Current Agreements

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Supply agreement for nitric oxide for inhalation

Bellerophon Therapeutics
INO Therapeutics

Feb 09 2014

Supply agreement for nitric oxide for inhalation

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

- Details
- Financials
- Termsheet
- Press Release
- Filing Data
- Contract

Details

Announcement date:	Feb 09 2014
Start date:	Feb 09 2014
Industry sectors:	Pharmaceutical Services
Asset type:	Compound Technology
Therapy areas:	Cardiovascular
Technology types:	Small molecules
Deal components:	Supply

Financials

Deal value, US$m:	n/d

Termsheet

Not available.

Press Release

Not available.

Filing Data

Not available.

Contract

DRUG CLINICAL SUPPLY AGREEMENT

This Drug 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”), (b) primary or idiopathic pulmonary arterial hypertension (“PAH”), and pulmonary hypertension secondary to idiopathic pulmonary fibrosis (“IPF”; collectively, the “Pulse Technologies Clinical Programs”);

WHEREAS, prior to the Spin-Out, Ikaria manufactured nitric oxide for inhalation (the “NO”) and corresponding placebo (“Placebo”; collectively, “Product”) for use 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 supply, and Ikaria wishes to continue to manufacture and supply, the Product 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 “Certificate of Analysis” means a document, signed by an authorized representative of Ikaria, describing (i) the Specifications for the applicable Product; (ii) the testing and methods applied to a batch or lot for such Product in order to verify compliance with the Specifications, and (iii) the results of such testing.

1.3 “cGMP” means the regulatory requirements for current good manufacturing practices promulgated by the FDA under the Food and Drug Act, including at 21 C.F.R. parts 210, 211 and 820. and under the Public Health Service Act, Biological Products, 21 C.F.R. parts 600 et seq., as the same may be amended from time to time.

1.4 “COGS” means, as to Ikaria and its Affiliates, with respect to the Product, the aggregate of internal and external costs of Ikaria and its Affiliates to manufacture such Product, calculated as follows: (a) to the extent that Ikaria or its Affiliates performs all or any part of the manufacturing of such Product, the actual direct material costs and direct labor costs for, plus manufacturing overhead reasonably allocable to, such manufacturing of such Product (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 Product 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.

1.5 “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 the Product. 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.

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

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

1.8 “Facility” means Ikaria’s manufacturing facilities located in Port Allen, LA, or such other manufacturing site(s) specified by Ikaria from time to time.

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

1.10 “Federal Health Care Programs” shall have the meaning set forth in Section 7.3.

1.11 “Forecast” shall have the meaning set forth in Section 2.4.

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

1.13 “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.

1.14 “IPF” shall have the meaning set forth in the recitals to this Agreement.

1.15 “NO” shall have the meaning set forth in the recitals to this Agreement.

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

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

1.18 “Placebo” shall have the meaning set forth in the recitals to this Agreement.

1.19 “Product” shall have the meaning set forth in the recitals to this Agreement.

1.20 “Product IP” shall have the meaning set forth in Section 2.9.

1.21 “Pulse Technologies Clinical Programs” shall have the meaning set forth in the recitals to this Agreement.

1.22 “Quality Agreement” has the meaning set forth in Section 4.1.

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

1.24 “Specifications” means, with respect to the Product and Placebo, the specifications in effect for the Product immediately prior to the Spin-Out.

1.25 “Term” has the meaning set forth in Section 10.1.

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

2. Supply of Product.

2.1 Obligations of Ikaria. During the Term of this Agreement, Ikaria shall use commercially reasonable efforts to manufacture and supply Pulse Technologies’ requirements, and Pulse Technologies shall acquire from Ikaria its requirements, for the Product 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 Product, nor shall anything in this Agreement require Ikaria to prioritize manufacturing and supplying the Product to Pulse Technologies over performing similar services for its own benefit.

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

2.3 Commercial Supply. If Pulse Technologies desires to obtain supply of any Product (or any variant thereof or any version with different specifications) for commercial use, then prior to negotiating the terms of an agreement for such agreement, Pulse Technologies shall promptly notify Ikaria thereof in writing. Ikaria shall, within 60 days after receipt of such notice, indicate to Pulse Technologies in writing whether Ikaria or any of its Affiliates wishes to enter into such an agreement and, if Ikaria indicates that Ikaria or any of its Affiliates do wish to enter into such agreement, the Parties shall negotiate in good faith to enter into mutually agreeable terms pursuant to which Ikaria or any of its

Affiliates would enter into agreement with Pulse Technologies. In such negotiations, Ikaria may elect to supply [**]% of Pulse Technologies requirements for the Product(s) in question, or such lesser quantity as Ikaria may elect in its sole discretion. If either (a) Ikaria indicates it does not wish to pursue such agreement, (b) Ikaria fails to indicate its interest within such 30 day period or (c) Ikaria indicates it wishes to enter into such agreement but the Parties fail to reach agreement on the terms of such agreement or to execute a definitive agreement prior to 90 days after the date of Ikaria’s indication of interest, then Pulse Technologies shall be free, without any further obligation to Ikaria under this Agreement with respect thereto, to enter into such an agreement with a Third Party; provided that, in the event clause (c) of this sentence is applicable, if Pulse Technologies proposes to enter such agreement with a Third Party on terms that are materially less favorable to Pulse Technologies than the terms last offered in writing to Pulse Technologies by Ikaria, then (i) Pulse Technologies shall, prior to entering into such agreement with such Third Party, offer such terms to Ikaria, (ii) Ikaria shall have 15 days after the date of receipt of such offer from Pulse Technologies to notify Pulse Technologies in writing of its acceptance of such offer and (iii) (A) if Ikaria so accepts, the Parties shall promptly enter into a definitive agreement for the commercial supply of such Product(s) on such terms, or (B) if Ikaria does not accept, then Pulse Technologies shall be free, without any further obligation to Ikaria under this Agreement with respect thereto, to enter into such commercial supply agreement with a Third Party; provided further that if Pulse Technologies does not enter into a definitive agreement for such commercial supply with a Third Party within

180 days after the expiration of Ikaria's under this Section 2.3, Ikaria's rights under this Section 2.3 shall be reinstated.

2.4 Forecasts; Committed Quantities.

(a) 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 which Pulse Technologies expects to order from Ikaria over the next 36 months (the "Forecast"). 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 a purchase commitment by Pulse Technologies or a supply commitment by Ikaria; provided, however, that the first six months of each such forecast shall constitute a binding purchase order hereunder for the specific Product for the quantities specified for that six-month period.

(b) Each purchase of Product, and any acknowledgment thereof, shall be governed by the terms of this Agreement. If a Party uses forms or documents to place or accept a 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.

2.5 Delivery. Ikaria shall deliver the Product to a carrier selected by Pulse Technologies. The Products shall be made available EXW the Facility (Incoterms 2010). Title and risk of loss will pass to Pulse Technologies when the Products 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.

2.6 Certificates. An appropriate Certificate of Analysis shall be provided with the shipment of each batch or lot of Product delivered to Pulse Technologies.

2.7 Shipping Instructions. Pulse Technologies will provide Ikaria with packaging and shipping instructions, including temperature requirements, temperature monitoring instructions and packaging specifications. Notwithstanding any other provision of this Agreement, Ikaria will not be

liable for any loss or damage caused by Ikaria's compliance with Pulse Technologies' packaging and shipping instructions or any loss or damage caused by Pulse Technologies' carrier.

2.8 Limited Use. Pulse Technologies acknowledges and agrees that the Products may only be used in the Pulse Technologies Clinical Programs (and, if Ikaria has exercised its right under Section 2.3 to supply Products for commercial use, then also for that limited commercial use) and for no other uses or purposes.

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 the Product (collectively, the "Product IP").

2.10 Changes. Ikaria shall use commercial reasonable efforts to accommodate any reasonable changes to the Specifications for Product requested by Pulse Technologies, it being understood and agreed that Pulse Technologies shall bear any and all costs associated with such changes.

3. Price and Payment

3.1 Pricing. Pricing for the Product and Placebo shall be COGS plus [**] percent.

3.2 Payment. 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) thirty (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.

3.3 Late Payments. 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.

4. Quality.

4.1 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 Product. 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.

4.2 Quality Assurance. Ikaria shall perform quality testing using assays agreed to by the Parties in order to assure that Product complies with the Specification, and shall retain samples of Product as required by applicable law. Ikaria shall maintain records, including batch or lot records, with respect to the quality testing.

5. Non-Conforming Product.

(a) Each batch or lot of Product delivered to Pulse Technologies hereunder shall be accompanied by a Certificate of Analysis. Pulse Technologies shall have 30 days from the date of receipt of Product 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 Product only if: (i) Pulse Technologies claims a material breach of Ikaria's representations and warranties in Section 7.2 of this Agreement with respect to such Product; or (ii) Ikaria has failed to deliver a Certificate of Analysis for such Product. 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 Product.

(b) If Pulse Technologies provides Ikaria with a timely notice of rejection as set forth in Section 5(a), Pulse Technologies shall return the rejected Product to Ikaria at Ikaria's expense. Ikaria shall have 30 days following receipt of the rejected Product in which to test such Product. If Ikaria does not dispute a rejection, Ikaria shall rework or replace the rejected Product, 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 Product, 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 Product shall be submitted to an independent laboratory or consultant mutually acceptable to the Parties, whose decision as to the conformity of such Product with the applicable Specification shall be final and binding. The Party against whom the dispute is decided shall pay any charges for such laboratory or consultant. If the laboratory or consultant determines that the returned Product did not conform to the Specification, Ikaria shall rework or replace the rejected Product 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 Product.

6. 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 Product under this Agreement. Ikaria shall reasonably cooperate with Pulse Technologies in conducting such audits and inspections.

7. Warranties.

7.1 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.

7.2 Warranties by Ikaria. Ikaria warrants to Pulse Technologies that the Product delivered hereunder shall (a) conform in all material respects with its applicable Specifications and (b) be manufactured in compliance applicable law (including applicable cGMPs). 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 7.2 are set forth in Section 5(b) of this Agreement.

7.3 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.

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

8. 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 Product.

9. Compliance.

9.1 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 Product, including the U.S. Export Administration Regulations, and will obtain any required export and import authorizations to perform its obligation hereunder.

9.2 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 the Product.

9.3 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 Product at the Facility.

10. Term and Termination.

10.1 Term. Unless earlier terminated under Section 10.2, this Agreement shall commence as of the Effective Date, and unless earlier terminated pursuant to Section 10.2, shall expire on a Product by Product basis as follows (the "Term"):

(a) With respect to Product for the Pulse Technologies Clinical Program for COPD, at the point in time that Pulse Technologies is no longer actively and continuously engaged that Pulse Technologies Clinical Program;

(b) With respect to Product for the Pulse Technologies Clinical Program for PAH, at the point in time that Pulse Technologies is no longer actively and continuously engaged that Pulse Technologies Clinical Program; and

(c) With respect to Product for the Pulse Technologies Clinical Program for IPF, at the point in time that Pulse Technologies is no longer actively and continuously engaged that Pulse Technologies Clinical Program.

10.2 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). In addition, Ikaria may terminate this Agreement for any reason or no reason by giving 30 days' notice to Pulse Technologies.

10.3 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 Product 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 (except in the case of a material breach hereof by Pulse Technologies, in which case Ikaria may elect not to supply and manufactured but not yet delivered Product). Notwithstanding any expiration or termination of this Agreement, the following provisions shall survive: Sections 2.3, 2.8, 2.9, 5, 7.4, 8, 10.3, 11.1, 12 and 13.

11. Confidentiality.

11.1 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 11.2, shall not be disclosed by the Receiving Party to any Person without the prior written consent of the Disclosing Party.

11.2 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 the Product, 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.

12. Limitations of Liability.

12.1 EXCEPT IN CONNECTION WITH PULSE TECHNOLOGIES' INDEMNIFICATION OBLIGATIONS UNDER SECTION 8, 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.

12.2 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.

13. Miscellaneous.

13.1 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

13.2 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.

13.3 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.

13.4 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.

13.5 Assignment. Except as otherwise provided in this Section 13.5, 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.

13.6 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.

13.7 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.

13.8 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.

13.9 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.

13.10 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.

13.11 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 Drug 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

[Signature Page to Drug Clinical Supply Agreement]