, compared to $3.6 million in the prior year period. The increase was primarily due to higher consulting fees.

Balance Sheet

As of June 30, 2020, the Company had cash and cash equivalents of $59.3 million, compared to $9.9 million at December 31, 2019. In the second quarter of 2020, Bellerophon closed a public offering of common stock and two registered direct offerings, with gross proceeds of approximately $59.0 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 and infectious 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 June 30, 2020 (Unaudited)	As of December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 59,307	$ 9,874
Restricted cash	103	103
Prepaid expenses and other current assets	903	405
Total current assets	60,313	10,382
Restricted cash, non-current	300	300
Right of use asset, net	1,811	2,110
Property and equipment, net	228	316
Total assets	$ 62,652	$ 13,108
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,838	$ 3,106
Accrued research and development	1,843	2,117
Accrued expenses	1,216	1,703
Current portion of operating lease liability	680	658
Total current liabilities	6,577	7,584
Long-term operating lease liability	1,314	1,659
Common stock warrant liability	1,361	274
Total liabilities	9,252	9,517
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value per share; 200,000,000 shares authorized, 9,497,777 and 4,580,127 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	95	46
Preferred stock, $0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Additional paid-in capital	251,858	193,308
Accumulated deficit	(198,553)	(189,763)
Total stockholders' equity	53,400	3,591
Total liabilities and stockholders' equity	$ 62,652	$ 13,108

Bellerophon Therapeutics, Inc.

Condensed Consolidated Statement of Operations (Unaudited)

(in thousands except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 3,451	$ 2,629	$ 5,689	$ 4,934
General and administrative	2,308	1,596	4,180	3,633
Total operating expenses	5,759	4,225	9,869	8,567
Loss from operations	(5,759)	(4,225)	(9,869)	(8,567)
Change in fair value of common stock warrant liability	(193)	673	(1,087)	2,289
Warrant amendment charge	—	(674)	—	(674)
Interest income and other, net	7	121	41	251
Pre-tax loss	(5,945)	(4,105)	(10,915)	(6,701)
Income tax benefit	2,125	—	2,125	1,801
Net loss	$ (3,820)	$ (4,105)	$ (8,790)	$ (4,900)
Weighted average shares outstanding:				
Basic	7,554,023	4,543,993	6,084,534	4,445,597
Diluted	7,554,023	4,543,993	6,084,534	4,445,597
Net loss per share:				
Basic	$ (0.51)	$ (0.90)	$ (1.44)	$ (1.10)
Diluted	$ (0.51)	$ (0.90)	$ (1.44)	$ (1.10)