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): January 4, 2017

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))

Item 7.01. Regulation FD Disclosure.

Bellerophon Therapeutics, Inc. (the "Company") issued a press release on January 4, 2017 announcing that it received confirmation from the U.S. Food and Drug Administration (FDA) of the Agency's acceptance of all modifications proposed by the Company to its Phase 3 program for INOpulse in Pulmonary Arterial Hypertension (PAH). Under the newly modified Phase 3 program, the ongoing one-year INOvation-1 study, and a second confirmatory randomized withdrawal study with approximately 40 patients who will be crossing over from the INOvation-1 study, can serve as the two adequate and well-controlled studies to support a New Drug Application filing for INOpulse in PAH subjects on long term oxygen treatment (LTOT). INOvation-1 and the randomized withdrawal study are planned to be conducted on near parallel timelines, which could reduce the time to market for INOpulse in PAH by approximately two years. A copy of this press release is attached hereto as Exhibit 99.1. The information included in 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 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:

Exhibit No.	Description
99.1	Press Release dated January 4, 2017 (furnished and not filed for purposes of Item 7.01)

SIGNATURE

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: January 4, 2017

By: /s/ Fabian Tenenbaum

Fabian Tenenbaum
Chief Executive Officer

Bellerophon Therapeutics Announces FDA Acceptance of Modifications to INOpulse Pulmonary Arterial Hypertension Phase 3 Program

Protocol Changes have Potential to Reduce Time to Market for INOpulse by Approximately Two Years and Will Result in Substantial Cost Savings for Company

Warren, NJ, January 4, 2017 -Bellerophon Therapeutics, Inc. (Nasdaq: BLPH), a clinical-stage biotherapeutics company, today announced that it received confirmation from the U.S. Food and Drug Administration (FDA) of the Agency's acceptance of all modifications proposed by the Company to its Phase 3 program for INOpulse in Pulmonary Arterial Hypertension (PAH). Under the newly modified Phase 3 program, the ongoing one-year INOvation-1 study, and a second confirmatory randomized withdrawal study with approximately 40 patients who will be crossing over from the INOvation-1 study, can serve as the two adequate and well-controlled studies to support a New Drug Application filing for INOpulse in PAH subjects on long term oxygen treatment (LTOT). INOvation-1 and the randomized withdrawal study are planned to be conducted on near parallel timelines, which could reduce the time to market for INOpulse in PAH by approximately two years.

Both studies include an interim analysis approximately half-way through each study, estimated to occur by the end 2017 for the INOvation-1 study and in the second half of 2018 for the withdrawal study. The interim analysis will allow both studies to be stopped early if efficacy is demonstrated.

The original Phase 3 program called for two studies, the INOvation-1 study (n=188; placebo arm and iNO 75 arm), followed by the INOvation-2 study (n=282; placebo arm, iNO 50 arm and iNO 75 arm). Based on these parameters, the Company anticipated that INOpulse could receive regulatory approval in 2022. With the approved modifications to the Phase 3 program, the INOvation-2 study will be replaced with the randomized withdrawal study, a much smaller study in approximately 40 subjects over a four-month enrichment period and two month randomized withdrawal. Under this revised clinical trial protocol, INOpulse could receive regulatory approval as early as 2020.

"We are gratified that the FDA has agreed with the proposed modifications to our PAH Phase 3 program, which have the potential to make INOpulse available to PAH patients approximately two years earlier than otherwise would have been possible under the original Phase 3 program," said Fabian Tenenbaum, President and Chief Executive Officer of Bellerophon. "PAH is a rare disease and many patients continue to suffer from poor outcomes with currently available treatments. We believe INOpulse has the potential, if approved, to be an effective and well-tolerated treatment alternative for these patients. The modification of our Phase 3 program will also substantially reduce Bellerophon's clinical development costs."

In the modified Phase 3 program, following completion of INOvation-1, subjects will receive at least four months of active, open-label iNO treatment with a dose of 75 mcg/kg IBW/hr (iNO75). Those subjects who demonstrate ≥ 30 meter improvement in six minute walk distance, the primary endpoint of INOvation-1, and can tolerate the iNO, will constitute an "enriched" population of iNO responders who will be randomized to either placebo or iNO75 in the withdrawal study. Changes in clinical status (defined as clinical worsening) within an individual patient during the randomized withdrawal period will provide the necessary evidence of whether the improvements observed during the enrichment phase were related or non-related to iNO therapy. The proposed study design, therefore, provides the formal confirmatory evidence of whether iNO at a dose of 75 mcg/kg IBW/hr delivered via the INOpulse delivery device for up to 24 hours per day is efficacious in subjects with PAH concomitantly using approved PAH medication and LTOT.

About the INOpulse Clinical Program

The lead indication for INOpulse is Pulmonary Arterial Hypertension (PAH). In February 2016, Bellerophon announced encouraging results from the long-term extension of the Company's Phase 2 PAH clinical trial demonstrating benefit for patients on long-term oxygen therapy whose disease is progressing despite taking one or more existing PAH therapies. The Phase 3 program will include two confirmatory trials in 188 patients. The primary endpoint for the INOvation-1 trial is six minute walk distance (6MWD), with time to clinical worsening (TTCW) as a secondary endpoint. The primary endpoint for the randomized withdrawal study will be TTCW. Bellerophon also intends to continue with Phase 2 testing in Pulmonary Hypertension (PH) associated with Chronic Obstructive Pulmonary Disease (PH-COPD) and PH associated with Idiopathic Pulmonary Fibrosis (PH-IPF), for which results are anticipated in 2017.

About Bellerophon

Bellerophon Therapeutics is a clinical-stage biotherapeutics company focused on developing innovative therapies at the intersection of drugs and devices that address significant unmet medical needs in the treatment of cardiopulmonary diseases. The Company is currently developing three product candidates under its INOpulse program, a proprietary pulsatile nitric oxide delivery device. The first candidate is for the treatment of pulmonary arterial hypertension (PAH), for which the Company has

commenced Phase 3 clinical trials in 2016. The second is for the treatment of pulmonary hypertension associated with chronic obstructive pulmonary disease (PH-COPD) and the third candidate is for the treatment of pulmonary hypertension associated with Idiopathic Pulmonary Fibrosis (PH-IPF); both of these products are in Phase 2 development. 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," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "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 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.

Contact
Bellerophon Therapeutics:
Fabian Tenenbaum, Chief Executive Officer
(908) 574-4819

LifeSci Advisors
Bob Yedid, Managing Director
(646) 597-6989
bob@lifesciadvisors.com