

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): December 17, 2019

Bellerophon Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation)	001-36845 (Commission File Number)	47-3116175 (IRS Employer Identification No.)
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184 Liberty Corner Road, Suite 302 Warren, New Jersey (Address of Principal Executive Offices)	07059 (Zip Code)
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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))

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).

Securities registered pursuant to Section 12(b) of the Act:

	Title of each class Common Stock, \$0.01 par value per share	Trading Symbol(s) BLPH	Name of each exchange on which registered The Nasdaq Capital Market
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 1.01 Entry into a Material Definitive Agreement.

On December 16, 2019, Bellerophon Therapeutics, Inc. (the “Company”) and New Mountain Partners II AIV-A LP, New Mountain Partners II AIV-B LP, Allegheny New Mountain Partners LP, New Mountain Affiliated Investors II LP, Puissance Capital Management LP, Jonathan M. Peacock, Naseem Amin and Ted Wang (each a Lender and collectively, the “Lenders”) entered into a Binding Term Sheet and Agreement for Line of Credit Facility (the “Term Sheet”). Pursuant to the Term Sheet, the Lenders will make available to the Company, on a pro rata basis, a \$10,000,000 line of credit facility pursuant to which the Company will have the right to draw down \$5,000,000 after March 31, 2020, provided that the Company has randomized the first patient in its iNO-PF Phase 3 clinical trial by such date, and another \$5,000,000 after June 30, 2020, provided that no drawdowns shall be made later than December 31, 2020, and such drawdowns shall be convertible into shares of the Company’s common stock, par value \$0.01 per share, immediately prior to a change of control pursuant to the terms and conditions of the Term Sheet (the “Credit Line”). It shall be a condition to each drawdown that there has been no material adverse change in the condition (financial or otherwise), properties, business or operation of the Company since the date of the Term Sheet.

The Company shall pay the Lenders a fee in cash equal to \$300,000 in the aggregate (divided pro rata among each Lender) upon the earliest of (i) the occurrence of a Change of Control (as defined below), (ii) the first drawdown or (iii) the completion by the Company of a single capital raise with gross proceeds of at least \$10,000,000.

The Company has no obligation to draw down on the Credit Line and anticipates that it would only do so if financing was not available on more favorable terms. Accordingly, the Company views the Credit Line as a resource that will strengthen its financial position and providing a source of capital if needed.

The Credit Line matures on December 16, 2021 and bears interest at 8.0% per annum, which is payable in kind. The Lenders have the right to require the repayment of the loan at any time after the Company completes a single capital raise with gross proceeds of at least \$15,000,000. Events of default under the Credit Facility include a Change of Control, bankruptcy and insolvency.

Immediately prior to the consummation of a Change of Control, each Lender will have a right to convert outstanding drawdown loan amounts into shares of common stock of the Company at a conversion price per share equal to \$0.4138 (subject to adjustment for stock splits and similar transactions); provided that the aggregate number of shares of common stock of the Company to be issued upon conversion of the drawdown loan amounts under the Credit Facility to a Lender other than New Mountain Capital (or its affiliates), in addition to shares of Company common stock owned by or otherwise issued to such Lender, shall not exceed 19.99% of the Company’s issued and outstanding common stock in the aggregate pursuant to the Company’s obligations under Nasdaq Listing Rule 5635(c) (or any successor or similar rule or interpretation thereof) unless stockholder approval is obtained. “Change of Control” shall mean (i) a merger or consolidation of the Company with another corporation (other than a merger effected exclusively for the purpose of changing the domicile of the Company), (ii) the sale, assignment, transfer, conveyance or other disposal of all or substantially all of the properties or assets or all or a majority of the outstanding voting shares of capital stock of the Company, (iii) a purchase, tender or exchange offer accepted by the holders of a majority of the outstanding voting shares of capital stock of the Company, or (iv) a “person” or “group” (as these terms are used for purposes of Section 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) is or shall become the “beneficial owner” (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly of at least a majority of the voting power of the capital stock of the Company.

The foregoing summary of the Term Sheet does not purport to be complete and is subject to, and qualified in its entirety by, the full text of such document, a copy of which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On December 17, 2019, the Company issued a press release announcing the execution of the Term Sheet and the top-line results from Cohort 2 of its Phase 2/3 Study of INOpulse® for treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease, and is holding a conference call regarding the top-line results. The press release is furnished herewith as Exhibit 99.1 and is incorporated by reference herein. A copy of the presentation which will be referenced during the conference call and posted on the Company’s website is furnished herewith as Exhibit 99.2 and is incorporated by reference herein.

The information set forth in this Item 7.01 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, nor shall such information be deemed incorporated by reference in any filing under the Securities Exchange Act of 1934, as amended, or the Securities Act of 1933, as amended.

Item 8.01 Other events.

As reported under Item 7.01 of this Current Report on Form 8-K, on December 17, 2019, the Company issued a press release announcing the execution of the Term Sheet and the top-line results from Cohort 2 of its Phase 2/3 Study of INOpulse® for treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease, and is holding a conference call regarding the top-line results.

Cohort 2 of iNO-PF demonstrated statistically significant placebo corrected improvement in moderate to vigorous physical activity (“MVPA”), defined as walking, stairs, yardwork, etc., in subjects treated with iNO45 (45 mcg/kg IBW/hr) versus placebo. The improvements in MVPA were underscored by benefits in other actigraphy parameters, as well as patient reported outcomes. Subjects on iNO demonstrated a placebo corrected benefit in the following top-line parameters:

- MVPA improved by 14 minutes per day, representing a 20% improvement (p=0.02)
- Overall activity improved by 100 counts/min, representing a 7% improvement
- St. George Respiratory Questionnaire (“SGRQ”) Total score improved by 3 points
- SGRQ Activity score improved by 5 points
- University of California, San Diego Shortness of Breath Questionnaire improved by 5 points

INOpulse was well-tolerated with no safety concerns.

Cohort 2 included 44 subjects randomized 2:1 to either iNO45 or placebo for a 4-month blinded treatment period followed by an open label extension.

Any statements in this Current Report on Form 8-K or on the conference call 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 Current Report on Form 8-K or the

conference call represent the Company’s views only as of the date of this report or the conference call 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 report or presented on the conference call, except as required by law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
10.1	Binding Term Sheet and Agreement for Line of Credit Facility dated December 16, 2019 between the Company and the signatories identified therein
99.1	Press Release dated December 17, 2019
99.2	Presentation dated December 17, 2019

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: December 17, 2019

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum
Title: Chief Executive Officer

Bellerophon Therapeutics, Inc.

Binding Term Sheet and Agreement for Line of Credit Facility

This Binding Term Sheet and Agreement for Line of Credit Facility (the "Agreement") is entered into as of December 16, 2019, by and among the signatories hereto.

NOW, THEREFORE, in consideration of the mutual agreements and covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, intending to be legally bound, the parties agree as follows:

Borrower: Bellerophon Therapeutics, Inc. (the "Borrower" or the "Company")

Lenders: Each of New Mountain Partners II AIV-A LP, New Mountain Partners II AIV-B LP, Allegheny New Mountain Partners LP, New Mountain Affiliated Investors II LP, Puissance Capital Management LP, Jonathan M. Peacock, Naseem Amin and Ted Wang (each a Lender and collectively, the "Lenders") will participate as a Lender in the Credit Facility as follows:

	<u>Pro-rata %</u>	<u>Pro-rata \$</u>
New Mountain Partners II AIV-A LP	43.19%	4,318,672
New Mountain Partners II AIV-B LP	6.63%	663,180
Allegheny New Mountain Partners LP	3.90%	389,955
New Mountain Affiliated Investors II LP	0.90%	90,096
Puissance Capital Management LP	29.94%	2,994,156
Jonathan M. Peacock	6.77%	676,824
Naseem Amin	6.56%	656,240
Ted Wang	2.11%	210,878
TOTAL	100.0%	\$ 10,000,000

Use of Proceeds: Working capital and general corporate purposes.

Credit Facility: Up to \$10,000,000

Drawdowns: Provided that the Company has randomized the first patient in its iNO-PF Phase 3 clinical trial, the Company will have the right to draw down \$5,000,000 after March 31, 2020 and another \$5,000,000 after June 30, 2020, provided that no drawdowns shall be made later than December 31, 2020. Drawdowns will be made to the Company by the Lenders on a pro rata basis. It shall be a condition to each drawdown that there has been no material adverse change in the condition

(financial or otherwise), properties, business or operations of the Company since the date of this Agreement.

Commitment Fee:	The Company shall pay the Lenders a fee in cash equal to \$300,000 in the aggregate (divided pro rata among each Lender) upon the earliest of (i) the occurrence of a Change of Control (as defined below), (ii) the first drawdown or (iii) the completion by the Company of a single capital raise with gross proceeds of at least \$10,000,000.
Board Approval:	The Company will be required to receive approval from its Board of Directors prior to each drawdown, including from a majority of its disinterested directors.
Prepayment:	The Lenders will have the right to require the repayment of the loan at any time after the Company completes a single capital raise with gross proceeds of at least \$15,000,000.
Maturity Date:	24 months from the date that the parties execute this Agreement.
Interest:	8.0% per annum, which is payable in kind ("PIK").
Conversion Terms:	Immediately prior to the consummation of a Change of Control (as defined below), each Lender will have a right to convert outstanding drawdown loan amounts into shares of common stock of the Company at a conversion price per share equal to the Nasdaq Official Closing Price immediately preceding the signing of this Agreement relating to this Credit Facility (subject to adjustment for stock splits and similar transactions); provided that the aggregate number of shares of common stock of the Company to be issued upon conversion of the drawdown loan amounts under this Credit Facility to a Lender other than New Mountain Capital (or its affiliates), in addition to shares of Company common stock owned by or otherwise issued to such Lender, shall not exceed 19.99% of the Company's issued and outstanding common stock in the aggregate pursuant to the Company's obligations under Nasdaq Listing Rule 5635(c) (or any successor or similar rule or interpretation thereof) unless stockholder approval is obtained. "Change of Control" shall mean (i) a merger or consolidation of the Company with another corporation (other than a merger effected exclusively for the purpose of changing the domicile of the Company), (ii) the sale, assignment, transfer, conveyance or other disposal of all or substantially all of the properties or assets or all or a majority of the outstanding voting shares of capital stock of the Company, (iii) a purchase, tender or exchange offer accepted by the holders of a majority of the outstanding voting shares of capital stock of the Company, or (iv) a "person" or "group" (as these terms are used for purposes of Section 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) is or shall become the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly of at least a majority of the voting power of the capital stock of the Company.
Events of Default:	Events of default under the Credit Facility shall include a Change of Control, bankruptcy and insolvency.
Announcements:	The Company must announce the material terms of this Agreement in a Form 8-K filed with the SEC within four business days.
No Third Party Beneficiaries:	Nothing in this Agreement, express or implied, is intended to confer upon any third party (other than a permitted successor or assign of a party hereto) any rights, remedies, obligations or liabilities.
Governing Law:	This Agreement shall be governed by, interpreted and construed, and all claims and disputes, whether in tort, contract or otherwise be resolved in accordance with the substantive laws of the State of Delaware without reference to any rules of conflict of laws.

Counterparts:

This Agreement may be executed in two or more counterparts (including by facsimile or e-mail), each of which will together represent one and the same agreement and all signatures need not appear on any one counterpart.

IN WITNESS WHEREOF, the parties hereto have duly executed this Binding Term Sheet and Agreement, as of the day and year first above written.

Bellerophon Therapeutics, Inc.

By: _____
Name: _____
Title: _____

New Mountain Partners II AIV-A LP

By: _____
Name: _____
Title: _____

New Mountain Partners II AIV-B LP

By: _____
Name: _____
Title: _____

Allegheny New Mountain Partners LP

By: _____
Name: _____
Title: _____

New Mountain Affiliated Investors II LP

By: _____
Name: _____
Title: _____

Puissance Capital Management LP

By: _____
Name:
Title:

Jonathan M. Peacock, individually

Naseem Amin, individually

Ted Wang, individually

Bellerophon Announces Positive Top-line Results from Cohort 2 of Phase 2/3 Study of INOpulse® for Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease*Statistically Significant Improvement Demonstrated in Moderate to Vigorous Physical Activity**Bellerophon Intends to Initiate Pivotal Phase 3 in First Quarter of 2020**Company Enters Into \$10M Convertible Financing Facility Led By Existing Institutional Shareholders, Extending Cash Runway to 2021**Bellerophon to Host Conference Call and Live Webcast Today at 8:30 AM ET*

WARREN, N.J., December 17, 2019 -- Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company, today announced positive top-line results from Cohort 2 of its ongoing Phase 2/3 randomized, double-blind, placebo-controlled clinical study (iNO-PF) of INOpulse® for the treatment of Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD).

Subjects in Cohort 2 of iNO-PF treated with iNO45 (45 mcg/kg IBW/hr) demonstrated statistically significant improvement in moderate to vigorous physical activity (MVPA), defined as walking, climbing stairs, yard work, and similar activities, versus placebo. The improvements in MVPA were underscored by benefits shown in other actigraphy parameters, as well as patient reported outcomes. Subjects on iNO demonstrated improvements versus placebo in the following top-line parameters:

- MVPA improved by 14 minutes per day, representing a 20% improvement ($p=0.02$)
- Overall activity improved by 100 counts/min, representing a 7% improvement
- St. George Respiratory Questionnaire (SGRQ) Total score improved by 3 points
- SGRQ Activity score improved by 5 points
- SGRQ Impacts score improved by 6 points
- University of California, San Diego Shortness of Breath Questionnaire improved by 5 points

INOpulse was well-tolerated with no safety concerns.

"The top-line results from Cohort 2 in the iNO-PF study are exciting and highlight the potential therapeutic benefit of INOpulse," said Steven D. Nathan, M.D., F.C.C.P., Medical Director of the Advanced Lung Disease and Lung Transplant Program at Inova Fairfax Hospital and Chair of Bellerophon's Steering Committee. "It is validating and reassuring to see the results from Cohort 2. The statistically significant benefit shown by INOpulse in MVPA, as well as the consistent benefit in overall activity over a four month period, are especially encouraging considering that this patient population has a median life expectancy of approximately 18 months. An additional positive finding was the improvement in patient reported outcomes corroborating the improvements demonstrated in the actigraphy data, pointing to the fact that patients feel better while doing more. I look forward to the continued development of INOpulse and am excited by the potential prospects of this promising therapy in PH-ILD patients who have limited ability to perform even the most basic daily tasks."

"The positive top-line data from Cohort 2 of iNO-PF represent a defining milestone for our INOpulse clinical development program," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "The significant improvement demonstrated in MVPA confirms the benefits previously observed in Cohort 1 and in our earlier trials and positions INOpulse to potentially become the first approved therapy to address this serious unmet medical need."

As previously agreed upon with the U.S. Food and Drug Administration, MVPA will serve as the primary endpoint for the Phase 3 study, which we expect to initiate in the first quarter of 2020.”

Cohort 2 included 44 subjects randomized 2:1 to either iNO45 or placebo for a 4 month blinded treatment period followed by an open-label extension.

Bellerophon also announced today that it has entered into an agreement for a \$10 million convertible financing facility, led by existing institutional investors, including New Mountain Capital and Puissance Capital Management.

“We are gratified by the support and confidence in Bellerophon demonstrated through this investment by our current investors,” continued Mr. Tenenbaum. “Importantly, this capital extends our cash runway into 2021, further strengthening our cash position as we prepare to initiate pivotal Cohort 3 of iNO-PF.”

Conference Call Details

Tuesday, December 17, 2019, at 8:30 AM ET

Toll Free: 877-705-6003

International: 201-493-6725

Conference ID: 13697553

Webcast (with slides): <http://public.viaavid.com/index.php?id=137374>

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.

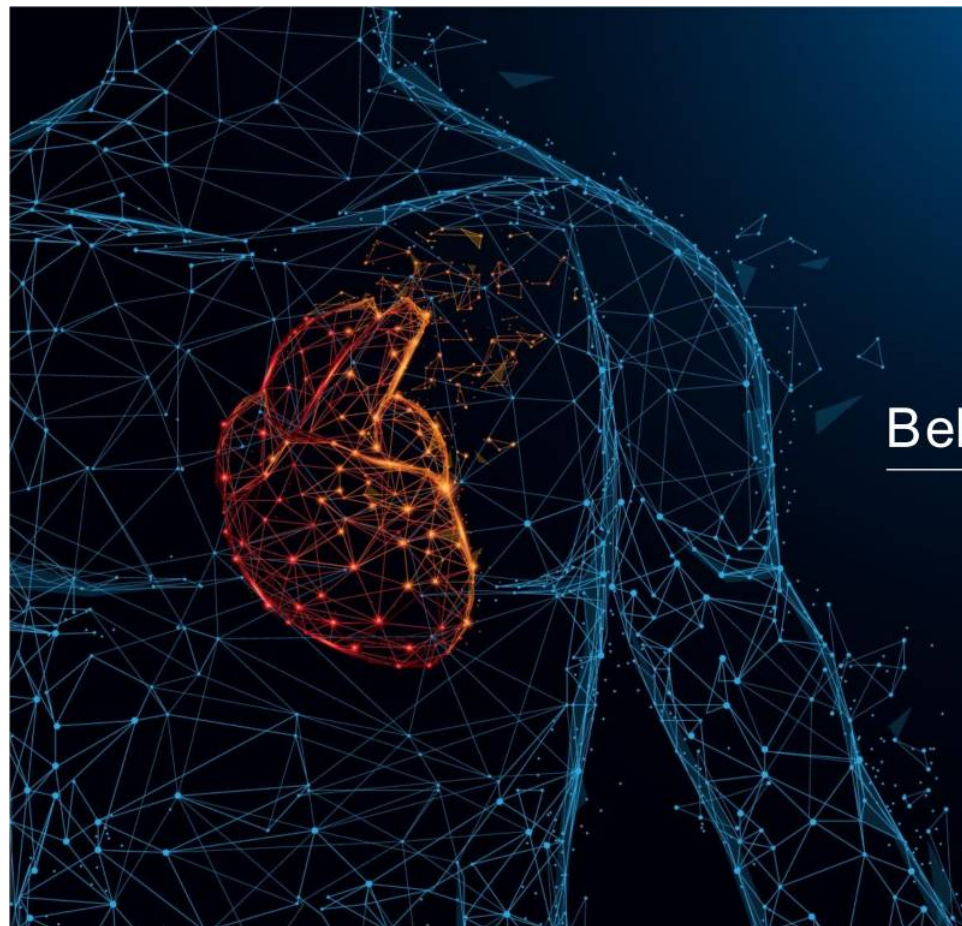
Contacts

At Bellerophon:

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(908) 574-4767

At LifeSci Advisors:

Brian Ritchie
(212) 915-2578
britchie@lifesciadvisors.com



Bellerophon Therapeutics

iNO-PF Cohort 2 Top-Line Data Call
December 17, 2019
Nasdaq: BLPH

Bellerophon
THERAPEUTICS

Forward Looking Statements

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make due to a number of important factors, including risks and uncertainties relating to: the timing and outcomes of our ongoing and expected clinical trials for our product candidates; our ability to successfully develop, commercialize and market any of our product candidates; our ability to obtain, maintain and enforce intellectual property rights; competition; our reliance on third parties; our ability to obtain necessary financing; and those risk factors discussed in the “Risk Factors” section and elsewhere in our recent Form 10-K and other periodic filings we make with the SEC.

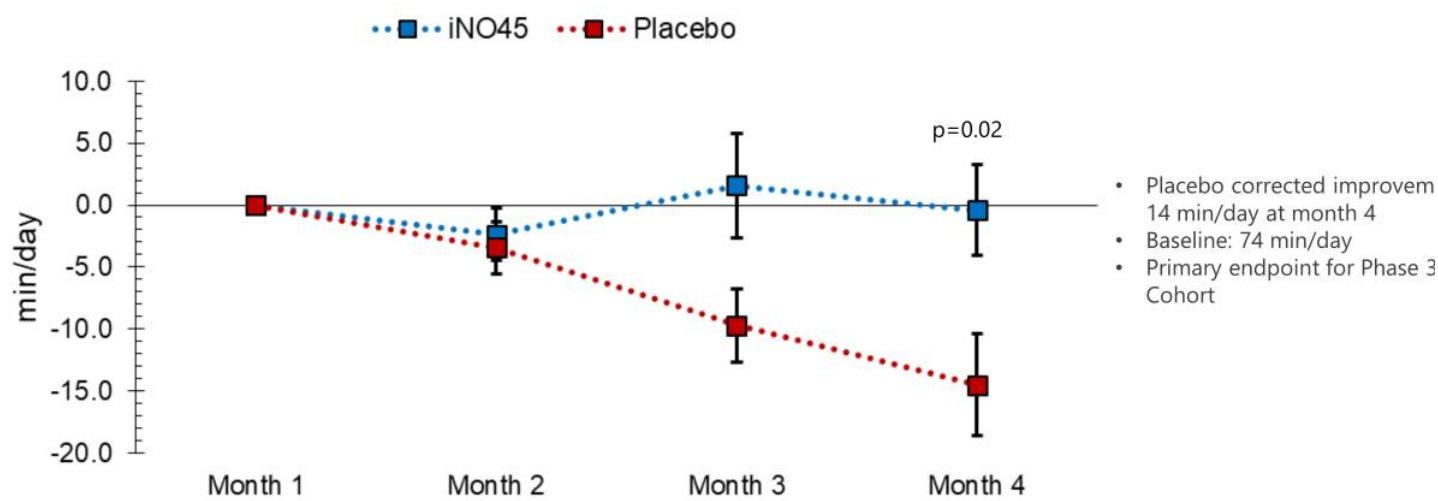
All forward-looking statements contained in this presentation reflect our current views with respect to future events. We assume no obligation except as required by applicable law, to update any forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

iNO-PF Cohort 2 Top-Line Results

- Statistically and clinically significant placebo corrected improvement of 14 minutes/day in MVPA
- Consistent and meaningful benefit in overall activity
- Clinically meaningful benefit in SGRQ and UCSD demonstrating improvement in quality of life and dyspnea
- Pulsed inhaled NO was safe and well-tolerated

Statistically Significant Benefit Over Placebo Demonstrated in MVPA

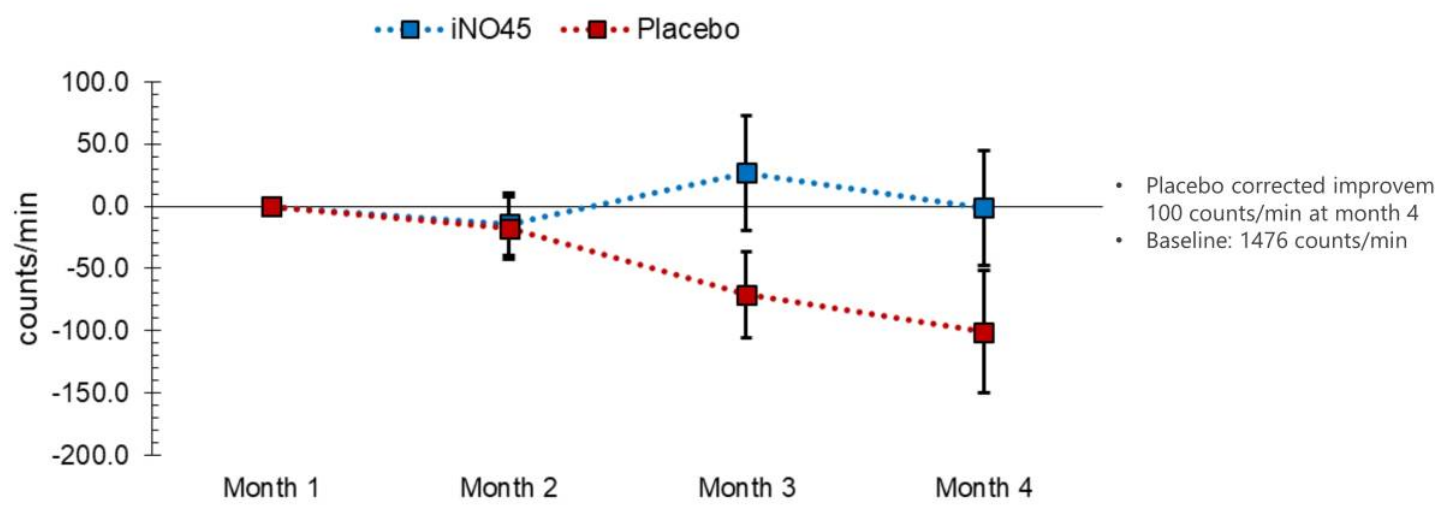
Normalized MVPA - Change from baseline



- MVPA = moderate to vigorous physical activity
- Data points and error bars = mean and standard error
- Cohort 2: n=44; randomized 2:1

Consistent and Meaningful Benefit Exhibited in Overall Activity

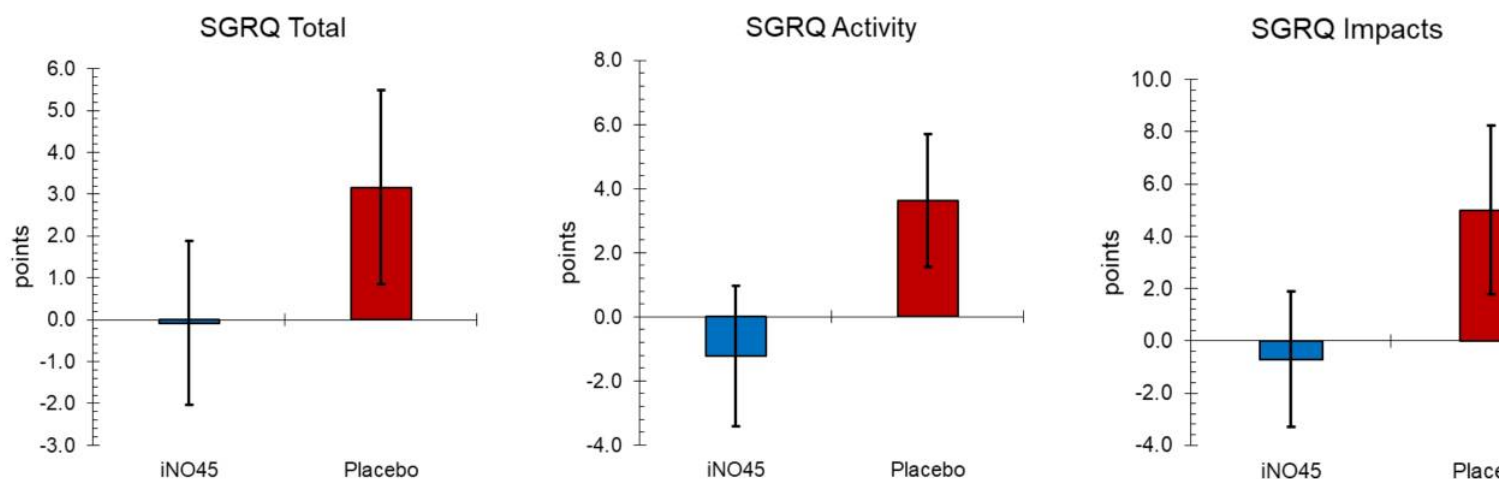
Overall Activity - Change from baseline



• Data points and error bars = mean and standard error
• Cohort 2: n=44; randomized 2:1

St. George's Respiratory Questionnaire (SGRQ) Indicates QOL Benefit in Multiple Measures

Increased score indicative of worsening



- Placebo corrected improvement of 3 points
- Measures health status and quality of life

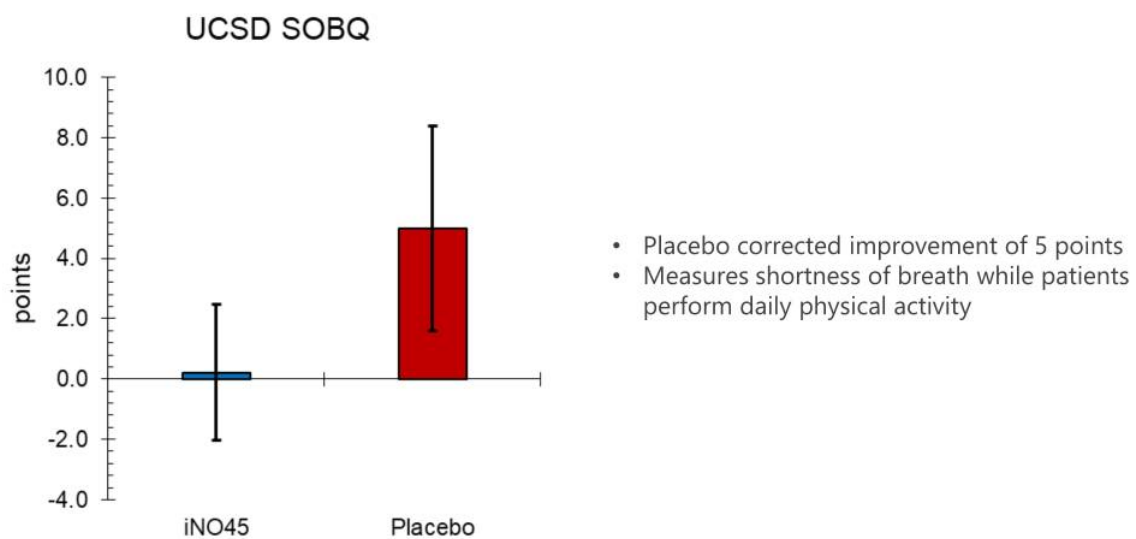
- Placebo corrected improvement of 5 points
- Measures disturbances to patients' daily physical activity

- Placebo corrected improvement of 5 points
- Measures psychological and social aspects of the disease

- Data points and error bars = mean and standard error
- Change from baseline at month 4
- Cohort 2: n=44; randomized 2:1

UCSD Shortness of Breath Questionnaire (SOBQ) Indicates Benefit in Dyspnea

Increased score indicative of worsening



- Data points and error bars = mean and standard error
- Change from baseline at month 4
- Cohort 2: n=44; randomized 2:1

Safety Summary

- Pulsed Inhaled Nitric Oxide was well-tolerated in Cohort 2
 - Incidence of AEs and SAEs was low in both active and placebo groups
 - AEs were generally non-serious with no observable trends
 - All SAEs were reported as unrelated to the study drug

	iNO 45 n=30	Placebo n=14
Total Adverse Events Reported	26 (0.87/subject)	9 (0.64/subject)
Total Serious Adverse Events Reported	5 (0.17/subject)	7 (0.50/subject)
Subjects with Serious Adverse Events	3 (10%)	3 (21.4%)
Deaths	0	0

Next Steps in PH-ILD

- Results from Cohort 2 support continuing program into Phase 3 with MVPA as primary endpoint
- Phase 3 initiation expected in 1Q2020 upon selection of dose and confirmation of trial size
- Company entered into \$10M convertible financing facility with existing institutional investors, extending cash runway into 2021



Investor Contact

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Brian Ritchie
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212-915-1234

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