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 8, 2019

Bellerophon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36845**	**47-3116175**
	(Commission	(IRS Employer
(State or Other Jurisdiction of Incorporation)	File Number)	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):

☐ 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
Common Stock, $0.01 par value per share	**BLPH**	**The Nasdaq Global 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).

☒ 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 August 8, 2019, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the three and six months ended June 30, 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:

99.1 Press Release dated August 8, 2019.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated August 8, 2019 (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 8, 2019

By: /s/ Assaf Korner

Name: Assaf Korner
Title: Chief Financial Officer

Exhibit 99.1

Bellerophon Provides Business Update and Reports Second Quarter 2019 Financial Results

WARREN, N.J., August 8, 2019 -- Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company, today provided a business update and reported financial results for the three and six months ended June 30, 2019.

"In the first half of 2019, Bellerophon has achieved substantial clinical and regulatory progress with our INOpulse® pipeline. For our lead program in Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD), we presented positive data from Cohort 1 (iNO30) of our ongoing iNO-PF Phase 2/3 study, which demonstrated clinically and statistically significant improvement in moderate to vigorous physical activity (MVPA), further supported by improvements in other important activity and cardiopulmonary parameters," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "Based on these compelling results, we reached agreement with the U.S. Food and Drug Administration (FDA) on modifying the iNO-PF study to allow Cohort 3 to serve as the pivotal Phase 3 study, with MVPA as the primary endpoint. More recently, we were pleased to complete enrollment in Cohort 2 of the iNO-PF study, which will assess a higher dose (iNO 45 mg/kg) for a 16-week treatment evaluation period."

"As we enter the second half of 2019, we look forward to several important catalysts and expect to report top-line results for Cohort 2 by the end of the year. Per the agreement with the FDA, the results from Cohorts 1 and 2 will be used to determine the optimal dose between iNO30 and iNO45 to progress into the pivotal Cohort 3, which we expect to initiate in the first quarter of 2020. PH-ILD is a debilitating and life threatening disease characterized by severe functional impairment and the inability to perform basic daily tasks. The improvements in MVPA seen in our first Cohort and the recent regulatory agreement for our Phase 3 Cohort position INOpulse to potentially become the first approved therapy in this serious unmet medical need," concluded Mr. Tenenbaum.

Key Recent Highlights

PH-ILD:

- **Cohort 1**: Bellerophon presented results from Cohort 1 of iNO-PF, a randomized, double-blind, placebo-controlled clinical study of INOpulse for the treatment of PH-ILD, as a late-breaking abstract oral presentation at the American Thoracic Society 115th International Conference. Cohort 1, the first of 3 cohorts, included 41 subjects randomized 1:1 to either iNO 30 (30 mcg/kg IBW/hr) or placebo, for a period of 8 weeks of blinded treatment. Top-line data from Cohort 1 demonstrated clinically and statistically significant improvement in MVPA, as well as other physical activity parameters measured by continuous activity monitoring (actigraphy):
  - MVPA (walking, stairs, yardwork, etc.) improved by 34% (8% increase on iNO vs. 26% decrease on placebo; p=0.04)
    - 23% of subjects on iNO had a clinically significant improvement in MVPA, compared to 0% of subjects on placebo (placebo corrected difference of 23%)
    - 39% of subjects on iNO had a clinically significant decline in MVPA, compared to 71% of subjects on placebo (placebo corrected difference of 32%)
  - Overall activity improved by 12% (stable on iNO vs. 12% decrease on placebo; p=0.05)
  - Calorie expenditure improved by 12% (6% decrease on iNO vs. 18% decrease on placebo; p=0.05)
  - Oxygen saturation improved by 20% (9% improvement on iNO vs. 11% deterioration on placebo)
  - Subjects on open-label extension demonstrated consistent improvements in MVPA and overall activity, with subjects transitioning from placebo to open-label experiencing a reversal from worsening to improving

- **Cohort 2**: The Company recently completed recruitment in Cohort 2, which will assess a higher dose (iNO45), as well as a 16-week blinded treatment period. Cohort 2 includes 44 subjects randomized 2:1 to either iNO45 (45 mcg/kg IBW/hr) or placebo. Subjects will complete 16 weeks of blinded treatment on iNO45 vs. placebo, and then continue onto open-label treatment. Bellerophon expects to report top-line results by year-end 2019.

- **Cohort 3**: Based on the results from Cohort 1, the Company reached agreement with the FDA on the use of MVPA as the primary endpoint in the pivotal Phase 3 study. In addition, the FDA agreed with Bellerophon's proposal that the ongoing Phase 2b study be amended to a Phase 2/3 trial, allowing Cohort 3 to serve as the pivotal Phase 3 cohort for approval. The results from Cohorts 1 and 2 will be used to determine the optimal dose between iNO30 and iNO45 to progress into Phase 3. The Company anticipates initiating Phase 3 in the first quarter of 2020, with approximately 300 subjects randomized 1:1 to active or placebo for a period of 16 weeks of blinded treatment.

PH-Sarcoidosis: Bellerophon has initiated a Phase 2 dose escalation study in PH associated with sarcoidosis. The study is a dose escalation safety and efficacy study that will assess the hemodynamic benefit of INOpulse via right heart catheterization. PH-Sarcoidosis is an unmet medical need with a median survival of approximately five years after diagnosis. Similar to PH-ILD and PH-

COPD, PH-Sarcoidosis cannot be treated with currently available systemic vasodilators.

PH-COPD: Following positive results from its Phase 2 study for INOpulse in PH-COPD and agreement with the FDA, Bellerophon finalized the design of a Phase 2b study in PH-COPD. This trial will be a randomized, double-blind, placebo-controlled study that will evaluate multiple clinically relevant endpoints.

Second Quarter Ended June 30, 2019 Financial Results
For the three months ended June 30, 2019, the Company reported a net loss of $4.1 million, or $(0.06) per basic and diluted share, compared to a net loss of $11.5 million, or $(0.20) per basic and diluted share, in the three months ended June 30, 2018.

Net loss for the three months ended June 30, 2019, included an adjustment of $0.7 million due to a change in fair value of the Company's common stock warrant liability, as compared to an adjustment of $(3.7) million for the three months ended June 30, 2018.

Research and development expenses for the three months ended June 30, 2019, were $2.6 million compared to $5.8 million in the prior year period. The decrease was primarily due to the conclusion of the INOvation-1 PAH trial, which was partially offset by increased activity in the PH-ILD Phase 2b program.

General and administrative expenses for the three months ended June 30, 2019, were $1.6 million compared to $2.1 in the prior year period. The decrease was primarily due to a decrease in stock-based compensation expenses.

Six Months Ended June 30, 2019 Financial Results
For the six months ended June 30, 2019, the Company reported a net loss of $4.9 million, or $(0.07) per basic and diluted share, compared to a net loss of $7.4 million, or $(0.13) share, in the six months ended June 30, 2018. On a diluted basis, the Company reported a loss of $(0.16) per share for the six months ended June 30, 2018.

Net loss for the six months ended June 30, 2019, included an adjustment of $2.3 million due to a change in fair value of the Company's common stock warrant liability, as compared to an adjustment of $3.4 million for the six months ended June 30, 2018.

Research and development expenses for the six months ended June 30, 2019, were $4.9 million compared to $12.2 million in the prior year period. The decrease was primarily due to the conclusion of the INOvation-1 PAH trial, which was partially offset by increased activity in the PH-ILD Phase 2b program.

General and administrative expenses for the six months ended June 30, 2019, were $3.6 million compared to $4.2 million in the prior year period. The decrease was primarily due to lower consulting expenses, as well as a decrease in stock-based compensation expenses.

Balance Sheet
As of June 30, 2019, the Company had cash and cash equivalents of $16.8 million, compared to $16.6 million at December 31, 2018.

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.

Contacts

At Bellerophon:
Fabian Tenenbaum
Chief Executive Officer
(908) 574-4767

At LifeSci Advisors:
Brian Ritchie
(212) 915-2578
britchie@lifesciadvisors.com

Bellerophon Therapeutics, Inc.

Condensed Consolidated Balance Sheets

(in thousands except share and per share data)

	As of June 30, 2019	As of December 31, 2018
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 16,798	$ 16,645
Restricted cash	102	101
Prepaid expenses and other current assets	825	650
Total current assets	17,725	17,396
Restricted cash, non-current	300	300
Right of use asset, net	2,065	—
Property and equipment, net	488	664
Total assets	$ 20,578	$ 18,360
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,822	$ 2,755
Accrued research and development	2,580	3,771
Accrued expenses	752	1,013
Current portion of operating lease liability	556	—
Total current liabilities	6,710	7,539
Long-term operating lease liability	1,739	—
Common stock warrant liability	667	6,965
Total liabilities	9,116	14,504
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value per share; 200,000,000 shares authorized, 68,906,765 and 58,679,492 shares issued and outstanding at June 30, 2019 and December 31, 2018 respectively	689	587
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	192,169	179,765
Accumulated deficit	(181,396)	(176,496)
Total stockholders' equity	11,462	3,856
Total liabilities and stockholders' equity	$ 20,578	$ 18,360

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,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 2,629	$ 5,815	$ 4,934	$ 12,195
General and administrative	1,596	2,058	3,633	4,170
Total operating expenses	4,225	7,873	8,567	16,365
Loss from operations	(4,225)	(7,873)	(8,567)	(16,365)
Change in fair value of common stock warrant liability	673	(3,689)	2,289	3,361
Warrant amendment charge	(674)	—	(674)	—
Interest income and other, net	121	91	251	190
Pre-tax loss	(4,105)	(11,471)	(6,701)	(12,814)
Income tax benefit	—	—	1,801	5,439
Net loss	$ (4,105)	$ (11,471)	$ (4,900)	$ (7,375)
Weighted average shares outstanding:				
Basic	68,159,901	57,229,259	66,683,967	57,145,041
Diluted	68,159,901	57,229,259	66,683,967	66,289,414
Net loss per share:				
Basic	$ (0.06)	$ (0.20)	$ (0.07)	$ (0.13)
Diluted	$ (0.06)	$ (0.20)	$ (0.07)	$ (0.16)