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): November 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 November 5, 2020, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the three and nine months ended September 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 November 5, 2020.

EXHIBIT INDEX

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

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

Exhibit 99.1

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

WARREN, N.J., Nov. 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 third quarter ended September 30, 2020.

"Bellerophon continues to advance multiple development programs for its INOpulse® inhaled nitric oxide therapy," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "We are pleased with the rate of enrollment in our ongoing COViNOX Phase 3 clinical trial of INOpulse for the treatment of COVID-19. The results of a planned interim analysis are expected shortly, as the first 100 patients have now completed their 28-day assessment period. In support of our development and manufacturing plans in COVID-19, we have applied for government funding and are in discussions with a number of federal agencies, including Operation Warp Speed."

"In our pivotal Phase 3 REBUILD trial for fibrotic interstitial lung disease (fILD) patients at risk of associated pulmonary hypertension, we initiated the first clinical research sites, allowing us to begin patient enrollment," continued Mr. Tenenbaum. "The Phase 3 trial builds upon our successful Phase 2 studies, and we look forward to presenting both our Phase 2 results and the design of our Phase 3 REBUILD trial this week at the American Thoracic Society (ATS) Interstitial Lung Disease Mini Symposia and the Pulmonary Fibrosis Foundation (PFF) Meeting."

"Moreover, we continue to operate from a position of financial strength. Importantly, our current balance sheet provides us with the resources to progress our INOpulse development program through upcoming near-term catalysts and top-line results from the Phase 3 REBUILD trial," concluded Mr. Tenenbaum.

Clinical Program Highlights:

COVID-19 (Coronavirus)

- **COViNOX Phase 3 Study:** Bellerophon continues to enroll patients in the Company's ongoing Phase 3 clinical study of INOpulse inhaled nitric oxide (iNO) therapy for the treatment of COVID-19 and anticipates the availability of the results from a planned interim analysis shortly. The Phase 3 randomized, placebo-controlled COViNOX study is evaluating 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 approval. In parallel, Bellerophon has applied for government funding and remains in ongoing discussions with multiple federal agencies to support the Company's development and manufacturing plans in COVID-19.

fILD

- **REBUILD Phase 3 Study**: Bellerophon successfully completed its End-of-Phase 2 meetings with the U.S. Food and Drug Administration and finalized its Phase 3 REBUILD registrational study of INOpulse for the treatment of fILD. The first research sites in the Phase 3 REBUILD study have been initiated, allowing the Company to begin recruiting patients into the trial. The REBUILD study will enroll 300 fILD patients who will be treated with either INOpulse or placebo. The primary endpoint is change in moderate to vigorous physical activity (MVPA). If approved, INOpulse would become the first therapy to treat a broad fILD population that includes patients at low-, intermediate- and high-risk of pulmonary hypertension.

  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 fILD. 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 and the St. George's Respiratory Questionnaire.

  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 will be presented at the ATS Interstitial Lung Disease Mini Symposia. These results demonstrated the safety and efficacy of the iNO45 dose and established the dose and endpoints for the pivotal REBUILD Phase 3 study. In addition, Bellerophon will present its planned Phase 3 REBUILD study at the upcoming 2020 PFF Meeting.

Pulmonary Hypertension-Sarcoidosis (PH-Sarc)

- **Phase 2 Clinical Study:** Bellerophon is continuing enrollment in a Phase 2 dose escalation study in PH-Sarc, and anticipates the availability of top-line data around the end of 2020. 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 August 2020, Bellerophon strengthened its management team through the appointment of cardiopulmonary disease expert, Wassim Fares, M.D., MSCR, as Chief Medical Officer.

- In September 2020, the Company presented at the Cantor Fitzgerald Virtual Global Healthcare Conference and H.C. Wainwright 22nd Annual Global Investment Conference.

Third Quarter Ended September 30, 2020 Financial Results

For the three months ended September 30, 2020, the Company reported an operating loss of $8.3 million, compared to $4.6 million in the three months ended September 30, 2019.

For the three months ended September 30, 2020, the Company reported a net loss of $7.9 million, or $(0.84) per basic and diluted share, compared to a net loss of $4.3 million, or $(0.94) per basic and diluted share, for the three months ended September 30, 2019.

Research and development expenses for the three months ended September 30, 2020 were $6.1 million, compared to $3.3 million in the prior year period. The increase was primarily due to increased activities related to the development of INOpulse for the treatment of COVID-19 and fILD patients.

General and administrative expenses for the three months ended September 30, 2020 were $2.2 million, compared to $1.3 million in the prior year period. The increase was primarily due to higher expenses related to stock based compensation, financing, IP and legal fees.

Nine Months Ended September 30, 2020 Financial Results

For the nine months ended September 30, 2020, the Company reported an operating loss of $18.1 million, compared to $13.2 million in the nine months ended September 30, 2019.
For the nine months ended September 30, 2020, the Company reported a net loss of $16.7 million, or $(2.31) per basic and diluted share, compared to a net loss of $9.2 million, or $(2.05) per basic and diluted share, in the nine months ended September 30, 2019.

Net loss for the nine months ended September 30, 2020 included an expense of $0.8 million due to a change in fair value of the Company's common stock warrant liability, as compared to an income of $2.5 million for the nine months ended September 30, 2019.

Research and development expenses for the nine months ended September 30, 2020 were $11.8 million, compared to $8.2 million in the prior year period. The increase was primarily due to increased activities related to the development of INOpulse for the treatment of COVID-19 and fILD patients.

General and administrative expenses for the nine months ended September 30, 2020 were $6.4 million, compared to $5.0 million in the prior year period. The increase was primarily due to higher expenses related to financing, IP and legal fees.

Balance Sheet
As of September 30, 2020, the Company had cash and cash equivalents of $54.0 million, compared to $9.9 million at December 31, 2019.

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 September 30, 2020	As of December 31, 2019
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 53,970	$ 9,874
Restricted cash	103	103
Prepaid expenses and other current assets	633	405
Total current assets	54,706	10,382
Restricted cash, non-current	300	300
Right of use asset, net	1,659	2,110
Property and equipment, net	198	316
Other non-current assets	177	—
Total assets	$ 57,040	$ 13,108
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,820	$ 3,106
Accrued research and development	3,097	2,117
Accrued expenses	1,380	1,703
Current portion of operating lease liability	692	658
Total current liabilities	8,989	7,584
Long-term operating lease liability	1,136	1,659
Common stock warrant liability	1,042	274
Total liabilities	11,167	9,517
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value per share; 200,000,000 shares authorized and 9,497,777 and 4,580,127 shares issued and outstanding at September 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 September 30, 2020 and December 31, 2019	—	—
Additional paid-in capital	252,264	193,308
Accumulated deficit	(206,486)	(189,763)
Total stockholders' equity	45,873	3,591
Total liabilities and stockholders' equity	$ 57,040	$ 13,108

Bellerophon Therapeutics, Inc.

Condensed Consolidated Statement of Operations (Unaudited)

(in thousands except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 6,065	$ 3,259	$ 11,754	$ 8,193
General and administrative	2,196	1,332	6,376	4,965
Total operating expenses	8,261	4,591	18,130	13,158
Loss from operations	(8,261)	(4,591)	(18,130)	(13,158)
Change in fair value of common stock warrant liability	319	215	(768)	2,504
Warrant amendment charge	—	—	—	(674)
Interest income and other, net	9	89	50	340
Pre-tax loss	(7,933)	(4,287)	(18,848)	(10,988)
Income tax benefit	—	—	2,125	1,801
Net loss	$ (7,933)	$ (4,287)	$ (16,723)	$ (9,187)
Weighted average shares outstanding:				
Basic	9,491,111	4,553,535	7,228,349	4,481,972
Diluted	9,491,111	4,553,535	7,228,349	4,481,972
Net loss per share:				
Basic	$ (0.84)	$ (0.94)	$ (2.31)	$ (2.05)
Diluted	$ (0.84)	$ (0.94)	$ (2.31)	$ (2.05)