

Bellerophon Therapeutics, Inc.
Form 8-K
January 04, 2017

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 (IRS Employer
File Number) Identification No.)

184 Liberty Corner Road, Suite 302 07059
Warren, New Jersey
(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))
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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