Current Agreements

Dealdoc

Supply agreement for nitric oxide delivery devices

Bellerophon Therapeutics
INO Therapeutics

Feb 09 2014

Supply agreement for nitric oxide delivery devices

Companies:	Bellerophon Therapeutics INO Therapeutics
Announcement date:	Feb 09 2014
Deal value, US$m:	n/d

Details

Announcement date:	Feb 09 2014
Start date:	Feb 09 2014
Industry sectors:	Drug delivery Medical device
Asset type:	Technology
Therapy areas:	Cardiovascular
Technology types:	Devices Drug delivery
Deal components:	Supply

Financials

Deal value, US$m:	n/d

Termsheet

Not available.

Press Release

Not available.

Filing Data

Not available.

Contract

DEVICE CLINICAL SUPPLY AGREEMENT

This Device Clinical Supply Agreement (this “Agreement”) is entered into as of February 9, 2014 (the “Effective Date”) by and between by and between INO Therapeutics LLC, a Delaware limited liability company, with offices at Perryville III Corporate Park, 53 Frontage Road, Third Floor, Hampton, NJ 08827 d/b/a Ikaria (“Ikaria”), and Bellerophon Pulse Technologies LLC, a Delaware limited liability company, with offices at Perryville III Corporate Park, 53 Frontage Road, Third Floor, Hampton, NJ 08827 d/b/a Ikaria (“Pulse Technologies”). Ikaria and Pulse Technologies may be individually referred to as a “Party” and together as the “Parties.”

WHEREAS, the Parties were formerly owned by a common parent company, Ikaria, Inc. (“Ikaria Parent Company”);

WHEREAS, Pulse Technologies has, as part of certain spin-out transactions (the “Spin-Out”), ceased to be a direct or indirect subsidiary of Ikaria Parent Company, and is now therefore not owned by, or affiliated with, either Ikaria Parent Company or Ikaria;

WHEREAS, Pulse Technologies is engaged in the business of developing, manufacturing, and commercializing products for (a) pulmonary hypertension secondary to chronic obstructive pulmonary disease (“COPD”) and (b) primary or idiopathic pulmonary arterial hypertension (“PAH”) (collectively, the “Pulse Technologies Clinical Programs”);

WHEREAS, prior to the Spin-Out, Ikaria manufactured the nitric oxide delivery devices listed in Exhibit A to this Agreement (the “Devices”) used by Pulse Technologies as part of the Pulse Technologies Clinical Programs; and

WHEREAS, Pulse Technologies wishes Ikaria to continue on a short term basis to manufacture, and Ikaria wishes to continue to manufacture, the Devices for Pulse Technologies, all subject to and in accordance with the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the foregoing premises, which are incorporated into and made a part of this Agreement, and of the mutual covenants which are recited herein, the Parties agree as follows:

1. Definitions.

1.1 “Affiliate” means, with respect to a Party, any Person directly or indirectly controlling, controlled by or under common control with, such Party. For purposes of this definition only, “control” of a Person shall mean the ability, directly or indirectly, to direct the activities of the relevant Person, and with respect to corporate entities shall mean (a) ownership or direct control of fifty percent (50%) or more of the outstanding voting stock or other ownership interest of such Person, or (b) direct or indirect possession, of the power to elect or appoint fifty percent (50%) or more of the members of the governing body of such Person. Notwithstanding the foregoing or any direct or indirect control relationship that exists between them, Ikaria and Pulse Technologies shall be deemed not to be Affiliates of one another.

1.2 “COGS” means, as to Ikaria and its Affiliates, with respect to the Devices, the aggregate of internal and external costs of Ikaria and its Affiliates to manufacture such Devices, calculated as follows: (a) to the extent that Ikaria or its Affiliates performs all or any part of the manufacturing of such Devices, the actual direct material costs and direct labor costs for, plus manufacturing overhead reasonably allocable to, such manufacturing of such Devices (which may include the costs of audits, all directly incurred manufacturing variances, manufacturing administrative and facilities costs (including

depreciation)), all calculated in accordance with GAAP; and (b) to the extent that manufacturing of such Devices is performed by a Third Party, the costs paid to such Third Party for such activities and the reasonably allocated direct labor costs incurred by Ikaria or any of its Affiliates in managing and overseeing the Third Party relationship, determined in accordance with GAAP.

1.3 “Confidential Information” means information disclosed by a Party or its Affiliate (such Party referred to as the “Disclosing Party”) to the other Party or its Affiliate (such Party referred to as the “Receiving Party”), which information relates either directly or indirectly to the business of the Disclosing Party, including information and data regarding the manufacture or use, pre-clinical or clinical data regarding, the status of research or development of any Device. Confidential Information of the Disclosing Party excludes any information that the Receiving Party can establish by written records: (a) was known by the Receiving Party prior to receipt from the Disclosing Party; (b) was disclosed to the Receiving Party by a Third Party having the right to do so; (c) was, or subsequently became, publicly known through no fault of the Receiving Party or its Affiliates; or (d) was concurrently or subsequently developed by personnel of the Receiving Party without having had access to the Disclosing Party’s Confidential Information.

1.4 “COPD” shall have the meaning set forth in the recitals to this Agreement.

1.5 “Cross License” shall mean the Exclusive Cross-License, Technology Transfer, and Regulatory Matters Agreement by and between the Parties dated of even date herewith.

1.6 “Devices” shall have the meaning set forth in the recitals to this Agreement.

1.7 “Device IP” shall have the meaning set forth in Section 2.9.

1.8 “Effective Date” shall have meaning set forth in the preamble to this Agreement.

1.9 “Facility” means Ikaria’s manufacturing facilities located in Madison, WI, or such other manufacturing site(s) specified by Ikaria from time to time.

1.10 “FDA” means the United States Food and Drug Administration or any successor organization.

1.11 “Federal Health Care Programs” shall have the meaning set forth in Section 5.4.

1.12 “Forecast” shall have the meaning set forth in Section 2.5.

1.13 “Ikaria Parent Company” shall have the meaning set forth in the recitals to this Agreement.

1.14 “Intellectual Property” means, collectively, patents, trademarks, copyrights (including to any software, whether in object code or source code form), trade secrets, know-how, and any other intellectual or proprietary property or rights.

1.15 “PAH” shall have the meaning set forth in the recitals to this Agreement.

1.16 “Person” means any individual, governmental authority, partnership, corporation, limited liability company, unincorporated organization or association, any trust or any other business entity.

1.17 “Pulse Technologies Clinical Programs” shall have the meaning set forth in the recitals to

this Agreement.

1.18 “Purchase Order” means a written purchase order issues by Pulse Technologies to Ikaria for the purchase of Devices.

1.19 “Quality Agreement” has the meaning set forth in Section 3.

1.20 “Regulatory Authority” means any competent governmental authority which regulates the manufacture, development or sale of any Device.

1.21 “Specification” means, with respect to each Device, the specifications in effect at Ikaria for that Device immediately prior to the Spin-Out.

1.22 “Term” has the meaning set forth in Section 8.1.

1.23 “Third Party” means any Person who is not a Party or an Affiliate of a Party.

2. Supply of Devices.

2.1 Obligations of Ikaria. During the Term of this Agreement, Ikaria will use commercially reasonable efforts to manufacture and supply Pulse Technologies’ requirements for Devices for the Pulse Technologies Clinical Programs in accordance with the terms of this Agreement and the Quality Agreement. Pulse Technologies acknowledges and agrees that nothing in this Agreement shall require Ikaria to hire, obtain, or retain additional resources of any type (whether personnel, infrastructure, or otherwise), or to make capital expenditures of any kind, in order to manufacture and supply the Devices, nor shall anything in this Agreement require Ikaria to prioritize manufacturing and supplying the Devices to Pulse Technologies over performing similar services for its own benefit.

2.2 Obligations of Pulse Technologies. Pulse Technologies will provide Ikaria with such information and cooperation as may be necessary for the manufacture and supply of the Devices in accordance with this Agreement and the Quality Agreement.

2.3 Changes. Ikaria shall use commercial reasonable efforts to accommodate any reasonable changes to the Specifications for the Devices, it being understood and agreed that Pulse Technologies shall bear any and all costs associated with such changes. Pulse Technologies further acknowledges and agrees that no such requested change may be inconsistent with, or violative of, the terms and conditions of the Cross License, including the restricted abilities, attributes, capabilities, capacities, functions, and specifications set forth in Exhibit A to the Cross License.

2.4 Pricing. Pricing for the Devices shall be as set forth in Exhibit B to this Agreement, and shall be subject to the other terms and conditions set forth therein.

2.5 Forecasts. Within 10 business days after the Effective Date, Pulse Technologies shall provide to Ikaria a written forecast of all Devices which Pulse Technologies expects to order from Ikaria during the Term (the “Forecast”). Pulse Technologies shall update the Forecast in writing on a monthly basis. The Forecast shall constitute a non-binding, good faith estimate provided by Pulse Technologies solely to assist Ikaria in production planning, and shall not represent any purchase commitment by Pulse Technologies or a supply commitment by Ikaria.

2.6 Purchase Orders.

(a) During the Term, Pulse Technologies may place Purchase Orders with Ikaria. Acknowledging that the lead time for the Devices is estimated to be between four and six months, Pulse Technologies agrees to submit all Purchase Orders no later than six months after the Effective Date. Each Purchase Order shall specify the specific Devices ordered. Ikaria shall be deemed to have accepted a Purchase Order unless it objects within 30 days after receiving such Purchase Order. If Ikaria’s believes it will be unable to manufacture the requested Devices (e.g., because of an inability to obtain required component parts), Ikaria shall promptly inform Pulse Technologies thereof. If a Purchase Order is accepted by, or deemed accepted by Ikaria under this Section 2.6(a), then Ikaria shall use commercially reasonable efforts to produce the quantity of Devices set forth in the Purchase Order.

(b) Each Purchase Order and any acknowledgment thereof shall be governed by the terms of this Agreement. If a Party uses forms or documents to place or accept Purchase Order that contain terms and conditions that are in addition to or contrary to those in this Agreement, the Parties agree and acknowledge that such forms or documents will be used for convenience only, and that no terms or conditions set forth therein, except with respect to quantity, shall be of any force or effect.

2.7 Delivery. Ikaria shall deliver the Devices to a carrier selected by Pulse Technologies. The Devices shall be made available EXW the Facility (Incoterms 2010). Title and risk of loss will pass to Pulse Technologies when the Devices are made available to the carrier selected by Pulse Technologies. Pulse Technologies is responsible for payment of all shipment costs, including any insurance necessary to guard against loss or damage during shipment.

2.8 Inspection and Acceptance of Devices.

(a) Pulse Technologies shall have 30 days from the date of receipt of each Device to inspect and reject acceptance by written notice to Ikaria; provided, however, that any such notice shall set forth Pulse Technologies' reasons for rejection in reasonable detail and provided, further, that Pulse Technologies may reject a Device only if Pulse Technologies believes that the Device in question does not conform in all material respects with the applicable Specifications. If Ikaria does not receive Pulse Technologies' written notice of rejection within such 30 day period, Pulse Technologies shall be deemed to have accepted such Device.

(b) If Pulse Technologies provides Ikaria with a timely notice of rejection under Section 2.8(a), Pulse Technologies shall return the rejected Device(s) to Ikaria at Ikaria's expense. Ikaria shall have 30 days following receipt of the rejected Devices in which to test such Devices. If Ikaria does not dispute a rejection, Ikaria shall rework or replace the rejected Device(s), at Ikaria's expense and such rework or replacement shall constitute Pulse Technologies' exclusive remedy and Ikaria's sole liability with respect to such rejection. If Ikaria disputes a rejection, Ikaria shall provide Pulse Technologies with written notice of such dispute within 30 days after receiving the returned Devices, and the Parties shall use commercially reasonable efforts to resolve the dispute amicably and promptly. If the Parties are unable to reach a resolution within 30 days after Pulse Technologies' notice of rejection, the returned Devices shall be submitted to an independent consultant mutually acceptable to the Parties, whose decision as to the conformity of such Devices with the applicable Specification shall be final and binding. The Party against whom the dispute is decided shall pay any charges for such consultant. If the consultant determines that the returned Devices did not conform to the Specification, Ikaria shall rework or replace the rejected Devices at no charge to Pulse Technologies, and such replacement shall constitute Pulse Technologies' exclusive remedy and Ikaria's sole liability with respect to such rejected Devices.

2.9 No Licenses. Pulse Technologies acknowledges and agrees that nothing in this Agreement grants, or shall be deemed or interpreted to grant, to Pulse Technologies any right, title, or interest in or to any Intellectual Property reflected, contained, or incorporated in, or practice under, as part

of or in the process of manufacturing and delivery of Devices (collectively, the "Device IP"). Pulse Technologies acknowledges and agrees that it is obtaining ownership to the physical Devices only under this Agreement, and not to or in any of the Device IP.

3. Quality Agreement. The Parties shall use reasonable efforts to negotiate and conclude a quality agreement ("Quality Agreement") within 60 days after the Effective Date. The Quality Agreement shall detail the division of responsibilities between the Parties regarding quality and regulatory controls and reporting concerning the Devices. In the case of a conflict between the Quality Agreement and this Agreement, the terms of this Agreement shall control unless such term in the Quality Agreement expressly references such conflict and the Parties intend to have the Quality Agreement control such provision.

4. Audit Rights. Pulse Technologies shall have the right to conduct reasonable audits and inspections of the Facility, Ikaria's manufacturing operations, and Ikaria's records relating to the manufacture of Devices under this Agreement. Ikaria shall reasonably cooperate with Pulse Technologies in conducting such audits and inspections.

5. Warranties.

5.1 General Warranties. Each Party warrants to the other Party that (a) it has the right and authority to enter into this Agreement and to carry out its obligations hereunder; (b) it is validly existing in the jurisdiction in which it is incorporated and is authorized to do business under the laws of each jurisdiction in which it engages in business activities; and (c) it is not aware of any legal, contractual or other restriction, limitation or condition that might adversely affect its ability to perform its obligations hereunder.

5.2 Warranties by Ikaria. Ikaria warrants to Pulse Technologies that each Device delivered hereunder shall conform in all material respects with its applicable Specifications. Pulse Technologies agrees that its exclusive remedies, and Ikaria's sole liabilities, with respect to any breach of the warranty set forth in this Section 5.2 are set forth in Section 2.8 of this Agreement.

5.3 Pass Through Warranties. Ikaria shall use commercially reasonable efforts to pass-through to Pulse Technologies the benefit of any warranties on component parts incorporated into the Devices to the extent Ikaria has the right to do so. Pulse Technologies acknowledges and agrees that this Section 5.3 does not provide Pulse Technologies with any additional rights or remedies vis-à-vis Ikaria beyond those stated in Section 5.

5.4 Debarment. Each party represents and warrants that, as of the Effective Date and throughout the Term, it (and each of its employees and agents) (a) is not currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs as defined in 42 U.S.C. 1320a7b(f) (the “Federal Health Care Programs”); (b) has not been convicted of a criminal offense related to the provision of healthcare items or services but yet to be excluded, debarred or otherwise declared ineligible to participate in the Federal Health Care Programs; and (c) is not under investigation or otherwise aware of any circumstances which may result in it (or its agents, employees or any substitutes thereof performing any duties under this Agreement) being excluded from participation in the Federal Health Care Programs.

5.5 DISCLAIMER. EXCEPT AS EXPRESSLY PROVIDED HEREIN, NEITHER PARTY MAKES NOR RECEIVES ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, OR ARISING FROM A COURSE OF DEALING OR USAGE OF TRADE PRACTICE, WITH REGARD TO THE DEVICES OR OTHERWISE UNDER

THIS AGREEMENT, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT, OR FITNESS FOR A PARTICULAR PURPOSE.

6. Indemnity. Pulse Technologies shall indemnify, defend and hold Ikaria, its Affiliates and their respective directors, officers, employees, agents, successors and assigns harmless from and against any damages, losses, judgments, claims, suits, actions, liabilities, costs and expenses (including, but not limited to, reasonable attorneys’ fees), as and when incurred, resulting from any Third Party claims or suits arising out of the ownership, use, handling, development, distribution, marketing, or sale of any Device.

7. Compliance.

7.1 Compliance with Laws. Each Party shall comply with all applicable laws and regulations governing the performance of such Party’s obligations under this Agreement. Without limiting the foregoing, each Party shall comply with applicable US and other laws, rules and regulations that govern the import, export and re-export of the Devices, including the U.S. Export Administration Regulations, and will obtain any required export and import authorizations to perform its obligation hereunder.

7.2 Regulatory Filings. Pulse Technologies, at its expense, shall be solely responsible for the preparation, filing, and maintenance of all regulatory documents and all governmental permits, licenses and other approvals as may be necessary with respect to the formulation, marketing, distribution, sale, and use of each Device.

7.3 Permits. Ikaria at its expense shall be solely responsible for, and has the obligation to prepare, file, and maintain during the Term, all licenses, permits, and approvals as may be necessary with respect to the manufacture of Devices at the Facility.

8. Term and Termination.

8.1 Term. Unless otherwise terminated under this Section 8, this Agreement will commence as of the Effective Date and will continue for a period of twelve months (the “Term”); provided, however, that if a Purchase Order that has been accepted by Ikaria has not been fulfilled at the expiration of the Term, this Agreement shall continue to remain in effect for so long as necessary to complete the delivery of Devices under that Purchase Order.

8.2 Termination. This Agreement may be terminated by either Party upon 60 days written notice of the other Party’s material breach of any provision of this Agreement; provided, however, that the breaching Party will have an opportunity to (a) cure the breach during the 60 day notice period, or (b) provide the non-breaching Party with a plan to remedy the breach within the 60 day notice period, and if so cured, no termination will be deemed to have occurred as long as the breaching Party diligently pursues the plan to remedy the breach and completes such plan in accordance with the time frame agreed to by the Parties (such time frame not to exceed an additional 60 days).

8.3 Effect of Termination. Termination or expiration of this Agreement shall not release either Party from any liability, right of action or other obligation which has arisen prior to such termination or expiration, including Ikaria’s obligation to deliver to Pulse Technologies such quantity of Devices under any accepted Purchase Order to the effective date of termination or expiration, and Pulse Technologies’ obligation to pay Ikaria the amount set forth in such Purchase Order. Notwithstanding any expiration or termination of this Agreement, the following provisions shall survive: Sections 2.6(b), 2.8(b), 2.9, 5.5, 6, 8.3, 9, 10, and 11, as well as Pulse Technologies’ payment obligations under Exhibit B.

9. Confidentiality.

9.1 Non-Use and Non-Disclosure of Confidential Information. Each Receiving Party agrees that all Confidential Information of the Disclosing Party (a) shall not be used by the Receiving Party except to perform its obligations or exercise its rights under this Agreement, (b) shall be maintained in confidence by the Receiving Party, and (c) except as permitted by Section 9.2, shall not be disclosed by the Receiving Party to any Person without the prior written consent of the Disclosing Party.

9.2 Permitted Disclosures.

(a) The Receiving Party may provide the Disclosing Party's Confidential Information (i) to its Affiliates and to their employees, consultants, advisors, and contractors who have a need to know such Confidential Information for purposes of the Receiving Party exercising or granting licenses or sublicenses, (ii) in communications with existing or bona fide prospective acquirers, merger partners, lenders or investors, in each case of (i) and (ii), on a need to know basis and under appropriate confidentiality provisions substantially equivalent to those of this Agreement.

(b) The Receiving Party may provide the Disclosing Party's Confidential Information:

(i) to the Receiving Party's employees, consultants, advisors and contractors who have a need to know such Confidential Information and are bound by an obligation to maintain the confidentiality of the Disclosing Party's Confidential Information;

(ii) to patent offices or regulatory authorities in order to seek or obtain patent rights or approval to conduct clinical trials, or to gain regulatory approvals;

(iii) as reasonably required for development of Devices, in accordance with normal and customary commercial practice; or

(iv) if such disclosure is required by law (including by rules or regulations of any securities exchange) or to defend or prosecute litigation or arbitration; provided, that prior to such disclosure, to the extent permitted by law or such rules or regulations, the Receiving Party promptly notifies the Disclosing Party of such requirement and furnishes only that portion of the Disclosing Party's Confidential Information that the Receiving Party is legally required to furnish.

10. Limitations of Liability.

10.1 EXCEPT IN CONNECTION WITH PULSE TECHNOLOGIES' INDEMNIFICATION OBLIGATIONS UNDER SECTION 6, IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES, BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS, LOST DATA, OR LOSS OF USE) ARISING OUT OF THIS AGREEMENT, REGARDLESS OF WHETHER SUCH DAMAGES ARE BASED ON TORT, WARRANTY, CONTRACT OR ANY OTHER LEGAL THEORY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THIS EXCLUSION IS INDEPENDENT OF ANY OTHER REMEDY SET FORTH IN THIS AGREEMENT.

10.2 TO THE FULLEST EXTENT PERMITTED BY LAW, IKARIA'S LIABILITY TO PULSE TECHNOLOGIES UNDER THIS AGREEMENT IS LIMITED TO THE AGGREGATE AMOUNTS PAID OR PAYABLE BY PULSE TECHNOLOGIES TO IKARIA IN RESPECT OF THE RELEVANT PURCHASE ORDER FROM WHICH THE CLAIM AROSE.

11. Miscellaneous.

11.1 Notices. All notices required or permitted to be given under this Agreement must be in writing and delivered to the other Party as set forth below. Notices are validly given upon the earlier of confirmed receipt by the receiving Party or three business days after dispatch by a reputable courier or certified mail, return receipt requested. Either Party may change its designated contact and address for purposes of notice by giving notice to the other Party in accordance with these provisions.

If to Ikaria:

INO Therapeutics LLC

Perryville III Corporate Park

53 Frontage Road, Third Floor

P. O. Box 9001

Hampton, NJ 08827

Attention: General Counsel

If to Pulse Technologies:

Bellerophon Pulse Technologies LLC

Perryville III Corporate Park

53 Frontage Road, Third Floor

P. O. Box 9001

Hampton, NJ 08827

Attention: General Counsel

11.2 Escalated Dispute Resolution. Prior to pursuing legal remedies hereunder, the Parties' relationship managers agree to negotiate in good faith to resolve any disputes arising during performance of this Agreement. If such negotiations and meetings do not resolve the dispute within 10 business days after notice of the dispute, then a senior executive from each Party will meet within 10 days or as agreed between them to attempt to resolve such dispute. If the dispute is not resolved to the satisfaction of these executives within 10 days, then either Party may pursue all available legal remedies. Notwithstanding the foregoing, either Party may seek injunctive relief with respect to any disputed matter without following the dispute resolution procedure set forth above.

11.3 Force Majeure. Neither Party will be liable for any failure or delay in performance of its obligations under this Agreement to the extent such failure or delay is caused by any event beyond such Party's reasonable control, which may include fire, flood, explosion, unavailability of utilities or raw materials, labor difficulties, war, riot, act of God, export control regulation, or other laws or regulations, action or failure to act of any governmental authority, or any judgment, injunction or order of a court, administrative agency or regulatory authority having the effect of preventing or adversely affecting either Party's performance under this Agreement.

11.4 Independent Contractors. The relationship of the Parties established under this Agreement is that of independent contractors and neither Party is a partner, employee, agent or joint venturer of or with the other.

11.5 Assignment. Except as otherwise provided in this Section 11.5, neither this Agreement nor any part hereof may be assigned or transferred by either Party, whether by operation of law or otherwise, without the other Party's prior written consent. Notwithstanding the foregoing, either Party

may assign this Agreement, without the other Party's prior consent, in the event of a sale or transfer of the business as to which this Agreement relates, whether such sale or transfer occurs by merger, reorganization, asset and/or stock purchase, or by any other means, provided that the assignee agrees in writing to assume all of the assignor's obligations under this Agreement. Any assignment or purported assignment in violation hereof shall be void. This Agreement will be binding upon and inure to the benefit of the Parties and their permitted successors and assigns.

11.6 Headings; Construction; Interpretation. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. The terms of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause or Exhibit shall be deemed to be a reference to any Article, Section, subsection, paragraph, clause or Exhibit, of or to, as the case may be, this Agreement. Except where the context otherwise requires, (a) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein); (b) any reference to any law refers to such law as from time to time enacted, repealed or amended; (c) the words "herein," "hereof" and "hereunder," and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof; (d) the words "include," "includes," "including," "exclude," "excludes," and "excluding," shall be deemed to be followed by the phrase "but not limited to," "without limitation" or words of similar import; and (e) all references in this Agreement to "days" will, unless otherwise specified herein, mean calendar days.

11.7 No Third Party Beneficiaries. No provisions of this Agreement are intended to confer or give, or will be construed to confer or give, to any person or entity other than Ikaria and Pulse Technologies any rights, remedies or other benefits under or by reason of this Agreement.

11.8 Severability. If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid or unenforceable in any respect, such determination will not impair or affect the validity, legality or enforceability of the remaining provisions hereof, and each provision is hereby declared to be separate, severable and distinct. To the extent that any such provision is found to be invalid, illegal or unenforceable, the Parties will negotiate in good faith to substitute for such provision, to the extent possible, a new provision that most nearly effects the Parties' original intent in entering into this Agreement or to provide an equitable adjustment in the event no such provision can be added. The other provisions of this Agreement will remain in full force and effect.

11.9 Entire Agreement. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior communications, representations or agreements, whether oral or written. No modifications, amendments, or waiver of any term, condition or provision of this Agreement will be binding on either Party unless in writing and signed by an authorized representative of each Party.

11.10 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New Jersey, USA, without giving effect to any conflict of law provisions.

11.11 Counterparts. This Agreement may be executed in counterparts each of which, when executed and delivered, shall be original, but all such counterparts shall constitute one and the same document. The Parties agree that signatures transmitted via portable document format (PDF) shall be deemed originals until originals replace such copies.

IN WITNESS WHEREOF, each of the Parties has caused this Device Clinical Supply Agreement to be executed on its behalf by a duly authorized officer on the date first set forth above.

INO THERAPEUTICS LLC d/b/a IKARIA

BELLEROPHON PULSE

TECHNOLOGIES LLC

By:

/s/ Matthew M. Bennett

By:

/s/ Daniel Tassé

Name: Matthew M. Bennett

Name: Daniel Tassé

Title: Vice President & Secretary

Title: Chief Executive Officer

EXHIBIT A

DEVICES

INOpulse DS for PAH

INOpulse DS-C for COPD

INOpulse Mark 1

CCM (Clinical Control Module)

EXHIBIT B

PRICING

Pricing for the Devices shall be as follows:

Device

Pricing

INOpulse DS for PAH

COGS plus [**]%

INOpulse DS-C for COPD

COGS plus [**]%

INOpulse Mark 1

COGS plus [**]%

CCM (Clinical Control Module)

COGS plus [**]%

Ikaria shall invoice Pulse Technologies as follows in respect of each Purchase Order accepted by Ikaria hereunder:

(a) promptly following acceptance of a Purchase Order by Ikaria, Ikaria shall invoice Pulse Technologies for estimated COGS for the Devices covered by the applicable Purchase Order; and

(b) upon completion of the Devices (i.e., the Devices are available for pickup by Pulse Technologies EXW Ikaria's Facilities as described in Section 2.7 of the Agreement), Ikaria shall invoice Pulse Technologies for (i) any actual COGS in excess of estimated COGS (or if actual COGS is less than estimated COGS, then Ikaria shall grant a credit in the appropriate amount), and (ii) the additional percentage fee specified in this Exhibit B.

Pulse Technologies shall promptly pay each invoice hereunder (but in all events, within 30 days after each such invoice has been issued by Ikaria), it being acknowledged and agreed by Pulse Technologies that (a) Ikaria shall not be required to take any further action with respect to the Devices under a Purchase Order unless and until Pulse Technologies has paid the applicable invoice in full, and (b) Ikaria shall not be required to release any Devices for pick-up until the applicable invoice has been paid in full.

All amounts not paid when due shall bear interest from the due date at the rate of the lesser of (a) [**] percent ([**]%) per month or (b) the maximum amount permitted by applicable law.