

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 16, 2015**

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.)

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):

- 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))

Item 1.01. Entry into a Material Definitive Agreement.

On November 16, 2015, Bellerophon Pulse Technologies LLC ("Pulse Technologies"), a subsidiary of Bellerophon Therapeutics, Inc. (together with Pulse Technologies, the "Company"), entered into a Second Amendment (the "Supply Amendment") to Drug Clinical Supply Agreement, dated as of February 9, 2014, between Pulse Technologies and INO Therapeutics LLC ("INO Therapeutics"), a subsidiary of Ikaria, Inc. (together with INO Therapeutics, "Ikaria"), (the "Supply Agreement") and a Third Amendment (the "Cross-License Amendment" and together with the Supply Amendment, the "Amendment") to Exclusive Cross-License, Technology Transfer, and Regulatory Matters Agreement (the "Cross-License"), dated as of February 9, 2014, between Pulse Technologies and INO Therapeutics. The parties entered into the Supply Agreement and the Cross-License in connection with the Company's spin-out from Ikaria, its former parent company.

Pursuant to the terms of the Supply Amendment, the Company has paid to Ikaria an upfront payment in an amount equal to \$6.6 million for Cartridges and Drug Fills (each term as defined in the Supply Amendment) primarily to support the first of two Phase 3 clinical trials for INOpulse for pulmonary arterial hypertension. The Supply Amendment also provides that the Company will pay to Ikaria an additional payment of \$1.75 million upon the Successful Completion Of Trial (as defined in the Supply Amendment).

Subject to the terms set forth therein, the Cross-License Amendment provides that the Company will pay INO Therapeutics a royalty equal to three percent (3%) of PAH Net Sales (as defined in the Cross-License Amendment).

The foregoing description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the Amendment attached hereto as Exhibit 10.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
10.1	Second Amendment to Drug Clinical Supply Agreement and Third Amendment to Exclusive Cross-License, Technology Transfer, and Regulatory Matters Agreement, dated November 16, 2015, between Bellerophon Pulse Technologies LLC and INO Therapeutics LLC

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: January 12, 2016

By: /s/ Jonathan M. Peacock

Name: Jonathan M. Peacock

Title: Chairman and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
10.1	Second Amendment to Drug Clinical Supply Agreement and Third Amendment to Exclusive Cross-License, Technology Transfer, and Regulatory Matters Agreement, dated November 16, 2015, between Bellerophon Pulse Technologies LLC and INO Therapeutics LLC

SECOND AMENDMENT TO DRUG CLINICAL SUPPLY AGREEMENT

AND

THIRD AMENDMENT TO EXCLUSIVE CROSS-LICENSE, TECHNOLOGY TRANSFER, AND REGULATORY MATTERS AGREEMENT

THIS SECOND AMENDMENT TO DRUG CLINICAL SUPPLY AGREEMENT AND THIRD AMENDMENT TO EXCLUSIVE CROSS-LICENSE, TECHNOLOGY TRANSFER, AND REGULATORY MATTERS AGREEMENT (this "Amendment") is entered into the later of the dates in the signature block below (the "Amendment Effective Date") by and between INO Therapeutics LLC, a Delaware limited liability company having a place of business at Perryville III Corporate Park, 53 Frontage Road, Third Floor, Hampton, NJ 08827 ("Ikaria"), and Bellerophon Pulse Technologies LLC, a Delaware limited liability company, with offices at 184 Liberty Corner Road, Suite 302, Warren, NJ 07059 ("Pulse Technologies").

All capitalized terms not defined herein shall (a) have the same meanings ascribed thereto in the Exclusive Cross-License, Technology Transfer, and Regulatory Matters Agreement dated as of February 9, 2014 by and between Ikaria and Pulse Technologies (as amended on March 27, 2014 and July 27, 2015, the "License Agreement") for amendments to the License Agreement and (b) have the same meanings ascribed thereto in the Drug Clinical Supply Agreement dated as of February 9, 2014 by and between Ikaria and Pulse Technologies (as amended on July 27, 2015 in the second amendment to the License Agreement, the "Supply Agreement") for amendments to the Supply Agreement. Ikaria and Pulse Technologies may be individually referred to as a "Party" and together as the "Parties."

WHEREAS, Pulse Technologies relocated its headquarters on or about October 1, 2015; and

WHEREAS, Ikaria and Pulse Technologies wish to amend certain provisions of the Supply Agreement to, among other things, change the pricing terms; and

WHEREAS, Ikaria and Pulse Technologies wish to amend certain provisions of the License Agreement to, among other things, add royalty terms, as additional consideration for the Products to be supplied under the Supply Agreement.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

1. **Amendments to Supply Agreement.**

1.1 "Perryville III Corporate Park, 53 Frontage Road, Suite 301, Hampton, NJ 08827" shall be replaced with "184 Liberty Corner Road, Suite 302, Warren, NJ 07059" in each instance that it appears throughout the Supply Agreement.

1

1.2 **Definitions.**

(a) The following new subsections are hereby added to Section 1 of the Supply Agreement:

1.27 "Cartridge" means a high pressure refillable aluminum cylinder and valve which is considered the drug container closure.

1.28 "Drug Fill" means (a) filling a Cartridge with its intended content and capacity of quality conforming drug or placebo, manufactured conforming to all process steps and material requirements, (b) enclosing around the filled Cartridge a disposable plastic enclosure and (c) labeling and packaging the Cartridge for delivery.

1.29 "Initial PAH Clinical Trials" means the first PAH Phase III study entitled "INOvation 1" (the "Initial PAH Phase III Trial") and extension of patients on the previous study entitled "PAH-006".

1.30 "Successful Completion Of Trial" means that the top line results from the Initial PAH Phase III Trial allow Pulse Technologies to proceed with the PAH program. In the event that Pulse Technologies does not proceed with the PAH program, Ikaria shall have the right to terminate this Agreement in accordance with Section 10.2 of this Agreement. For clarity, if Pulse Technologies or its Affiliates (a) commences a second PAH Phase III trial after conclusion of the Initial PAH Phase III Trial, (b) continues to recruit patients in the second PAH Phase III trial after the conclusion of the Initial PAH Phase III trial if already started, (c) files for regulatory approval using the Initial PAH Phase III Trial results, or (d) otherwise proceeds with the PAH program at the conclusion of the Initial PAH Phase III Trial, then Successful Completion Of Trial has occurred.

(b) Section 1.19 of the Supply Agreement is hereby amended and restated in its entirety as set forth below:

1.19 "Product" has the meaning set forth in the recitals to this Agreement and expressly includes Cartridges and Drug Fills.

1.3 **Modification of Section 2.2 (Obligations of Pulse Technologies).** The following is hereby added to the end of Section 2.2 of the Supply Agreement:

"To enable Ikaria to fulfill each Drug Fill order, Pulse Technologies shall (a) return to inventory at Ikaria at the end of each month, at least 105% of the Cartridges to support the following month's Forecast, (b) place an order for 100% of the Cartridges required to be filled in such Drug Fill order with a delivery date at least 12 weeks in advance of such Drug Fill order delivery date, or (c) perform a combination of the foregoing clauses (a) and (b) sufficient for the Drug Fill order. If Pulse Technologies fails to timely perform the requirements of the foregoing clause (a), (b) or (c), Ikaria's delivery deadline for

2

such Drug Fill order shall be extended by the duration of the delay in Pulse Technologies' meeting the foregoing clause (a), (b) or (c)."

1.4 Modification of Section 2.4 (Forecasts; Committed Quantities). The first sentence of Section 2.4(a) of the Supply Agreement is hereby amended and restated as follows:

"Commencing on the Effective Date and on the first business day of each calendar month thereafter, Pulse Technologies shall submit to Ikaria a written rolling forecast of the quantity of each Product, including the number of Cartridges to be returned and the number of new Cartridges that Pulse Technologies expects to order from Ikaria over the next 36 months (the "Forecast").

1.5 Modification of Section 3.1 (Price) and 3.2 (Payment).

(a) Section 3.1 of the Supply Agreement is hereby amended and restated in its entirety as set forth below:

3.1 Pricing.

(a) Pricing for Products not sold for use in the Initial PAH Clinical Trials shall be COGS plus 20%.

(b) Pricing for Products sold for use in the Initial PAH Clinical Trials shall be:

(i) \$6,600,000 (the "Upfront Payment"),

(ii) upon Successful Completion of Trial, \$1,750,000 (the "Additional Payment") which covers up to 52,000 Cartridges and up to 275,400 Drug Fills; and

(iii) Regardless of whether there is Successful Completion of Trial, \$40.83 per Cartridge in excess of 52,000 and \$17.63 per Drug Fill in excess of 275,400, plus any additional capital expenditures Ikaria is required to undertake in connection with any such excess orders by Pulse Technologies. Ikaria shall obtain advance approval from Pulse Technologies before making any such capital expenditures; provided that if such approval is not received from Pulse Technologies, Ikaria shall have no obligation to supply such excess Cartridges or Drug Fills.

(iv) The pricing in Sections 3.1(i), 3.1(ii) and 3.1(iii) is all inclusive including full depreciation of existing equipment installed in Port Allen, and no additional charges shall apply for the Cartridges and Drug Products other than for excess Cartridges and Drug Products as set forth in Section 3.1(iii) above.

(b) Section 3.2 of the Supply Agreement is hereby amended and restated in its entirety as set forth below:

3.2 Payment.

(a) Within 10 days of the Amendment Effective Date (as defined in the second amendment to this Agreement, the "Amendment Effective Date"), Pulse Technologies shall pay to Ikaria the Upfront Payment, which includes payment for the amounts previously invoiced to Pulse Technologies as set forth below. Upon receipt of the Upfront Payment, the invoices below shall be deemed paid in full.

<u>Title</u>	<u>Invoice</u>	<u>Date</u>	<u>Cost</u>
Empty Cartridge Builds	1800003738	09/25/2015	\$ 165,359.20
IK7 August 2015 Monthly Fee	1800003737	08/28/2015	\$ 210,583.00
IK7 Sept 2015 Monthly Fee	1800003730	09/25/2015	\$ 210,583.00

(b) No later than the earlier of (i) 10 days of the public disclosure of Successful Completion Of Trial, (anticipated to occur on or before March 31, 2018) or (ii) 45 days from Successful Completion Of Trial, Pulse Technologies shall pay to Ikaria the Additional Payment. This Section 3.2(b) shall survive the expiration or termination of this Agreement.

(c) For any Products covered by the pricing set forth in Sections 3.1(a) or 3.1(b)(ii), Ikaria shall invoice Pulse Technologies at the time of shipment of Product in accordance with this Agreement. Payment of an invoice is due the later of (a) 30 days from the date of Pulse Technologies' receipt of invoice; or (b) delivery of Product to the carrier in accordance with Section 2.5

(d) If the Initial PAH Phase III Clinical Trial is not completed by March 31, 2018, Pulse Technologies shall pay to Ikaria an additional amount of \$75,000 (an "Additional Amount") for each month (or partial month) after March 31, 2018 during which the Initial PAH Phase III Clinical Trial is ongoing. The Additional Amount shall be paid on the first of each month and is creditable (at the Price set forth in 3.1(b)(iii)) for Drug Fills that both (1) exceed the quantity specified in Section 3.1(b)(ii) and (2) are conducted in the calendar quarter for which the Additional Amount was due. For clarity, such credit is limited to the calendar quarter for which the Additional Payments are due and does not carry over into subsequent calendar quarters.

1.6 Modification of Section 10.3 (Effect of Termination): The last sentence of Section 10.3 of the Supply Agreement is hereby amended and restated as set forth below.

"Notwithstanding any expiration or termination of this Agreement, the following provisions shall survive: Sections 2.3, 2.8, 2.9, 3.2(b), 5, 7.4, 8, 10.3, 11.1, 12 and 13."

2. Amendments to License Agreement

2.1 “Perryville III Corporate Park, 53 Frontage Road, Suite 301, Hampton, NJ 08827” shall be replaced with “184 Liberty Corner Road, Suite 302, Warren, NJ 07059” in each instance that it appears throughout the License Agreement.

2.2 The following Section 6.5 is hereby added to the License Agreement:

“6.5 PAH Products.

6.5.1 In addition to any other royalties due Ikaria under this Agreement, Pulse Technologies shall pay to Ikaria three percent (3%) of PAH Net Sales (as defined below).

6.5.2 Pulse Technologies shall make all payments due to Ikaria under this Section 6.5 within 45 days after the end of each calendar quarter and each payment shall be accompanied by a report providing with respect to PAH Products (as defined below): (a) the PAH Net Sales for such calendar quarter separated by country, (b) the total deductions used to calculate the above noted PAH Net Sales with each specific deduction itemized, and (c) the amount of payments payable to Ikaria for such year, as well as the computation thereof.

6.5.3 Section 6.1 (Maintenance of Records and Audit Rights) of this Agreement shall apply with respect to PAH Products and shall apply with respect to the documentation, records, and premises of Pulse Technologies, its Affiliates and its (or its Affiliates’) licensees of PAH Products.

6.5.4 The following terms shall have the following meanings:

(a) “PAH Net Sales” shall have the same meaning as Net Sales but with PAH Product replacing R&D Product in every instance and with gross receipts of Pulse Technologies, its Affiliates and its (or its Affiliates’) licensees of PAH Products included.

(b) “PAH Product” shall mean any product or service that utilizes, contains or includes nitric oxide for the treatment, prevention or diagnosis of PAH as well as all disposables and accessories used with such product. For the avoidance of doubt, a PAH Product may also be an R&D Product if such PAH Product also falls within the definition of R&D Product.

6.5.6 This Section 6.5 shall survive any expiration or earlier termination of this Agreement.”

3. Miscellaneous.

3.1 Ratification. Except as set forth in Sections 1 and 2 of this Amendment, all of the other terms and conditions of the Supply Agreement and License Agreement are hereby ratified and confirmed to be of full force and effect, and shall continue in full force and effect. This Amendment is hereby integrated into and made a part of the Supply Agreement and License Agreement, as applicable.

3.2 Counterparts. This Amendment may be executed in two counterparts (including by facsimile or by e-mail delivery of a “.pdf” file), each of which shall be effective as of the Amendment Effective Date, and all of which shall constitute one and the same instrument. Each such counterpart shall be deemed an original, and it shall not be necessary in making proof of this Amendment to produce or account for more than one such counterpart.

3.3 Execution and Delivery. This Amendment shall be deemed executed by the Parties when any one or more counterparts hereof, individually or taken together, bears the signatures of each of the Parties hereto.

IN WITNESS WHEREOF, each Party has caused this Amendment to be executed by its duly authorized representatives effective as of the Amendment Effective Date.

INO THERAPEUTICS LLC

BELLEROPHON PULSE TECHNOLOGIES LLC

By: /s/ Kathleen A. Schaefer

By: /s/ Jonathan Peacock

Name: Kathleen A. Schaefer

Name: Jonathan Peacock

Title: President

Title: Chairman & CEO

Date: 11/16/15

Date: November 13, 2015