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): September 7, 2018

OPIANT PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38193**	**46-4744124**
(State or other jurisdiction of incorporation)	(Commission File Number	(IRS Employer Identification No.)

201 Santa Monica Boulevard, Suite 500 Santa Monica, CA	**90401**
(Address of Principal Executive Offices)	(Zip Code)

(310) 598 5410
Registrant's telephone number, including area code

(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:

☐ 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 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).

Emerging growth company ☐
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 September 7, 2018, Opiant Pharmaceuticals, Inc. (the "**Company**") entered into a Development Agreement ("**Development Agreement**") and an Agreement for Reimbursement of Capital Expenditure and Service Fees ("**Reimbursement Agreement**") with Aesica Queenborough Limited ("**Aesica**"), a wholly owned subsidiary of Consort Medical plc, related to the Company's product OPNT003 (intranasal nalmefene), a potent long acting opioid antagonist for the treatment of opioid overdose. As part of the Development Agreement, Aesica will supply the Company with clinical samples and registration batches for the purpose of performing clinical studies and obtaining regulatory approvals. Further, as part of the Development Agreement, the Company and Aesica agreed that, upon approval by the U.S. Food and Drug Administration, Aesica will manufacture and supply the commercial device for the Company upon mutually agreed terms. Under the terms of the Reimbursement Agreement, the Company has agreed to reimburse Aesica for certain service, tooling, equipment and facility alteration expenses incurred by Aesica under certain circumstances, including termination of the Development Agreement and the failure to complete a definitive manufacturing and supply agreement.

Copies of the Development Agreement and Reimbursement Agreement are attached to this Current Report on Form 8-K and incorporated herein by reference. The descriptions of the Development Agreement and Reimbursement Agreement provided herein are qualified in their entirety by reference to the terms of the agreements as set forth in Exhibit 10.84 and Exhibit 10.85.

On September 10, 2018, the Company issued a press release announcing the entry into the Development Agreement and Reimbursement Agreement. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 8.01. Other Events.

On September 5, 2018, the Company's Board of Directors (the "**Board**"), following a review of its corporate governance practices matters by the Nominating and Governance Committee as well as the full Board, determined to enhance its governance practices by establishing the position of lead independent director and eliminating the position of Chairman of the Board. The position of Chairman of the Board, until September 5, 2018, was held by Dr. Michael Sinclair, who was not an independent member of the Board as determined in accordance with Nasdaq's marketplace rules. In addition to creating the new position of lead independent director, the Board also appointed Dr. Gabrielle Silver to serve as lead independent director. Dr. Silver has been an independent member of the Board since May 5, 2016, has been the Chairperson of the Company's Nominating and Corporate Governance Committee since January 29, 2017, and has been a member of the Company's Compensation Committee since May 26, 2017. Dr. Silver has extensive experience managing the growth and profitability of pharmaceuticals, healthcare services and diagnostics businesses. Dr. Silver's qualifications to serve on the Board and as the lead independent director include her healthcare business leadership experience.

On June 8, 2018 and June 11, 2018, Dr. Phil Skolnick and Dr. Roger Crystal, respectively, (the " **Executives**") adopted Rule 10b5-1 trading plans to, over time, exercise certain options to purchase Company common stock and automatically sell the shares issued on exercise of such options in accordance with each plan's specifications. 160,000 options (in the case of Dr. Skolnick) and 225,000 options (in the case of Dr. Crystal) are subject to the trading plans. The trading plans were established as part of the Executives' investment strategies for asset diversification and liquidity over time. The trading plans were adopted during an "open window" in accordance with guidelines specified by Rule 10b5-1 under the Securities Exchange Act of 1934, as amended, and as permitted by the Company's insider trading policy. Sales under the trading plans may commence on October 1, 2018, are based upon pre-established stock price thresholds and will expire once all of the shares have been sold or on January 31, 2020 (in the case of Dr. Skolnick) and July 31, 2019 (in the case of Dr. Crystal), whichever is earlier. Actual sale transactions will be disclosed publicly through Form 144 and Form 4 filings with the Securities and Exchange Commission, as required.

Rule 10b5-1 allows persons who may be considered insiders to adopt pre-arranged written plans for trading specified amounts of stock. A plan establishes predetermined trading parameters that, among other things, do not permit the person adopting the plan to exercise subsequent influence over how, when or whether to effect

trades. Once a plan has been properly adopted, trades may be executed pursuant to the terms of the plan at times when the person would otherwise be restricted from trading. Trading plans are designed to allow persons to sell shares in an orderly fashion for asset diversification, liquidity, tax planning and other purposes when they might otherwise be restricted from doing so due to material, non-public information that they might possess at the time of the sale.

The Company does not undertake any obligation to report Rule 10b5-1 trading plans that may be adopted by any of its officers, directors or stockholders in the future, or to report any modifications or terminations of any publicly announced plan, except to the extent required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.84	Development and Manufacturing Agreement between the Company and Aesica Queensborough Limited dated September 7, 2018.
10.85	Agreement for Reimbursement of Capital Expenditures and Service Fees between the Company and Aesica Queensborough Limited dated September 7, 2018.
99.1	Press release dated September 10, 2018.

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.

OPIANT PHARMACEUTICALS, INC.

Dated: September 10, 2018 By: /s/ David D. O'Toole
Name: David D. O'Toole
Title: Chief Financial Officer

Exhibit 10.84

CONFIDENTIALTREATMENT REQUESTED

CONFIDENTIAL PORTIONS OF THIS DOCUMENT HAVE BEEN REDACTED AND HAVE BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION

DATED: SEPTEMBER 7, 2018

AESICA QUEENBOROUGH LIMITED

and

OPIANT PHARMACEUTICALS INC

DEVELOPMENT AGREEMENT

re: development of a device capable of administering Nalmefene hydrochloride

Index

Clause No. Page No.

THIS DEVELOPMENT AGREEMENT ("**Agreement**") is made on September 7, 2018 between:

(1) **AESICA QUEENBOROUGH LIMITED** (company number 06350087) with offices located at Breakspear Park, Breakspear Way, Hemel Hempstead, Hertfordshire HP2 4TZ UK ("**Aesica**"); and

(2) **OPIANT PHARMACEUTICALS, INC.** with offices located at 201 Santa Monica Blvd., Suite 500, Santa Monica, California, 90401, USA ("**Customer**").

INTRODUCTION

(A) Aesica is a developer and manufacturer of both active pharmaceutical ingredients and finished dose forms for the pharmaceutical industry.

(B) Bespak (an Affiliate of Aesica) is a developer and manufacturer of medical devices, including the Unidose Xtra Device.

(C) Customer is developing a portfolio of opioid antagonist nasal sprays for symptom-driven treatments of substance use and eating disorders.

(D) Aesica has agreed to undertake development work for Customer on the terms set out in this Agreement with a view to producing a clinically pre-filled Unidose Xtra Device with Nalmefene hydrochloride ("the **Product**").

AGREED TERMS

1. Definitions and interpretation

1.1 Definitions. In this Agreement, where the context so admits, the following words and expressions shall have the following meanings:

"**Aesica Invention**" has the meaning given to it in clause 12.4;

"**Affiliate**" means with respect to a person, any other person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such person, for so long as such control exists; "control" and, with correlative meanings, the terms "controlled by" and "under common control with", shall mean: (a) the possession, directly or indirectly, of the power to direct the management or policies of a person, whether through the ownership of voting securities, by contract or otherwise; or (b) the ownership, directly or indirectly, of at least fifty percent (50%) of the outstanding voting securities or other ownership interest of a person;

"**API**" means Nalmefene hydrochloride;

"**Background IPR**" means all Intellectual Property Rights owned by or licensed to a party prior to the Effective Date of this Agreement or subsequently generated by a party outside the scope of this Agreement;

"**Bespak**" means Bespak Europe Limited (company number 03515896) with offices located at Breakspear Park, Breakspear Way, Hemel Hempstead, Hertfordshire HP2 4TZ UK, an Affiliate of Aesica;

"**Bespak IPR**" means all Intellectual Property Rights owned by or licensed to Bespak prior to the Effective Date or subsequently generated by Bespak outside the scope of this Agreement;

"**Business Day**" means a day other than a Saturday, Sunday or public holiday in England and/or USA;

"**Change Order Request Form**" means the form for requesting amendments to the relevant Work Plan in the same or similar form as that set out in Schedule 3 which shall include details of the change's impact on timetable, scope and price;

"**Charges**" means the fees, prices and price estimates payable by Customer in respect of the Services, as set out in Schedule 2;

"**Clinical Samples**" means those Products that have been produced by Aesica for the purposes of enabling the Customer to undertake clinical trials;

"**Customer Invention**" has the meaning given to it in clause 12.5;

"**Customer Materials**" means all data, information or material (including Intellectual Property Rights owned by or licensed to Customer, but excluding, for the avoidance of doubt, any Deliverables) to be provided or made available by the Customer to Aesica as set out in the Work Plan and Schedule 4 hereto;

"**Deliverables**" means the materials or products resulting from the carrying out of the Services as identified in the Work Plan, including any Product and Clinical Samples and Registration Batches;

"**Diligent Effort**" means, with respect to a Party, the carrying out of obligations specified in this Agreement in a diligent, expeditious and sustained manner using efforts and resources, including reasonably necessary personnel and financial resources, that businesses operating in the same field as the relevant Party typically devote to such obligations;

"**DMF**" means the device master file, as defined in Part 314 of Title 21 of the United States Code of Federal Regulations, as may be amended from time to time, or any successor thereof, for the Unidose Xtra Device, or any comparable submission required by any other Specified Regulator, if applicable;

"**Effective Date**" means the date of this Agreement;

"**cGMP**" means all applicable good manufacturing practices, including but not limited to current Good Manufacturing Practice regulations of the FDA as set forth in Title 21 of the U.S. Code of Federal Regulations §§ 210 and 211 used for the manufacturing, testing, validation, labelling, packaging, storage, shipment and installation of any and all pharmaceutical products, equipment and related materials to ensure that such products and materials meet the applicable legal requirements as established by any applicable governmental authority;

"**Intellectual Property Rights**" or "**IPR**" means patents, patentable rights, copyright, design rights, utility models, trademarks (whether or not any of the above are registered), trade names, rights in domain names, rights in inventions, rights in data, database rights, rights in know-how and confidential information, and all other intellectual and industrial property and similar or analogous rights existing under the laws of any country and all

pending applications for and right to apply for or register the same (present, future and contingent, and including all renewals, extensions, revivals and all accrued rights of action);

"**Latent Defect**" means a defect attributable to an act or omission of Aesica that causes Product to fail to conform to the Specifications or relevant warranties provided by Aesica hereunder, which defect is not reasonably discoverable upon initial inspection and testing by Customer or its designee, as applicable;

"**Materials**" has the meaning given to it in clause 3.5(a);

"**Party Invention**" shall mean Intellectual Property Rights (other than Aesica Inventions or Customer Inventions) conceived, created, developed or reduced to practice under this Agreement solely by either party (and/or any of its Affiliates) or jointly by both parties (and/or any of their respective Affiliates);

"**Pass Through Charges**" means [***];

"**Pass Through Items**" means the following: [***];

"**Phase**" means each phase of the Services, as set out in the Work Plan;

"**Pre-existing Materials**" means all data, information or material provided or made available by Aesica and/or Bespak in connection with the Services which existed prior to the Effective Date, including designs and specifications (but excluding, for clarity, the Specifications);

"**Production Site**" means Aesica Queenborough Development Centre, North Road, Queenborough, Kent ME11 5EL;

"**Registration Batches**" means those units of the Product that have been produced by Aesica for the purposes of enabling validation of the Product by a Regulator;

"**Regulator**" means any relevant regulatory authority, government or governmental agency that regulates any aspect of the manufacture and/or commercialisation of the Product:

"**Reimbursement Agreement**" means the agreement entered into between the parties on or about the date hereof dealing with Customer's obligation to reimburse Aesica for certain costs incurred in the delivery of the Services in accordance with the terms thereof;

"**Services**" means the activities to be carried out by Aesica for Customer under this Agreement, as set out in the Work Plan;

"**Specifications**" means the requirements to which the Product must conform as agreed to in writing by the parties prior to Phase 4 of the Work Plan, as may be updated from time to time by written agreement of the parties;

"**Specified Regulator**" has the meaning given to it in clause 2.1(b);

"**Unidose Xtra Device**" means Bespak's single-use nasal drug delivery device referred to as the "Unidose Xtra" which is manufactured utilising Bespak IPR;

"**Work Plan**" means the description, specification and timeframe for the Services and Deliverables (including the provision of Clinical Samples and Registration Batches) as set out in Schedule 1.

1.2 Interpretation. In this Agreement (including the introduction and schedules) unless the context otherwise requires:

(a) reference to a person includes a legal person (such as a limited company) as well as a natural person;

(b) reference to this Agreement includes the schedules and appendices and other documents attached to it or incorporated by reference into it (all as amended, added to or replaced from time to time);

(c) references to clauses or schedules shall be to those in or to this Agreement and references to paragraphs shall be to paragraphs of the schedules or annexes to the schedules (as the case may be);

(d) clause headings are for convenience only and shall not affect the construction of this Agreement;

(e) reference to "**including**" or any similar terms in this Agreement shall be treated as being by way of example and shall not limit the general applicability of any preceding words;

(f) reference to any legislation shall be to that legislation as amended, extended or re-enacted from time to time and to any subordinate provision made under that legislation; and

(g) "**writing**" or "**written**" includes e-mail but not facsimiles.

2. Services

2.1 Aesica shall, and shall cause its Affiliates to:

(a) perform the Services and provide the Deliverables (including Clinical Samples and Registration Batches) in accordance with the Work Plan (Schedule 1);

(b) provide the Services using good faith, Diligent Efforts, care and skill in accordance with all relevant regulatory and industry standards and applicable laws and regulations specified by the US Food and Drug Administration (FDA), the European Union and such other Regulators as may be agreed between the parties in writing (collectively, the "**Specified Regulators**") (including cGMP when producing the Clinical Samples and Registration Batches);

(c) ensure that all Services will be performed by appropriately qualified and trained personnel;

(d) ensure that at all times it has and maintains at its own expense all the licences, permissions, authorisations, consents and permits that it needs to carry out its obligations under the Agreement.

2.2 Aesica and the Customer acknowledge that, as with all research and development projects, it is not possible to guarantee a successful outcome of the whole or any part

of the Work Plan, and Aesica shall not be liable for any failure to achieve a successful outcome of the whole or any part of any Phase or of the Work Plan as a whole, provided that it has provided the Services in accordance with the terms and conditions of this Agreement including, for the avoidance of doubt, clause 2.1(b) above.

2.3 Aesica shall, and shall cause its Affiliates to, use Diligent Efforts to meet any performance dates specified in the Work Plan, provided that any such dates shall, unless otherwise specifically stated in the Work Plan, be estimates only.

2.4 Aesica shall not have the right to engage subcontractors to fulfill its obligations hereunder without first obtaining the prior written consent of Customer (such consent not to be unreasonably withheld or delayed), provided that any such approval and engagement shall not relieve Aesica of its obligations under this Agreement, and Aesica shall be responsible and liable to Customer for all acts and omissions of any approved subcontractor. By signing this Agreement, Customer gives its consent to the appointment by Aesica of Bespak as a sub-contractor under this Agreement in accordance with this Clause 2.4.

2.5 Aesica shall, upon obtaining Customer's prior written consent (such consent not to be unreasonably withheld or delayed), have the right to make reasonable changes to the Services and Deliverables which are necessary to comply with any applicable law, regulatory approval or licence, or safety requirement.

3. Provision of APIs and Customer Materials

3.1 Aesica shall be responsible for sourcing the API from such supplier as designated by Customer.

3.2 The Customer shall:

(a) at its own cost and free of charge to Aesica, deliver or procure the delivery of all Customer Materials to Aesica at the Production Site, at a time and manner specified by Aesica and agreed to by Customer, together with:

(i) a certificate of analysis (as relevant);

(ii) TSE/BSE declaration (as relevant);

(iii) any handling and storage requirements and expiration dates in relation to the Customer Materials, together with any material safety data sheet (as relevant);

(b) promptly and at its own expense, provide such additional information, data and materials as Aesica shall reasonably request for the purpose of providing the Services;

(c) inform Aesica of any regulatory or safety requirements relevant to the handling or use of the Customer Materials (as relevant); and

(d) reasonably co-operate with Aesica in all matters relating to the Services.

3.3 Risk in the Customer Materials shall pass to Aesica on the completion of unloading of the Customer Materials at the Production Site. The Customer acknowledges that Aesica's liability in respect of the Customer Materials is limited pursuant to clause 15.3.

All Customer Materials remain the exclusive property of the Customer up until the point they are placed in the Unidose Xtra Device at which point they become the property of Aesica, provided that in the event Aesica provides a Unidose Xtra Device as a Deliverable hereunder (whether as a Product, Clinical Sample, Registration Batch or otherwise), any Customer Materials included in such Deliverable shall become the property of Customer.

3.4 The Customer warrants and represents that to the best of Customer's knowledge:

(a) the Customer Materials are of a good quality and are suitable in all respects for use in the provision of the Services, including where relevant for inclusion in the Product and in any manufacturing process referred to in the Work Plan, or which is developed pursuant to the Services;

(b) the Customer Materials and any other information provided to Aesica by the Customer from time to time are complete and accurate in all material respects;

(c) it is the sole legal and beneficial owner of the Customer Materials;

(d) the use by Aesica of the Customer Materials in the provision of the Services will not cause Aesica to be in breach of any applicable law;

(e) the Customer Materials are free from contaminating substances, (including but not limited to any Transmissible Spongiform Encephalopathies), microbiological organisms and products of any such organisms;

(f) the use of the Customer Materials in the provision of the Services on behalf of the Customer will not infringe the Intellectual Property Rights of any third party; and

(g) it will use the Deliverables only for the purposes of (i) assessing whether or not the outcome of the Work Plan is achievable; (ii) carrying out the relevant clinical trials (as appropriate); and (iii) making the relevant submissions to the Specified Regulators and not for any other purposes unless otherwise agreed to in writing by the parties.

3.5 Aesica shall:

(a) procure the delivery of all materials required for the conduct of Services other than Customer Materials (the "**Materials**"), as agreed with the Customer, to Aesica at the Production Site, together with all relevant documentation, either as a Pass-Through Item or otherwise where not identified as a Pass Through Item in this Agreement;

(b) procure the delivery of API from the manufacturer specified by the Customer, together with all relevant documentation, as a Pass-Through Item.

3.6 Aesica warrants and represents that to the best of Aesica's knowledge:

(a) the Materials are of a good quality and are suitable in all respects for use in the provision of the Services, including where relevant for inclusion in the Product and in any manufacturing process referred to in the Work Plan, or which is developed pursuant to the Services; and

(b) the Materials are free from contaminating substances, (including but not limited to any Transmissible Spongiform Encephalopathies), microbiological organisms and products of any such organisms.

3.7 Aesica agrees to handle and store Customer Materials in accordance with applicable laws and regulations and at conditions prescribed by the Customer or its designee in order to maintain their quality and suitability for use.

4. Excess Inventory

4.1 At the conclusion, revision or termination of this Agreement, the following provisions shall apply in respect of any excess inventory:

(a) where such items are (i) Pass Through Items that have already been invoiced by Aesica and paid for by the Customer; or (ii) Customer Materials, such items shall be, at the discretion of the Customer either (a) shipped to Customer, freight collect or (b) destroyed by Aesica;

(b) where such items are Deliverables (including, in this case, work-in-process and finished goods), Pass Through Items that have not yet been paid for by the Customer or Materials (that have not expired), the Customer shall pay for such items (at cost plus 10% in respect of the relevant Pass Through Items and Materials) in accordance with the provisions of this Agreement in respect of the Deliverables (on a pro rata basis where the Deliverables are not complete) and, once such items have been paid for, the items shall be, at the discretion of the Customer, either (a) shipped to Customer, freight collect or (b) destroyed by Aesica; and

(c) where such items are expired Materials or waste by-products, such items shall be destroyed by Aesica.

4.2 Customer shall bear one hundred percent (100%) of all destruction costs related to said excess inventory. All relevant destruction certification will be provided to the Customer.

4.3 Any such destruction shall be in accordance with all applicable laws and regulations. Aesica shall provide written notification to Customer of its intent to dispose and or store obsolete inventory. If Aesica does not receive disposition instructions from Customer within sixty (60) days from date of notification, obsolete inventory remaining at Aesica's facilities shall be subject to storage fees and or destruction costs at Aesica’s discretion.

5. Regulatory Issues and Compliance

5.1 Quality and Release: All Clinical Samples and Registration Batches supplied by Aesica shall meet the current Specifications therefor and shall be manufactured in accordance with cGMPs and all other applicable laws relating to such Product. Prior to each shipment of Clinical Samples or Registration Batches (as appropriate), Aesica shall perform quality control procedures and inspections to verify that such Product conforms fully to the Specifications, all applicable cGMPs and other applicable laws. Each shipment of Clinical Samples or Registration Batches shall be accompanied by a certificate of analysis describing all current requirements of the specifications and results of tests performed certifying that the quantities of Product supplied have been manufactured, controlled and released according to the Specifications and all applicable cGMPs at the Production Site.

5.2 Quality Agreement: As requested by the Customer, Aesica and the Customer shall enter into a technical agreement specifying the respective responsibilities for storage, release, quality control and quality assurance with respect to the Product (the "**Quality Agreement**"). The Quality Agreement is not intended and shall not be construed to limit any of the rights and obligations of Aesica or the Customer set forth in this Agreement. If there is any conflict or inconsistency between the terms of the Quality Agreement and the terms set forth in this Agreement, the terms set forth in this Agreement shall control.

5.3 Acceptance procedure:

(a) Rejection: Acceptance by Customer or its designee of any Clinical Sample or Registration Batch delivered by Aesica hereunder shall be subject to inspection and applicable testing by Customer or its designee. If, as a result of such inspection, Customer or its designee discovers that any Clinical Sample or Registration Batch delivered by Aesica under this Agreement fails to conform with the Specifications or otherwise fails to conform to the warranties given by Aesica (Section 13) ("**Rejected Goods**"), Customer or such designee may reject such Product by providing Aesica written notice thereof within sixty (60) days after Customer's or its designee's receipt of such Product.

(b) Where the cause of the Rejected Goods is not attributable to Aesica (as set out at clause 5.3(d) below) Aesica shall replace the Rejected Goods within the timescale agreed between the parties at the Customer's cost.

(c) In all other circumstances (subject to receipt of the relevant Customer Materials required in respect of such replacement Products) within sixty (60) days (or such longer period as the parties may agree in writing, acting reasonably) after its receipt of notice of such rejection at no additional cost to Customer or its designee (including transportation costs) other than the cost of supplying the relevant Customer Materials for such replacement Products, Aesica shall replace the Rejected Goods. Aesica shall make arrangements with Customer or its designee, as applicable, for the return or disposal of the Rejected Goods, and such return, shipping and disposal charges shall be paid by Aesica.

(d) Aesica will not be deemed to have caused any non-conformance in the Rejected Goods where the non-conformance (i) is caused by deficiencies in the Specifications; (ii) results from a defect in the Customer Materials that is not reasonably discoverable by Aesica using the test methods set forth in the Specifications and/or Quality Agreement (as appropriate) prior to use of the applicable Customer Material in the performance of the Services; (iii) results from a defect in the Pass-Through Items that is not reasonably discoverable by Aesica using the test methods set forth in the Specifications and/or Quality Agreement (as appropriate); (iv) is caused by actions of Customer or third parties occurring after the Product has been delivered by Aesica; (v) is due to any unascertainable reason despite Aesica having performed the Services in accordance with the Specifications, cGMPs, and Applicable Laws and a thorough root cause analysis in accordance with its standard operating procedures; or (vii) is due to any breach by Customer of its obligations under this Agreement.

(e) Disputes: Upon receipt of notification as set forth at Section 5.3(a) above, Aesica may request, and then the Customer must supply, samples of the Rejected Goods or some other evidence of deficiency that Aesica may reasonably specify. Within twenty (20) Business Days' of receipt of such samples or other evidence as appropriate, Aesica shall respond in writing to the rejection notice stating whether

it agrees that (i) the Products are Rejected Goods; and (ii) if the Products are Rejected Goods, Aesica's view of the cause of such Products constituting Rejected Goods. If the Customer does not agree with Aesica's response then Aesica and Customer, or Customer's designee, shall use reasonable efforts to resolve such disagreement as promptly as possible. Without limiting the foregoing, Aesica and Customer, or Customer's designee, shall discuss in good faith mutually acceptable testing procedures pursuant to which both Aesica and Customer, or Customer's designee, will re-test a sample of the Rejected Goods to determine whether such Product constitutes Rejected Goods and/or the cause of such Product being a Rejected Good. Notwithstanding the foregoing, in the event Aesica and Customer, or Customer's designee, are unable to resolve such disagreement within ten (10) Business Days of the date of the applicable rejection notice, either party (or, in the case of Customer, its designee) may submit a sample of the Rejected Goods to an independent laboratory to review records, test data and perform tests and/or analyses promptly on samples of such Rejected Good. Such independent laboratory shall be mutually agreed upon by the parties; provided that if the parties are unable to agree, then Customer shall designate the independent testing laboratory. The independent laboratory's results shall be delivered to the parties in writing and shall be final and binding save for manifest error. Unless otherwise agreed by the parties in writing, the costs associated with such testing and review shall be borne by the non-prevailing party.

(f) Latent Defects; Contamination: Notwithstanding Section 5.3(a), Customer or its designee shall have the continuing right to reject Product that fails to conform to the Specifications or otherwise fails to conform to the warranties given by Aesica in Section 13 due to a Latent Defect. In such case, Customer or its designee shall notify Aesica within fifteen (15) days of its confirmation of a Latent Defect. Any Rejected Goods notified in accordance with this clause 5.3(f) shall be subject to clauses 5.3(b) to (e) above as though they had been Rejected Goods following delivery.

5.4 Record keeping: Aesica shall prepare and maintain all original documents involving the manufacture and control for the Product including its raw materials, drug substance, and package components, including but not limited to inventory records, testing procedures and records related to Specifications, master and lot manufacturing instructions, data from testing and inspections, and original records of experimental work performed to establish capability to manufacture and test the Product. Aesica shall store these original documents in a safe and organised manner so that they may be provided upon request to Customer or to the FDA, Drug Enforcement Agency ("DEA") or other Specified Regulators.

5.5 Inspection: Customer or its designee shall have the right, upon reasonable advance notice and during regular business hours, to inspect and audit annually or more frequently if for cause: (a) the manufacturing facility or other facility at which any of the manufacturing or processing activities relating to the Product are performed, including to the extent applicable the Production Site; and/or (b) any of Aesica's manufacturing and quality control records and all other documentation relating to the manufacturing and processing activities with respect to the Product (including any internal quality control audits or reviews conducted by Aesica). Such inspections and audits shall be for the purpose of ascertaining compliance with applicable laws and regulation, the Specifications and other aspects of this Agreement.

5.6 Regulatory Actions: Aesica shall permit the FDA and other Specified Regulators to conduct inspections of the manufacturing facility and/or any other facility at which any of the manufacturing or processing activities relating to the Product are performed (including, to the extent applicable, the Production Site) as such regulatory authorities may request, including pre-approval inspections, and shall cooperate with such regulatory authorities with respect to the inspections and any related matters, in each case that are related to the Product or its manufacture. Aesica shall: (a) notify Customer in writing promptly following Aesica becoming aware that any such regulatory inspection will occur (or is being conducted, in the case of an unscheduled inspection); and (b) keep Customer informed about the results and conclusions of each such regulatory inspection, including actions taken by Aesica to remedy conditions cited in the inspections or in any other correspondence received by Aesica from a regulatory authority. Without limiting the foregoing, Aesica will provide Customer with copies of any written inspection reports, or any other request, directive or other communication issued by such regulatory authority, and all related correspondence with respect thereto (including, any applicable FDA Form 483s or other inspection reports, warning letters or citations or other similar notifications from a regulatory authority) in each case, relating to the Product, its manufacture or general manufacturing concerns (e.g., facility compliance or the like), in each case, no later than five (5) Business Days following Aesica's receipt of the same.

5.7 Regulatory Cooperation: Aesica agrees to promptly provide to Customer, as reasonably requested, at no additional charge to Customer (unless such co-operation requires support from external partners, for example, translation agencies, in which case such costs will be treated as Pass Through Items), all information and data in Aesica's possession or control necessary or useful for Customer and/or its designee(s) to apply for, obtain and maintain regulatory approvals for the Product with the FDA and other Specified Regulators.

(a) Aesica or its Affiliates, as applicable, shall file the DMF with the FDA and other Specified Regulators in accordance with the programme plan set out in the Work Plan, as such programme plan may be amended from time to time in accordance with clause 7.3. Aesica will maintain a design history file for the Unidose Xtra Device consistent with the quality systems regulation standards set forth in the ISO 13485 and related FDA compliance regulations, including 21 CFR 820.30.

(b) Aesica or its Affiliates, as applicable, hereby grants to Customer and its designees the right to reference the DMF as filed by Aesica or its Affiliates, including the data contained therein (collectively, the "**Unidose Regulatory Documentation**") to apply for, obtain and maintain regulatory approvals for the Product. Aesica or its Affiliates, as applicable, shall, at Customer's reasonable request, provide any required notice of such right of reference to the applicable Regulators and shall promptly provide Customer with a copy of each such notice. Aesica or its Affiliates shall provide copies of any data and regulatory correspondence contained in the Unidose Regulatory Documentation to the extent reasonably requested by Customer. Unidose Regulatory Documentation shall be used by Customer only to obtain regulatory approval for the Product and for no other purpose. The parties acknowledge and agree that certain Regulators do not use a DMF. Where Aesica has agreed to support an application to such Regulators (which agreement is deemed to have been obtained in the case of the Specified Regulators) then, as reasonably requested by Customer from time to time, Aesica or its Affiliates shall promptly provide Customer as reasonably requested, at no additional charge (unless such co-operation requires support from external partners, for example, translation agencies, in which case such costs will be treated as Pass Through Items), with

all available information in Aesica's or its Affiliates' control that is necessary or useful for Customer to apply for, obtain, and maintain regulatory approvals with such Regulators in respect of the Product, including information relating to the facilities, or the process, methodology and materials used in the manufacture and processing of the Unidose Xtra Device or the Product. Further, Aesica or its Affiliates, as applicable, agrees, at Customer's request and expense, to execute, acknowledge and deliver such further instruments, and take such other actions, all as promptly as possible, which may be necessary or appropriate to assist in the filing for, preparation, submission and maintenance of such regulatory approvals.

(c) DMF Updates; Answers to Questions. Subject to the provisions of this Agreement, Aesica or its Affiliates shall maintain the DMF and design history file in accordance with applicable law and keep the DMF and design history file updated with respect to the requirements of the FDA or the other Specified Regulators; provided that Aesica or its Affiliate shall (i) promptly notify Customer of any changes to the DMF and in any event in a timely manner such that Customer can make any corresponding changes under the regulatory approvals for the Product and (ii) not make any material changes to the DMF without following the change review process set out in clause 7.3 of this Agreement. Aesica or its Affiliates will assist Customer in preparing answers to questions from the FDA about the Product or Unidose Xtra Device or other Specified Regulator.

(d) DMF Audit. Aesica or its Affiliate will upon written request from Customer and subject to agreeing on a mutually convenient date and time, provide Customer and its designees (who are bound by obligations of confidentiality and use restrictions consistent with and no less onerous than those that bind Customer under the Agreement) with access, at Aesica's or its Affiliates' premises, to the design history file supporting the DMF to the extent reasonably required by Customer to support its filings necessary to obtain regulatory approval for the Product or to respond to any inquiry from any Specified Regulator regarding the Unidose Xtra Device for use in the Product.

6. Representatives

Aesica shall appoint a manager ("**Aesica Manager**") who shall be responsible for the co-ordination of all matters relating to the Services and other matters related to this Agreement. All communications, documentation and materials relating to the Services or this Agreement shall be sent, as appropriate, by the Aesica Manager to Customer's nominated manager. Customer's nominated manager shall be reasonably available to liaise with, and respond to queries from, the Aesica Manager. Each party shall notify the other in writing promptly in the event of any proposed change to these appointments.

7. Review meetings

7.1 The parties shall attend and participate in review meetings (including by conference call) at such frequency as determined by the mutual agreement of the parties, to discuss the progress of the Work Plan. Meetings shall be attended by the Aesica Manager and/or other appropriate delegates and Customer's nominated manager and/or other appropriate delegates. Others may be invited to attend such meetings by prior agreement of the parties.

7.2 During review meetings, the parties may raise, discuss and, where possible, resolve any specific issues concerning the Work Plan, Services, working relationships or procedures and any other matters nominated by either party.

7.3 If at any time either party wishes to make any changes to the Work Plan, it will inform the other party of the proposed changes and complete a Change Order Request Form. The parties will promptly discuss the proposed change and if it is agreed by the parties, the parties will execute a Change Order Request Form to the Work Plan setting out the agreed changes.

8. Clinical and Validation Supply

8.1 The provisions of this clause 8.1 shall apply where the Deliverables consist of the provision of Clinical Samples and Registration Batches. Aesica shall deliver the Clinical Samples and Registration Batches DDP (as defined in Incoterms 2010) at the location designated by Customer.

8.2 The Customer shall use the Clinical Samples and Registration Batches solely for the purposes of performing clinical studies and obtaining regulatory approvals, and shall not sell or otherwise supply or provide any of the Clinical Samples or Registration Batches to any third party, save where otherwise indicated in the Work Plan.

8.3 The Customer undertakes to maintain appropriate, up-to-date and accurate records to enable the recall of any Clinical Samples or Registration Batches, and shall procure that such recall takes place as required by law. If Aesica reasonably believes a recall may be necessary with respect to any Product or Deliverable provided under this Agreement, Aesica shall immediately notify Customer immediately and no later than within 24 hours of becoming aware of the need to recall. Notwithstanding the foregoing, if a recall of the Product arises out of or results from: (a) the gross negligence or willful misconduct of Aesica; or (b) a breach by Aesica of this Agreement (including a breach of any of the representations or warranties in Article 13), Aesica shall, subject to clause 15, bear all the costs and expenses of such recall, save to the extent that such costs and expenses are caused or contributed to by the gross negligence, willful misconduct, or breach of this Agreement by the Customer.

9. Commercial Supply

9.1 Both parties agree that Aesica will be the named manufacturer of the Product on the FDA regulatory submission documentation, and on approval by the FDA, to manufacture and supply the Product for commercial purposes. Both parties agree that within sixty (60) days of the Effective Date, Aesica shall prepare and circulate to Customer a draft manufacturing and supply agreement ("**MSA**") for negotiation, which shall incorporate the benchmark commercial supply pricing as set out at Appendix A. The parties shall negotiate in good faith the terms of the MSA within one hundred and eighty (180) days following Customer's receipt of the first draft agreement (or such longer period as the parties may agree to in writing) (the "**Negotiation Period**"). The parties acknowledge and agree that the benchmark commercial supply pricing set out at Appendix A may need to be revised during the Negotiation Period or thereafter to reflect the outputs from the Services, the clinical trials or as a result of the parties' discussions with Regulators under this Agreement in which case the parties shall in good faith negotiate and agree in writing upon modifications to such benchmark commercial supply pricing to accommodate such outputs or discussions (as appropriate).

9.2 If:

(a) by expiry of the Negotiation Period the parties have not reached final agreement on the terms of the MSA; or

(b) following agreement of the terms of the MSA, either party would like to revise the pricing in the agreed MSA to reflect any outputs from the Services, the clinical trials or as a result of the parties' discussions with Regulators under this Agreement that may have occurred after finalisation of the MSA but the other party does not agree to such proposed revisions,

then either party may refer the matter to each Party's Executive Officers who shall meet as soon as practicable and negotiate in good faith with a view to resolving such disagreement. If the respective Executive Officers are unable to reach final agreement within one (1) calendar month of referral to them, then either party may request the appointment of an independent expert (acting as an expert and not as an arbitrator) to resolve such outstanding terms. If the parties cannot agree on the appointment of the independent expert within ten (10) days following such request, then:

(i) to the extent that the disagreement relates to price to be charged by Aesica either party shall be entitled to request the Institute of Chartered Accountants in England and Wales appoint an independent expert of repute with international experience in the field of commercial manufacture of medical devices; and

(ii) in relation to all other disagreements, either party shall be entitled to request the Pharma and BioPharma Outsourcing Association (or equivalent trade body agreed upon by the parties) appoint an appropriately experienced expert. The independent expert shall have expertise and experience in commercial manufacture of medical devices, including all commercial and practical issues involved and terms typically included in agreements relating to such manufacture.

9.3 Within ten (10) days of the appointment of the independent expert, the parties shall exchange simultaneously statements of case in no more than ten thousand (10,000) words in total, excluding supporting documentation, and each party shall simultaneously send a copy of its statement of case to the independent expert. Each party may, within five (5) days of the date of exchange of statement of case, serve a reply to the other party's statement of case of not more than ten thousand (10,000) words, excluding supporting documentation. A copy of any such reply shall be simultaneously sent to the independent expert. The independent expert shall review the positions of each of the parties and shall make a decision on each of the outstanding terms within thirty (30) days of appointment and there shall be no oral hearing. The costs of the independent expert's appointment shall be borne equally by the parties. The decision of the independent expert shall be final and binding on the parties, and the parties shall be obligated to execute an MSA hereunder on the terms chosen by the expert.

10. Deliverables

10.1 Aesica shall provide the Deliverables in respect of each Phase, as set out in the Work Plan (Schedule 1). Risk in the Deliverables shall pass to the Customer on delivery.

10.2 Title to the Deliverables shall not pass to the Customer until Aesica has received payment in full in respect of such Deliverable.

11. Charges, invoicing and payment

11.1 Customer shall pay the undisputed Charges for the Services as set out in Schedule 2 and in accordance with the payment terms there set out.

11.2 In addition to the Charges, Aesica shall be entitled to invoice the Customer on a pass through basis in respect of any Pass Through Items it purchases in connection with the provision of the Services, as set forth in the Work Plan. In addition to the cost of the Pass Through Items, Aesica shall be entitled to invoice the Pass Through Charge in respect of any such Pass Through Items. Any invoices issued pursuant to this clause 11.2, shall be paid by the Customer within the time period specified on the applicable invoice (which may be such time period as Aesica may reasonably require in order to ensure that it receives the funds in time to make the necessary payment to the third party, if applicable. If Aesica does not require such pre-payment, then the provisions of clause 11.4 shall apply).

11.3 Save where otherwise provided in this agreement, all amounts referred to in this agreement are exclusive of value added tax (VAT) or other applicable sales tax which, where chargeable by Aesica, shall be payable by Customer at the rate and in the manner prescribed by law.

11.4 Customer must pay all undisputed invoices within thirty (30) days of its receipt of the applicable invoice ("**Due Date**"). Customer must pay all undisputed invoices, in full and in cleared funds, by the Due Date without deduction, set off or withholding of any kind.

11.5 If Customer fails to make any undisputed payment to Aesica under this Agreement by the applicable Due Date, Aesica shall, without prejudice to any other right or remedy available to Aesica, be entitled to suspend the performance or further performance of its obligations under the Work Plan, without liability to Customer and to charge interest on the overdue amount from the Due Date up to the date of actual payment, after as well as before judgment, at the rate of three percent (3%) per annum, or the maximum rate allowed by law, whichever is less.

11.6 The Charges shall be paid in pounds sterling, unless otherwise agreed in writing by Aesica.

12. Intellectual Property Rights

12.1 The Customer acknowledges and agrees that the Unidose Xtra Device is protected by Bespak IPR and that the Customer does not obtain any rights or licences in respect of such Bespak IPR as a result of entering into this Agreement except that Aesica and/or its Affiliates hereby grants to the Customer a non-exclusive, non-transferable, non-sublicensable (except to sub-contractors approved by Aesica in advance and licensees or collaborators granted the right to develop or commercialize the Product), fully paid up, royalty-free license under Bespak IPR to perform its obligations, and exercise its rights to perform clinical studies and obtain regulatory approvals with respect to the Product, under this Agreement.

12.2 As between Customer and Aesica, all Background IPR of Aesica and all rights in the Pre-existing Materials (together the "**Aesica Pre-existing IPRs**") shall remain solely owned by Aesica and/or its Affiliate (as the case may be) and all Background IPR of Customer shall remain solely owned by Customer.

12.3 Aesica hereby grants to Customer a non-exclusive, non-transferable, non-sublicensable (except to sub-contractors approved by Aesica in advance and licensees or collaborators granted the right to develop or commercialize the Product), fully paid up, royalty-free license under any Aesica Pre-existing IPRs, Aesica Inventions, Aesica Party Inventions and Joint Inventions to perform its obligations, and exercise its rights to

perform clinical studies and obtain regulatory approvals with respect to the Product, under this Agreement

12.4 Aesica shall be the sole and exclusive owner of any Intellectual Property Rights conceived, created, developed or reduced to practice by or on behalf of either party, whether alone or jointly, in conducting its activities under this Agreement, including for clarity in the course of performing Services under the Work Plan, to the extent such Intellectual Property Rights relate solely to the Unidose Xtra Device, including its design, manufacture, assembly, filling and stoppering ("**Aesica Inventions**"), and Customer hereby assigns to Aesica all of Customer's right, title and interest in and to all such Aesica Inventions.

12.5 Customer shall be the sole and exclusive owner of any Intellectual Property Rights conceived, created, developed or reduced to practice by or on behalf of either party, whether alone or jointly, in conducting its activities under this Agreement, including for clarity in the course of performing Services under the Work Plan, to the extent such Intellectual Property Rights relate solely to (a) the API or the API in spray form (including its composition of matter, formulation, methods of use, methods of manufacture, method of administration or dosing regimens), or (b) related excipients and absorption enhancers ("**Customer Inventions**"), and Aesica or its Affiliates (as applicable) hereby assigns to Customer all of Aesica's (or its Affiliates') right, title and interest in and to all such Customer Inventions.

12.6 Each party shall solely own all right, title and interest in and to any Party Invention conceived, created, developed or reduced to practice by such party (an "**Aesica Party Invention**" where Aesica is such party and a "**Customer Party Invention**" where Customer is such party).

12.7 The parties shall jointly and equally own all right, title and interest in and to any Party Invention conceived, created, developed or reduced to practice under this Agreement jointly by the parties ("**Joint Inventions**").

12.8 Customer hereby grants to Aesica a worldwide, fully paid-up, non-transferable, non-sublicenseable (except to Bespak or sub-contractors approved in accordance with this Agreement), non-exclusive licence under any Intellectual Property Rights owned by or licensed to Customer necessary or useful in order for Aesica to perform its obligations under this Agreement (including, for the avoidance of doubt, Customer Background IPR, Customer Inventions, Customer Party Inventions and Joint Inventions).

13. Warranties and Indemnity

13.1 Each party represents and warrants that it has full capacity and authority and has obtained all necessary consents to enter into and perform this Agreement and that this Agreement is executed by a duly authorised representative of such party.

13.2 Except as expressly set out in this Agreement and subject only to clause 15.1, no implied conditions, warranties or other terms, including any implied terms relating to satisfactory quality or fitness for any purpose, will apply to the Deliverables or Services or to anything supplied or provided by Aesica under this Agreement, or to any performance by Customer hereunder.

13.3 Customer shall indemnify and fully hold harmless Aesica, its Affiliates, and their respective employees, officers, directors and representatives (collectively, "**Aesica**

Indemnitees") against any loss or damage (including any legal costs incurred by any Aesica Indemnitee) that any Aesica Indemnitee incurs or suffers as a result of a claim by a third party arising out of:

(a) any breach by Customer of any of the warranties set out in clause 3.4; or

(b) infringement of Intellectual Property Rights of a third party in the development of the Product and/or Deliverables by Aesica, save to the extent that such claim relates to the Bespak IPR or any Aesica Pre-existing IPRs;

provided that in no case shall Customer be liable for any claims to the extent resulting from the negligence or willful misconduct of Aesica or its Affiliates.

13.4 Aesica agrees to indemnify and fully hold harmless Customer, its Affiliates, and their respective employees, officers, directors and representatives (collectively, "**Customer Indemnitees**") against any loss or damage (including any legal costs incurred by any Customer Indemnitee) that any Customer Indemnitee incurs or suffers as a result of any claim by a third party arising out of:

(a) any breach by Aesica of any of the warranties set out in clauses 13.5, 13.6 or 13.7;

(b) infringement of Intellectual Property Rights of a third party in the development, manufacture or commercialization of the Unidose Xtra Device or an infringement of the Intellectual Property Rights of a third party based upon the practice of Bespak IPR or Aesica Pre-existing IPRs,

provided that in no case shall Aesica be liable for any claims to the extent resulting from the negligence or willful misconduct of Customer or its Affiliates.

13.5 Aesica represents and warrants that all Clinical Samples and Registration Batches: (i) shall conform to the Specifications, as applicable; (ii) shall have been made, manufactured, labelled, packaged, stored, tested and released in accordance with all applicable cGMPs, other applicable laws, this Agreement, and the Quality Agreement.

13.6 Aesica represents and warrants that the Production Site, all equipment used for the manufacture of the Clinical Samples and the Registration Batches, and the activities to be conducted by Aesica hereunder, shall comply with all applicable laws and Aesica shall obtain and maintain all governmental registrations, permits, licenses and approvals necessary for it to manufacture and supply the Clinical Samples and the Registration Batches to Customer, and otherwise perform its obligations under this Agreement. Aesica further represents and warrants that, as at the Effective Date, there is no claim threatened or pending against Aesica or its Affiliates that alleges that the making, using, offering for sale, selling and importation of the Unidose Xtra Device or any Aesica Pre-existing IPRs infringes, misappropriates or otherwise violates the Intellectual Property Rights of a third party, and Aesica agrees to provide Customer with written notice within fifteen Business Days of becoming aware of any such claim.

13.7 Aesica represents and warrants that, as at the Effective Date, Aesica has not been debarred under Article 306 of the FDCA, 21 U.S.C. §335a(a) or (b), or any applicable equivalent foreign or local law, rule or regulation. In the event that Aesica becomes debarred, Aesica agrees to notify Customer immediately, and Customer shall have the right to terminate this Agreement in accordance with Section 18.1. Aesica certifies that it shall use best efforts not to use or employ in any capacity related to the manufacture of Clinical Samples or Registration Batches any individual, corporation, partnership, or

association which has been debarred under Article 306 of the FDCA, 21 U.S.C. §335a(a) or (b), or any applicable equivalent foreign or local law, rule or regulation. In the event that Aesica becomes aware of or receives notice of the debarment of any individual, corporation, partnership, or association providing services to Aesica which relate to the manufacture of Clinical Samples or Registration Batches, Aesica agrees to notify Customer promptly upon becoming aware of such debarment, and the parties will discuss the course of action in good faith.

14. Indemnified claims

14.1 If a party seeks indemnification from the other party pursuant to Section 13, the party seeking indemnification shall provide written notice to the other party of the assertion or commencement of any third party claim. The indemnifying party shall have the right to assume the defence of any such claim. The indemnified party shall, at the cost of indemnifying party, provide assistance and information reasonably required by the indemnifying party in its defence of such claim. Each indemnified party shall:

(a) not make any admission of liability, conclude any agreement in relation to such liability or make any compromise with any person, body or authority in relation to such liability without the prior written consent of the indemnifying party; and

(b) have the right to participate in (but not control) the defence of a claim and to retain its own counsel in connection with such claim at the expense of the indemnifying party.

15. Exclusions and limitations

15.1 Neither party's liability:

(a) for death or personal injury caused by its negligence or deliberate default;

(b) for fraudulent misrepresentation or for any other fraudulent act or omission;

(c) for breach of any obligations implied by section 12 of the Sale of Goods Act 1979 or section 2 of the Supply of Goods and Services Act 1982;

(d) under Part I of the Consumer Protection Act 1987;

(a) for breaches of its obligations of confidentiality set forth under Section 21;

(b) to pay sums properly due and owing to the other in the normal course of performance of this Agreement; or

(c) for any other liability which may not lawfully be excluded or limited;

is excluded or limited by this Agreement, except that liablity with respect to clause (e) shall not exceed two times the total amount of the Charges paid by the Customer to Aesica under this Agreement.

15.2 Subject to clause 15.1 and except as otherwise expressly set out in the Reimbursement Agreement, neither party shall under any circumstances be liable to the other party (whether from breach of contract, tort (including negligence), breach of statutory duty or otherwise) for any (a) loss of profit; (b) loss of sales; (c) loss of turnover, revenue or business; (d) loss of customers or contracts; (e) loss of or damage to reputation or

goodwill; (f) loss of opportunity; (g) loss of anticipated savings; (h) loss of any software or data; (i) loss of use of hardware, software or data; (j) loss or waste of management or other staff time; or (k) indirect, consequential or special loss (including but not limited to in relation to cancellation of further clinical trials and testing); arising out of or relating to this Agreement, whether or not such loss was foreseeable or if such party was advised of its possibility (and, for the purposes of this clause 15.2, the term "loss" includes a partial loss or reduction in value as well as a complete or total loss).

15.3 Subject to clause 15.1, each party's total liability arising out of or relating to this Agreement or its subject matter and to anything which it has done or not done in connection with the same (whether from breach of contract, tort (including negligence), breach of statutory duty or otherwise) shall in no circumstances exceed:

(a) In respect of a claim relating to the provision of the Services under Phase 1, 2 3 or 5, the Charges payable in respect of the Phase to which the claim relates; or

(b) In respect of a claim relating to the provision of Clinical Samples and/or Registration Batches under Phase 4 or 6 (as appropriate), the Charges payable in respect of the Clinical Samples and/or Registration Batches that are the subject of the claim; or

(c) In respect of any other claim, the total amount of the Charges paid by the Customer to Aesica under this Agreement.

15.4 Each party shall have a general duty to mitigate any loss or damage suffered by it (even if such loss or damage is the subject of an indemnity from the other party) and nothing in this Agreement shall in any way reduce or affect such duty.

16. Insurance

Each party shall effect and maintain in force for the duration of this agreement and for a period of five years thereafter, with reputable and substantial insurers, such policies of insurance as are reasonable for a business of that party's type taking into account the state of the insurance market at the relevant time and to cover potential liability of that party under this agreement. Each party shall provide the other party with a copy of the relevant insurance policies on request.

While this Agreement is in full force and effect and for a period of five (5) years following termination if written on a claims made basis, Customer shall maintain the following coverages: General Liability insurance covering bodily injury and property damage, premises liability and personal/advertising injury; Products Liability coverage and Clinical Trial Liability coverage. Insurance coverage shall be in the minimum amount of Five Million ($5,000,000) Dollars per occurrence with an annual aggregate amount of Five Million ($5,000,000) Dollars. Such evidence of insurance shall be provided, upon written request, in the form of a Certificate of Insurance.

Aesica shall maintain in full force and effect Products Liability Insurance coverage in the minimum amount of Five Million ($5,000,000) dollars per occurrence with an annual aggregate amount of Five Million ($5,000,000) dollars; employers liability coverage of One Million ($1,000,000) dollars per accident/disease/injury; general liability insurance, including contractual liability coverage, with limits of One Million ($1,000,000) dollars per occurrence and One Million ($1,000,000) annual aggregate. Such evidence of

insurance shall be provided, upon written request, in the form of a Certificate of Insurance.

Neither Customer nor Aesica intend for their respective insurance policies to stack on top of each other. To that end, both parties agree that if a loss is incurred for which Aesica has an obligation under Section 13 to indemnify Customer hereunder, Aesica's policies will be triggered and Aesica will defend Customer under the additional insured endorsement. Furthermore, if a loss is incurred for which Customer has an obligation under Section 13 to indemnify Aesica hereunder, then Customer's policies will be triggered and Customer will defend Aesica under the additional insured endorsement.

17. Term

This Agreement shall commence on the Effective Date and shall, unless earlier terminated in accordance with clause 18, continue in force until the later of (i) completion of the Services as set out in Schedule 1; (ii) provision of all Registration Batches to Customer hereunder; and (iii) completion of the negotiations in respect of the MSA as a result of each party having fulfilled each of their obligations set forth in clause 9.

18. Termination

18.1 Customer shall have the right to terminate this Agreement for any reason or no reason upon sixty (60) days' prior written notice to Aesica.

18.2 Without limiting any other rights or remedies to which it may be entitled, either party may terminate this Agreement by giving the other written notice if:

(a) the other materially breaches any term of this Agreement and it is not possible to remedy that breach;

(b) the other materially breaches any term of this Agreement and it is possible to remedy that breach, but the other fails to do so within thirty (30) days of being requested in writing to do so;

(c) a chargeholder, receiver, administrative receiver or other similar person takes possession of or is appointed over, or any distress, execution or other process is levied or enforced (and not discharged within sixty days) on, the whole or a material part of the assets of the other;

(d) the other or its directors or the holder of a qualifying floating charge or any of its creditors appoints an administrator;

(e) a petition is advertised, or a resolution is passed, or an order is made, for the administration or the winding-up, bankruptcy or dissolution of the other, which petition, resolution or order is not dismissed within sixty days of its institution;

(f) the other ceases to carry on business;

(g) any of the above (or any event analogous to any of the above) happens in relation to the other in any jurisdiction in which it is incorporated or resident or in which it carries on business or has assets; or

(h) the other is delayed in performing its obligations under this Agreement under clause 20 for a period of sixty (60) days.

For the purposes of this clause 18, in order for it to be possible to remedy a breach it must be possible to take steps so as to put the other party into the same position which (save as to the date) it would have been in if the breach had never occurred.

19. Consequences of termination

19.1 Termination of this Agreement will not affect any accrued rights or liabilities which either party may have by the time termination takes effect.

19.2 The termination of this Agreement for any reason will not affect the coming into force or the continuation in force of any of its provisions that expressly or by implication are intended to come into force or continue in force on or after the termination. Without prejudice to the foregoing, clauses 1, 4, 5, 8.3, 9, 12-16 and 19-28 shall survive termination of this agreement.

20. Force majeure

Neither party will be liable to the other for any breach of this Agreement which arises because of any circumstances which the defaulting party cannot reasonably be expected to control (which, for the avoidance of doubt, shall not include shortage or lack of available funds), provided that the defaulting party:

(a) notifies the other in writing as soon as reasonably practicable about the nature and extent of the circumstances and likely breach;

(b) uses Diligent Efforts to mitigate the effects of the circumstances and breach so as to minimise or avoid the breach;

(c) uses Diligent Efforts to resume performance as soon as reasonably practicable; and

(d) could not have avoided the breach by taking steps that it ought reasonably to have taken in light of the matters known to it before the circumstances arose.

21. Confidentiality

21.1 Confidential Information: The parties may from time to time disclose to each other Confidential Information. "Confidential Information" means any information, data or material disclosed by one party to the other party under this Agreement that: (a) if disclosed in tangible form, is marked "Confidential" or "Proprietary," or with a similar designation to indicate its confidential nature; (b) if disclosed orally, is identified as confidential or proprietary when initially disclosed and is confirmed in writing as confidential or proprietary within thirty (30) days following such disclosure; or (c) should otherwise reasonably be considered to be confidential or proprietary based on the nature of the information itself or the circumstances of its disclosure hereunder, even if not marked as "Confidential" or "Proprietary" or otherwise. Confidential Information of Customer shall also include any information provided to Aesica by any designee of the Customer. Notwithstanding the foregoing, each party's non-use and non-disclosure obligations under Section 21.2 shall not apply to any information, data or material that the receiving party can prove: (i) is or becomes generally available to the public other than as a result of a breach of this Agreement by the receiving party; (ii) is known to the receiving party prior to receipt from the disclosing party directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing party; (iii) was subsequently disclosed to the receiving party on a non-confidential basis by a

third party who does not have any obligations of confidentiality with respect to such information, data or material; or (iv) is independently developed by the receiving party, without use of or reference to the disclosing party's Confidential Information.

21.2 Non-Disclosure and Non-Use: Each party agrees to hold and maintain in strict confidence all Confidential Information of the other party. Each party further agrees not to disclose any Confidential Information of the other party except to those of its employees, agents or consultants who have a need to have access to such Confidential Information in connection with such party's performance of its obligations, and/or exercise of its rights, under this Agreement; provided that such employees, agents and consultants are bound by written non-disclosure and non-use obligations at least as protective of the disclosing party and its Confidential Information as this Section 21. Without limiting the foregoing, neither party shall use any Confidential Information of the other party except as otherwise permitted under this Agreement, or as may be necessary to perform such party's obligations or exercise such party's rights under this Agreement. The provisions of this Section 21 shall survive termination or expiration of this Agreement and shall continue for ten (10) years after the date of such termination or expiration.

21.3 Disclosures Required By Law: Nothing contained in this Section 21 shall prevent either party from disclosing any Confidential Information of the other party: (a) in the case of Customer, to any regulatory authority for the purpose of obtaining approval to sell, distribute, market or promote the Product; (b) to accountants, lawyers or other professional advisors or in connection with a merger, acquisition or securities offering, subject in each case, to appropriate confidentiality obligations under the circumstances; or (c) as required by law or regulation to be disclosed; provided, however, that the party subject to such disclosure requirement has provided written notice to the other party promptly upon receiving notice of such requirement in order to enable the other party to seek a protective order or otherwise prevent disclosure of such Confidential Information.

21.4 Confidential Terms. Each party agrees not to disclose to any third party any of the terms of this Agreement without the prior written consent of the other party, except (a) that each party may do so to its legal and financial advisors, potential or actual investors, potential or actual licensees, collaborators or acquisition partners and others on a need-to-know basis, under reasonable obligations of confidentiality; or (b) as required by law or regulation; provided, however, that the party subject to such disclosure requirement has provided written notice to the other party promptly upon receiving notice of such requirement and uses reasonable efforts to seek confidential treatment of sensitive business terms.

22. Entire agreement

22.1 This Agreement and the Reimbursement Agreement constitute the entire agreement between the parties about the subject matter of this Agreement and supersede all earlier understandings and agreements between the parties and all earlier representations by either party about such subject matter.

22.2 The parties have not entered into this Agreement in reliance upon any representation, warranty or promise and no such representation or warranty or any other term is to be implied in it whether by virtue of any usage or course of dealing or otherwise except as expressly set out in it.

22.3 If a party has given any representation, warranty or promise then, (except to the extent that it has been set out in this Agreement) the party to whom it is given waives any rights or remedies which it may have in respect of it.

22.4 This clause shall not exclude the liability of a party for fraud or fraudulent misrepresentation or concealment or any resulting right to rescind this Agreement.

23. Amendments

No amendment or variation of this Agreement shall be effective unless it is in writing and signed by the parties (or their authorised representatives).

24. Assignment and other dealings prohibited

24.1 Neither party may assign any or all of its rights or obligations under this Agreement without the prior written consent of the other, provided always that either party may assign this Agreement or any or all of its rights under this Agreement, without the other's consent, to (i) an Affiliate or (ii) a successor to all or substantially all of such party's business or assets to which this Agreement pertains, whether by merger, reorganization, consolidation, operation of law or otherwise, provided in all cases that it notifies the other promptly in writing if it does so.

24.2 Each party confirms that it is acting on its own behalf and not for the benefit of another person.

25. Freedom to contract

The parties declare that they each have the right, power and authority and have taken all action necessary to execute, deliver, exercise their rights and perform their obligations under this Agreement.

26. Notices and service

26.1 Any notice or other information required or authorised by this Agreement to be given by either party to the other may be given by hand or sent (by courier, first class recorded or registered post) to the other party at the address referred to in clause 22.6.

26.2 Any notice or other information given by post under clause 26.1 which is not returned to the sender as undelivered shall be deemed to have been given on the fifth (5th) Business Day after the envelope containing the same was so posted; and proof that the envelope containing any such notice or information was properly addressed, pre-paid, recorded or registered and posted, and that it has not been so returned to the sender, shall be sufficient evidence that such notice or information has been duly given.

26.3 Any notice or other information sent by email transmission to the address notified by the other party shall be deemed to have been duly sent on the date of transmission.

26.4 Any notice or other information delivered by hand or sent by courier shall be deemed to have been duly sent on the date received by the addressee.

26.5 Service of any legal proceedings concerning or arising out of this Agreement shall be effected by causing the same to be delivered to the party to be served at its principal place of business or its registered office, or to such other address as may from time to time be notified in writing by the party concerned.

26.6 Notices or other information to a party to this agreement shall be sent to the following address:

Aesica: UK General Manager
Aesica Queenborough Limited
North Road
Queenborough
Kent ME11 5EL

With a copy to: Company Secretary
Consort Medical plc
Breakspear Park
Breakspear Way
Hemel Hempstead
Hertfordshire HP2 4TZ

Customer: Opiant Pharmaceuticals, Inc.
201 Santa Monica Blvd., Suite 500
Santa Monica, CA 90401
USA
Attention: Chief Executive Officer

27. General

27.1 The Contracts (Rights of Third Parties) Act 1999. A person who is not a party to this Agreement has no right to enforce any term of this Agreement, whether under the Contracts (Rights of Third Parties) Act 1999 or otherwise.

27.2 No Partnership. This Agreement is not intended to and does not operate to create a partnership between the parties, or (other than to the extent expressly set out herein) to authorise either party to act as agent for the other, and neither party shall have authority (other than to the extent expressly set out herein) to act in the name or on behalf of or otherwise to bind the other party.

27.3 Further assurance. Without prejudice to any restriction or limitation on the extent of either party's obligations under this agreement, at any time after the Effective Date of this Agreement each party shall use reasonable endeavours to, and shall use all reasonable endeavours to procure that any necessary third party shall, at the sole cost and expense of that party, execute and deliver all such deeds and documents in a form reasonably satisfactory to the other party and do such matters, acts and things as may reasonably be required for the purpose of giving the other party the full benefit of all the terms, conditions and provisions of this Agreement.

27.4 Waiver and Remedies.

(a) A waiver of any term, provision or condition of, and any consent or approval granted under, this Agreement will be valid only if it is in writing, signed by the party giving the waiver or granting the consent or approval. Any such waiver, consent or approval will be valid only in the particular instance and for the particular purpose for which it is given and will not constitute a waiver of any other right or remedy.

(b) Any failure (in whole or in part) to exercise or delay in exercising any right, power or remedy ("**Right**") available under this Agreement or in law will not constitute a waiver of that or any other Right nor will any single or partial exercise of any Right preclude any other or further exercise of that or any other Right. The rights and remedies provided by this Agreement are cumulative and (unless otherwise expressly stated in this Agreement) and may be exercised without excluding any other rights or remedies available in law.

27.5 Invalidity. If any provision of this Agreement is or becomes invalid or unenforceable, in whole or in part, in any jurisdiction, the validity and enforceability of the other provisions of this Agreement and its validity and enforceability in any other jurisdiction shall not be affected.

27.6 Counterparts. This Agreement may be executed in any number of counterparts, each of which, when executed and delivered, is an original, but all the counterparts taken together shall constitute one document. This Agreement shall not take effect until it has been executed by both the parties. Counterparts of this Agreement also may be exchanged via electronic PDF copy, and an electronic PDF copy of any party's signature will be deemed to be an original signature for all purposes.

27.7 Announcements. Except as otherwise required by applicable law, neither party will make any public announcement or press release regarding the existence or terms of this Agreement without the prior written consent of the other party and mutual agreement as to the content of any such public announcement or press release. Notwithstanding the foregoing, each party may disclose the existence and terms of this Agreement to its professional advisors and actual or potential investors, acquirers, collaborators, licensees or other business partners on a reasonable need-to-know basis under reasonable conditions of confidentiality.

27.8 English Language. This Agreement shall be written and executed in the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

27.9 Interpretation. Headings included in this Agreement are for convenience only, do not form a part of this Agreement and will not affect the meaning or interpretation of this Agreement. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) the singular shall include the plural and vice versa; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable. In the event of any conflict between the terms of this Agreement and any exhibits attached hereto, the provisions of the main body of this Agreement shall prevail unless such exhibit expressly states an intent to supersede the provisions of the main body of this Agreement on a specific matter.

28. Governing law and jurisdiction

28.1 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of the State of Delaware.

28.2 Subject to Section 9.3 and 28.3, the parties irrevocably agree that the courts of the State of Delaware shall have exclusive jurisdiction to settle any dispute or claim that

arises out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims).

28.3 Dispute resolution:

Referral to Senior Management. Except with respect to any dispute described in Section 9.3 above which shall be resolved in accordance with the procedures described therein, if Customer and Aesica are unable to resolve any dispute between them, either party may, by written notice to the other, have such dispute referred to the Chief Executive Officer/Managing Director of such party, or authorized representative designated by the Chief Executive Officer/Managing Director, of each party for attempted resolution within thirty (30) days after the date of such notice.

This Agreement has been entered into on the Effective Date.

Signed for and on behalf of **AESICA QUEENBOROUGH LIMITED** by:	)	Signed for and on behalf of **OPIANT PHARMACEUTICALS INC** by:
……/s/ Manja Boerman…… (signature) …Manja Boerman…… (print name) Managing Director…… (position)	)	……/s/ Roger Crystal…… (signature) ……Roger Crystal…… (print name) ……Chief Executive Officer…… (position)

SCHEDULE 1 – WORK PLAN

BACKGROUND AND PURPOSE

The purpose of the Agreement is to design and develop the Product.

The Work Plan is split into six Phases as set out below.

PROJECT PHASES

1. Phase 1: Device Manufacturing

Key Activities

During Phase 1 the key activity to be performed by Aesica and/or its Affiliates will be an Initial Device Characterisation Study.

Deliverables

The Deliverables of Phase 1 will be:

1.1 assessing the suitability of the current Unidose Xtra Device (including its drug delivery mechanism and ergonomic characteristics) for the intended application;

1.2 managing suppliers to enable security of supply of bought in components;

1.3 producing components of the Unidose Xtra Device for use in Phase 2;

1.4 providing relevant documentation to support Opiant; and

1.5 developing packaging and labelling.

2. Phase 2: Formulation

Activities

During this Phase 2 the following activities will be undertaken by Aesica and/or its Affiliates:

2.1 formulation, preparation and research;

2.2 pre-formulation; and

2.3 formulation development**.**

Deliverables

The Deliverables of Phase 2 will be:

2.4 confirming the viability of the API supplier and EHS considerations;

2.5 studying drug compatibility with the chosen excipients and device components;

2.6 further optimising the current formulation; identifying Product attributes;

2.7 process optimisation; identifying critical process parameters;

2.8 applying QBD principles to justify the excipient levels and process parameters;

3. Phase 3: Analytical Method

Deliverables

The Deliverables of Phase 3 will be:

3.1 API and Product test method development and validation;

3.2 microbial method development and validation;

3.3 measuring drug plume characteristics, ensuring robustness and reproducibility;

3.4 extractable and leachable testing in accordance with FDA requirements; and

3.5 physical testing.

4. Phase 4: Clinical batch manufacture

The Deliverables of Phase 4 will be the Clinical Samples.

5. Phase 5: Development costs for scale-up, validation and Registration Batches

Deliverables

The deliverables of Phase 5 will be:

5.1 technical support for the manufacture of two scale-up batches at commercial scale; and

5.2 technical support for the manufacture and testing of 3 Registration Batches including stability testing

6. Phase 6: Registration batch manufacture

Deliverables

The deliverables of Phase 6 will be the Registration Batches.

PROGRAMME PLAN

The following indicative plan outlines key activities of the Work Plan. For the sake of completeness, the packaging referred to below has been included as part of Phase 1 above:

[***]

SCHEDULE 2 – PRICE AND PAYMENT

1. BREAKDOWN OF CHARGES:

Phase 1	[***]
Phase 2	[***]
Phase 3	[***]
Phase 4	[***]
Phase 5	[***]
Phase 6	[***]
Total	[***] plus any amounts payable for the Clinical Samples and Registration Batches as set out below.

The Charges shall be payable in [***] equal instalments, monthly in arrears. One month after the Effective Date, Aesica shall be entitled to raise the first invoice for [***], plus applicable taxes. One month thereafter Aesica shall be entitled to raise the next invoice and so on until all [***] invoices have been raised. The Customer shall pay such invoices in accordance with clause 11.

2. PRICING ASSUMPTIONS

The Charges have been calculated on the basis of the current Unidose Xtra Device configuration (form factor, colour, ergonomic and drug delivery characteristics). In the event that it is not suitable for the intended application in its current form, modifications to the configuration may be agreed but any such modifications will require reassessment of program timelines, investments and pricing impact.

The Charges do not include an exclusive licence to Bespak IPR. The Customer only has a licence to such Bespak IPR on the terms and conditions as set out in this Agreement.

The Charges have been calculated assuming that the Clinical Samples shall comprise a non-sterile fill of [***] batches of circa [***] units each.

The Charges do not include any 'Human Factors' activities. If requested by the Customer, Aesica shall quote for these and, if agreed in writing, such activities shall be provided by Aesica on the terms and conditions set out in this Agreement and invoiced by Aesica as agreed between the parties during the quoting process.

The Charges assume [***] (as defined in Incoterms 2010). [***]

3. MATERIALS AND EXPENSES

Aesica shall invoice Customer monthly on or after the last Business Day of each calendar month for all materials and expenses incurred in connection with the Services.

4. PRICE OF THE CLINICAL SAMPLES

The price for up to [***] Clinical Samples for use in clinical trials shall be [***] per Product/Clinical Sample. This price is subject to paragraph 2 of this Schedule 2. Aesica shall be entitled to invoice for each Clinical Sample following its delivery in accordance with the terms of this Agreement.

5. PRICE OF THE REGISTRATION BATCHES

The price for up to [***] Registration Batches for use in FDA NDA submission shall be [***] per Product/Registration Batch. This price is subject to paragraph 2 of this Schedule 2. Aesica shall be entitled to invoice for each Registration Batch in accordance with the terms of this Agreement.

SCHEDULE 3

Change Order Request Form

Change Order Number [ ]

1. **Date of this Change Order:**
2. **Date on which this Change Order is to take effect:**
3. **Reason for changes:**
4. **Details of the changes to be made to the Work Plan:**
5. **Details of any price changes:**
6. **Details of any Timetable changes:**

This Change Order is AGREED by the parties through their duly authorised representatives on the date written at the top of the first page of this Change Order:-

For and on behalf of: **OPIANT PHARMACEUTICALS, INC.**		For and on behalf of:- **AESICA QUEENBOROUGH LIMITED**	
Signed:	.....	Signed:	.....
Full Name:	.....	Full Name:	.....
Job Title	.....	Job Title:	.....

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED [***], IS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION

SCHEDULE 4

Customer Materials

Intravail

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED [***], IS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION

APPENDIX A

Benchmark Commercial Supply Pricing

Unit Price (£)		
For total annual quantities of up to 0.8M units	For total annual quantities of greater than 0.8M units and up to 1.1M units	For total annual quantities of greater than 1.1M units and up to and greater than1.5M units
[***]	[***]	[***]

Pricing assumes the current Unidose Xtra device configuration (form factor, colour, ergonomic and drug delivery characteristics) are suitable for the intended application. Any modifications will require assessment of pricing impact.

Pricing assumes EXW Aesica Queenborough UK (as defined in Incoterms 2010). For Product delivered DDP delivery charges shall be invoiced separately.

Exhibit 10.85

CONFIDENTIALTREATMENT REQUESTED

CONFIDENTIAL PORTIONS OF THIS DOCUMENT HAVE BEEN REDACTED AND HAVE BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION

EXECUTION COPY

AGREEMENT FOR REIMBURSEMENT OF CAPITAL EXPENDITURE AND SERVICE FEES

BETWEEN

AESICA QUEENBOROUGH LIMITED

And

OPIANT PHARMACEUTICALS INC

relating to the development, manufacture and supply of a device capable of administering Nalmefene hydrochloride

Exhibit 10.85

Contents

CLAUSE

THIS AGREEMENT FOR REIMBURSEMENT OF CAPITAL EXPENDITURE AND SERVICE FEES IS MADE SEPTEMBER 7, 2018

BETWEEN

(1) **OPIANT PHARMACEUTICALS, INC.**, with offices at 201 Santa Monica Blvd., Suite 500, Santa Monica, California, 90401, USA ("**Opiant**"), and

(2) **AESICA QUEENBOROUGH LIMITED,** a company incorporated and registered in England and Wales with company number 06350087 whose registered office is at Suite B Breakspear Park, Breakspear Way, Hemel Hempstead, Hertfordshire, England, HP2 4TZ ("**Aesica** ").

BACKGROUND

(A) Opiant and Aesica are parties to that certain Development Agreement dated on or about the date hereof (the "**Development Agreement**") for the development manufacture and supply of a device capable of administering Nalmefene hydrochloride ("**Nalmefene Finished Product**")

(B) In order to meet Opiant's timelines for the commercial manufacture and commercial launch of the Nalmefene Finished Product, it may be necessary for Aesica and/or its Affiliate to incur certain capital expenditure and associated service fees before the parties negotiate a definitive agreement for the commercial supply of Nalmefene Finished Product (a "**Supply Agreement**").

(C) The capital expenditure to be incurred by Aesica and/or its Affiliate comprises the Tooling Fees, the Equipment Fees and the Facility Alteration Fees (each as defined below). In addition, Aesica will incur the Service Fees (as defined below). Such total expenditure amounts to [***] unless the parties agree to revise the table at Schedule 1 in accordance with clause 7 below.

(D) In consideration for Aesica and/or its Affiliate incurring the Tooling Fees, Equipment Fees, Facility Alteration Fees and Service Fees, Opiant agrees to, upon the occurrence of certain events, reimburse Aesica for a portion of those costs as set forth in this agreement ("**Reimbursement Agreement**").

(E) All capitalized terms used but not defined herein shall have the meaning given to them in the Development Agreement.

AGREED TERMS

1. DEFINITIONS AND INTERPRETATION

1.1 In this Reimbursement Agreement, where the context so admits, the following words and expressions shall have the following meanings:

"**Aesica Fault Termination**" means those circumstances where Opiant terminates the Development Agreement pursuant to any of clauses 18.2(a) – 18.2(g) of the Development Agreement (inclusive);

"**Cumulative Amount**" means the total amount of the Tooling Fees, Equipment Fees, Facility Alteration Fees and/or Service Fees (as appropriate) incurred by Aesica as at the relevant Quarter, such Cumulative Amounts being set out in the second, seventh, ninth and eleventh rows of the table attached at Schedule 1 (as such table may be updated from time to time by the Parties in accordance with clause 7), less any such Tooling Fees, Equipment Fees, Facility Alteration Fees and/or Service Fees that can be unconditionally cancelled by or refunded to Aesica as of the Trigger Date;

"**Development Agreement**" has the meaning given to it in Recital (A);

"**Effective Date**" means the date of this Agreement;

"**Equipment**" means the metrology and spray analysis equipment, mold presses and equipment, filling and stoppering equipment and device assembly equipment required to be purchased by Aesica for the purposes of supporting the commercial manufacture of the Nalmefene Finished Product;

"**Equipment Fees**" means the amounts to be paid by Aesica on Equipment per Quarter as set out in the third, fourth, fifth and sixth rows of the table set out at Schedule 1 (as such table may be updated from time to time by the Parties in accordance with clause 7);

"**Facility Alterations**" means the alterations to Aesica's and/or its Affiliates' facilities required to be undertaken by Aesica for the purposes of supporting the commercial manufacture of the Nalmefene Finished Product;

"**Facility Alteration Fees**" means the amounts to be paid by Aesica on the Facility Alternations per Quarter as set out in the eighth row of the table set out at Schedule 1 (as such table may be updated from time to time by the Parties in accordance with clause 7);

"**Failure to Agree Commercial Supply**" means circumstances where the Parties have not entered into a Supply Agreement despite having fulfilled all obligations set forth in Clause 9 of the Development Agreement;

"**Force Majeure Termination**" means those circumstances where either party has terminated the Development Agreement pursuant to clause 18.2(h) of the Development Agreement;

"**Nalmefene Finished Product**" has the meaning given to it in Recital (A);

"**Opiant Fault Termination**" means those circumstances where Aesica terminates the Development Agreement pursuant to any of clauses 18.2(a) – 18.2(g) of the Development Agreement (inclusive);

"**Opiant No Fault Termination**" means those circumstances where Opiant terminates the Development Agreement pursuant to clause 18.1 of the Development Agreement;

"**Quarter**" means each three (3) month period starting on 1 January, 1 April, 1 July and 1 October in each calendar year;

"**Service Fees**" means the amount of its labour costs per Quarter that Aesica has allocated to the project, as set out in the tenth row of the table set out at Schedule 1 (as such table may be updated from time to time by the Parties in accordance with clause 7);

"**Supply Agreement**" has the meaning given to it in Recital (B);

"**Tooling**" means the tooling required to be purchased by Aesica for the purposes of supporting the commercial manufacture of the Nalmefene Finished Product;

"**Tooling Fees**" means the amounts to be paid by Aesica on Tooling as set out in the first row of the table set out at Schedule 1 (as such table may be updated from time to time by the Parties in accordance with clause 7);

"**Trigger Date**" means the following:

(a) Where there is a Failure to Agree Commercial Supply, the date of completion of the process set out in Clause 9 of the Development Agreement;

(b) Where there is an Opiant Fault Termination, an Opiant No Fault Termination or a Force Majeure Termination, the date that such termination takes effect in accordance with the terms of the Development Agreement.

1.2 A person includes a natural person, corporate or unincorporated body (whether or not having separate legal personality).

1.3 Unless the context otherwise requires, words in the singular shall include the plural and in the plural include the singular.

1.4 Unless the context otherwise requires, a reference to one gender shall include a reference to the other genders.

2. AESICA EXPENDITURE

2.1 It is hereby acknowledged that in order to support commercialisation of the Nalmefene Finished Product, prior to negotiating a Supply Agreement with Opiant, Aesica agrees to:

(a)purchase the Tooling and Equipment,

(a)incur the Service Fees, and

(b)make the Facility Alterations.

3. PROMISE TO REIMBURSE

3.1 In consideration for Aesica purchasing the Tooling and Equipment, incurring the Service Fees and carrying out the Facility Alterations, Opiant agrees to reimburse the following amounts to Aesica:

(a)In the event that there is a Failure to Agree Commercial Supply or a Force Majeure Termination either:

(i) the total sum of the Cumulative Amounts of the Tooling Fees, Equipment Fees, Facility Alteration Fees and Services Fees allocated to the Quarter in which the Trigger Date occurs; or

(ii)[***],

(whichever is lower).

(b)In the event that there is an Opiant Fault Termination or an Opiant No Fault Termination:

(i)the total sum of the Cumulative Amounts of the Tooling Fees, Equipment Fees, Facility Alteration Fees and Service Fees allocated to the Quarter in which the Trigger Date occurs,

(the amounts requiring to be paid under clauses 3.1(a) and 3.1(b) above each being referred to as the "**Reimbursement**").

3.2 For the avoidance of doubt, Opiant shall not be expected or required to reimburse any amounts in the event of an Aesica Fault Termination.

4. PAYMENT

4.1 Aesica shall be entitled to issue an invoice for that part of the Reimbursement that relates to Tooling Fees, Facility Alteration Fees and Service Fees from the Trigger Date, and Opiant shall pay that part

of the Reimbursement that relates to Tooling Fees, Facility Alteration Fees and Service Fees within 30 calendar days of the date of such invoice.

4.2 In respect of that part of the Reimbursement that relates to Equipment Fees then, for the one-hundred and eighty (180) calendar day period following the Trigger Date, Aesica shall use Diligent Efforts (as defined in the Development Agreement) to sell the Equipment purchased with such Equipment Fees to a third party. In the event that Aesica is able to sell any of the Equipment during such one-hundred and eighty (180) calendar day period then that portion of the Reimbursement that relates to Equipment Fees shall be reduced by the amount of proceeds generated from such sale. Following the expiry of the one-hundred and eighty (180) day period, Aesica shall issue an invoice to Opiant for the relevant Equipment Fees adjusted in accordance with this clause 4.2 and, if applicable, clause 3.1(a).

4.1 Aesica shall include with its invoice reasonable information and documentation (in sufficient detail, including without limitation any invoices, receipts, purchase orders or similar documentation relating to any portion of the Cumulative Amount) supporting the demand for reimbursement. Any payment due and owing by Opiant hereunder shall be paid by way of bank transfer to the bank account set out below (or such other bank account as Aesica may nominate in writing from time to time):

Bank: Natwest Plc
Sort code: 536138
BIC (Swift): NWBKGB2L
IBAN: GB45 NWBK 5361 3830 3342 76

5. DEFAULT INTEREST

Interest shall accrue on a daily basis on the undisputed amounts payable by Opiant to Aesica hereunder from the date such amounts becomes due and payable in accordance with clause 4 until the date of actual payment at the rate of three percent (3%) per annum above or the maximum rate allowed by law, if less.

6. REPAYMENT OF REIMBURSEMENT

6.1 Notwithstanding anything to the contrary set forth in this Reimbursement Agreement, if the Trigger Date arises solely from a Failure to Agree Commercial Supply and thereafter the parties enter into a Supply Agreement or the Nalmefene Finished Product is supplied as contemplated in Article 9 of the Development Agreement in the absence of a Supply Agreement, then Aesica shall, upon demand by and at the option of Opiant, with respect to any amounts paid by Opiant pursuant to clause 4, within 30 calendar days of the demand either repay such amounts to Opiant or credit such amounts against amounts Opiant owes to Aesica for the supply of Nalmefene Finished Product.

6.2 If a Trigger Date occurs and Opiant makes payment of the Reimbursement pursuant to clause 4, and Aesica thereafter enters into a written agreement with a third party related to the development of the Unidose Xtra Device (as defined in the Development Agreement) for a specific purpose pursuant to which Aesica is able to use all or any portion of the Tooling, Equipment, Facility Alterations and/or work product resulting from the Service Fees ("a **Third Party Agreement**"), then:

(a) If Aesica reaches the stage of first clinical supply under that Third Party Agreement ("the **Repayment Trigger Date**") on or before the date that is [***] after the Trigger Date, Aesica shall repay to Opiant [***] of that portion of the corresponding Tooling Fees, Equipment Fees, Facility Alterations and/or Service Fees previously reimbursed by Opiant pursuant to clause 4 that Aesica has been able to utilise under the relevant Third Party Agreement;

(b) If the Repayment Trigger Date occurs after the date that is [***] after the Trigger Date but on or before the date that is [***] after the Trigger Date, Aesica shall repay to Opiant [***] of that portion of the corresponding Tooling Fees, Equipment Fees, Facility Alterations and/or Service Fees previously reimbursed by Opiant pursuant to clause 4 that Aesica is able to utilise under the relevant Third Party Agreement; and

(c) If the Repayment Trigger Date occurs after the date that is [***] after the Trigger Date but on or before the date that is [***] after the Trigger Date, Aesica shall repay to Opiant [***] of that portion of the corresponding Tooling Fees, Equipment Fees, Facility Alterations and/or Service Fees previously reimbursed by Opiant pursuant to clause 4 that Aesica is able to utilise under the relevant Third Party Agreement.

Any such repayment shall be made by Aesica to Opiant within thirty (30) days after the occurrence of the Repayment Trigger Date, and Aesica shall provide with its payment reasonable information and documentation supporting the repayment amount (subject to any third party confidentiality obligations).

7. CHANGES TO SCHEDULE 1

Any changes to the estimated Tooling Fees, Equipment Fees, Facility Alteration Fees or Service Fees that either exceed £50,000 in respect of any one element or where the aggregate of the changes across all of the elements in any one Quarter exceeds £75,000 must be approved by Opiant in writing and in advance (such approval not to be unreasonably withheld or delayed).

8. ASSIGNMENT

Prior to the parties entering into a Supply Agreement, if any, this Reimbursement Agreement may only be assigned pursuant to (and in connection with) a permitted assignment of the Development Agreement and, after entering into the Supply Agreement, only pursuant to (and in connection with) an assignment of the Supply Agreement.

9. CONFIDENTIALITY

9.1 Article 21 (Confidentiality) of the Development Agreement is incorporated into and shall apply to the parties' disclosure of Confidential Information (as defined in the Development Agreement) under this Reimbursement Agreement.

10. MISCELLANEOUS

10.1 The waiver, express or implied, by any party of any right under this Reimbursement Agreement or any failure to perform or breach by another party shall not constitute or be deemed a waiver of any other right under this Reimbursement Agreement.

10.2 No amendment, change or addition hereto shall be effective or binding on any party unless reduced to writing and executed by all the parties for the time being.

10.3 Nothing in this Reimbursement Agreement shall constitute or be deemed to constitute a partnership between the parties or any of them, or a term of their employment.

10.4 Any notices given to a party under or in connection with this Reimbursement Agreement shall be in writing and shall be delivered by hand or by pre-paid first-class post or other next working day delivery service at its registered office and shall be deemed to have been received

(a) if delivered by hand, on signature of a delivery receipt

(b) if sent by pre-paid first-class post or other next working day delivery service, at 9.00 am on the second Business Day after posting;

10.5 If at any time any provision of this deed is or becomes invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions of this deed shall not be affected or impaired thereby.

10.6 Each party shall do, or procure the doing, of all reasonable acts and things, and execute, or procure the execution of, all documents, as may reasonably be required to give full effect to this Reimbursement Agreement.

10.7 A person who is not a party to this Reimbursement Agreement shall not have any rights under or in connection with it by virtue of the Contracts (Rights of Third Parties) Act 1999.

10.8 The right of the parties to terminate, rescind or agree any amendment, variation, waiver or settlement under this Reimbursement Agreement is not subject to the consent of any person that is not a party to this Reimbursement Agreement.

11. GOVERNING LAW AND JURISDICTION

This Reimbursement Agreement shall be governed by the laws of the State of Delaware, excluding conflict of law rules. With respect to any dispute arising out of or in connection with this agreement the parties agree to exclusive jurisdiction and venue of (i) a United States federal court of competent jurisdiction sitting in the state of Delaware; or (ii) if no such court has jurisdiction, then the Delaware Superior Court and, if related to equity, the Delaware Court of Chancery.

12. ENTIRE AGREEMENT

12.1 This Reimbursement Agreement, together with the Development Agreement, constitutes the entire agreement between the parties and supersedes and extinguishes all previous drafts, agreements, arrangements and understandings between them, whether written or oral, relating to the subject matter hereof.

This Agreement has been entered into on the Effective Date.

Signed for and on behalf of
AESICA QUEENBOROUGH LIMITED by:
…/s/ Manja Boerman……
(signature)
Manja Boerman……
(print name)
Managing Director……
(position)

) Signed for and on behalf of
) **OPIANT PHARMACEUTICALS INC** by:
)

……/s/ Roger Crystal……
(signature)
……Roger Crystal ……
(print name)

……Chief Executive Officer……
(position)

SCHEDULE 1

CAPITAL EXPENDITURE AND SERVICE FEES (£)

[***]

Exhibit 99.1

Opiant Pharmaceuticals, Inc. and Consort Medical plc Announce Manufacturing Agreement for OPNT003, Intranasal Nalmefene, for Treatment of Opioid Overdose

SANTA MONICA, CA, and HEMEL HEMPSTEAD, UK, September 10, 2018 – Opiant Pharmaceuticals, Inc. ("Opiant") (NASDAQ: OPNT), a specialty pharmaceutical company developing pharmacological treatments for addictions and drug overdose, and Consort Medical plc ("Consort") (LON: CSRT), a leading contract development and manufacturing organization, today announced a development and manufacturing agreement for Opiant's OPNT003 (intranasal nalmefene), a potent, long-acting opioid antagonist for the treatment of opioid overdose.

Under this agreement, Aesica and Bespak, wholly-owned subsidiaries of Consort, will work with Opiant to produce a pre-filled delivery nasal spray with nalmefene. As part of the agreement, Aesica will supply Opiant with clinical samples and registration batches for the purposes of performing clinical studies and obtaining regulatory approvals. Further, upon approval by the U.S. Food and Drug Administration (FDA), Aesica and Bespak will manufacture and supply the commercial device for Opiant.

"We are extremely pleased to be working with a group as highly-regarded as the Consort team," said Roger Crystal, M.D., Chief Executive Officer of Opiant. "OPNT003 has the potential to be a transformative treatment for opioid overdose, and Consort's significant expertise in inhalation technologies will help support our lead product candidate through commercialization."

"We are delighted to announce this agreement with Opiant, which highlights our expertise in the nasal delivery of drugs and the value of our unique offering of providing both drug manufacturing and delivery capabilities alongside one another," said Jonathan Glenn, Consort's Chief Executive Officer.

Following the completion of OPNT003 formulation studies, Opiant intends to initiate a confirmatory pharmacokinetic study in early 2019. Based on previously obtained feedback from the FDA, Opiant intends to pursue a 505(b)(2) development path for OPNT003. Opiant anticipates the potential to submit a New Drug Application for the drug and intranasal delivery device combination in 2020. Opiant retains full commercial rights to OPNT003, and this development work is largely funded by a $7.4 million National Institutes of Health (NIH) grant.

About Opiant Pharmaceuticals, Inc.
Opiant Pharmaceuticals, Inc. is a specialty pharmaceutical company developing pharmacological treatments for addictions and drug overdose. The National Institute on Drug Abuse, a component of the NIH, describes addictive disorders as chronic relapsing brain diseases which burden society at both the individual and community levels. With its innovative opioid antagonist nasal delivery technology, Opiant is positioned to become a leader in these treatment markets. Opiant's first drug overdose product, NARCAN® Nasal Spray, is approved for marketing in the U.S. and Canada by its commercialization partner, Adapt Pharmaceuticals. For more information please visit: www.opiant.com.

About Consort Medical plc
Consort Medical plc is a leading, global, single source pharma services drug and delivery device company. Consort is at the leading edge of innovation and is committed to investing in patient,

clinician and customer driven innovation to create new treatments, new markets and new opportunities. Consort's businesses:

Bespak is a global market leader in the manufacture of drug delivery devices for pharmaceutical partner companies, including respiratory, nasal, injectables and ocular products, and the manufacture of devices for the point of care diagnostics market: www.bespak.com.

Aesica is a leading provider of finished dose and active pharmaceutical ingredient (API) development and manufacturing services to pharmaceutical partners: www.aesica-pharma.com.

Consort employs approximately 2,000 people globally of which approximately 1,400 are located in the UK. Consort has UK facilities in King's Lynn, Cambridge, Nelson, Milton Keynes, Cramlington, Queenborough and Hemel Hempstead, German facilities in Monheim and Zwickau and a facility in Pianezza, Italy. Consort is a public company quoted on the premium list of the London Stock Exchange (LSE: CSRT): www.consortmedical.com.

Forward-Looking Statements

This press release contains forward-looking statements. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed, implied or inferred by these forward-looking statements, and among other things, our ability to maintain cash balances and successfully commercialize or partner our product candidates currently under development. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "would," "expects," "plans," "intends," "anticipates," "believes," "estimates," "predicts," "projects," "potential," or "continue" or the negative of such terms and other comparable terminology. These statements are only predictions based on our current expectations and projections about future events. You should not place undue reliance on these statements. Actual events or results may differ materially. In evaluating these statements, you should specifically consider various factors. Additional factors that could materially affect actual results can be found in our Form 10-KT for the transition period August 1 to December 31, 2017 and Form 10-Qs for the periods ended March 31, 2018 and June 30, 2018 filed with the Securities and Exchange Commission on March 7, 2018, May 8, 2018 and August 9, 2018, respectively, including under the caption titled "Risk Factors." These and other factors may cause our actual results to differ materially from any forward-looking statement. We undertake no obligation to update any of the forward-looking statements after the date of this press release to conform those statements to reflect the occurrence of unanticipated events, except as required by applicable law.

CONTACTS:

Dan Ferry
Managing Director
LifeSci Advisors, LLC
Daniel@lifesciadvisors.com
(617) 535-7746