

**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): July 22, 2020**

**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.)

**233 Wilshire Blvd. Suite 280  
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.

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

Title of each class	Trading symbol	Name of each exchange on which registered
Common stock, par value \$0.001 per share	OPNT	Nasdaq Stock Market LLC

**Item 1.01 Entry into a Material Definitive Agreement.**

On July 22, 2020, Opiant Pharmaceuticals, Inc. (the "Company") entered into a Project Scope Agreement ("PSA") pursuant to a Master Services Agreement ("MSA") with Summit Biosciences, Inc. ("Summit"), to support the development and manufacture of a nasal spray device for opioid overdose, with the ability to expand to additional programs in the future. In accordance with the PSA, Summit will develop and produce certain pre-filled nasal spray products using a device previously evaluated as part of other FDA-approved nasal spray products. Opiant will pay Summit estimated costs and fees up to approximately \$6.5 million.

Copies of the MSA and PSA are attached to this Current Report on Form 8-K and incorporated herein by reference. The descriptions of the MSA and PSA provided herein are qualified in their entirety by reference to the terms of the MSA and PSA as set forth in Exhibit 10.1.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit No. Description

10.1 [Master Services Agreement dated July 1, 2020 and Project Scope Agreement dated July 22, 2020 between the Company and Summit Biosciences, Inc.](#)

**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: July 28, 2020 By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

## MASTER SERVICES AGREEMENT

This Master Services Agreement (this “Agreement” or “MSA”) is made effective as of July 1, 2020 (the “Effective Date”) by and between **OPIANT PHARMACEUTICALS, INC.**, with principal executive offices at 233 Wilshire Blvd., Suite 280, Santa Monica, CA 90401 (“Client”) and **SUMMIT BIOSCIENCES INC.**, with principal executive offices at Coldstream Research Campus, 1513 Bull Lea Road, Lexington, Kentucky 40511 (“Service Provider” or “Summit”). Client and Service Provider are sometimes referred to individually herein as a “Party” and collectively as the “Parties.”

WHEREAS, the Client is engaged in the development of a nasal spray product for the treatment of opioid overdose;

WHEREAS, the Service Provider is engaged in nasal spray pharmaceutical product development and manufacturing and related matters; and

WHEREAS, the Client wishes to engage the Service Provider to provide such services, and the Service Provider wishes to provide such services to the Client.

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

### 1. DEFINITIONS

- (a) “Applicable Laws” means U.S. and/or foreign federal, state and local laws, rules, regulations, guidelines and industry standards, including, without limitation, the Act (as defined below) and applicable FDA and DEA regulations and guidelines, regulatory requirements, cGMPs, the Prescription Drug Marketing Act (“PDMA”), the Federal Anti-Kickback Statute, the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the Drug Supply Chain Security Act (“DSCSA”) and Drug Enforcement Administration (“DEA”) regulations, as may be applicable to a particular product, Service Provider’s or Client’s facilities, the applicable Project or the Services, as the case may be.
- (b) “Act” or “FDCA” means the United States Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder or any applicable governmental regulations.
- (c) “Affiliate” means any corporation or non-corporate entity that controls, is controlled by, or is under common control with the applicable Party. A corporation or non-corporate entity shall be regarded as in control of another corporation if it owns or directly or indirectly controls at least fifty percent (50%) of the voting shares of the other corporation or (a) in the absence of the ownership of at least fifty percent (50%) of the voting shares of a corporation or (b) in the case of a non-corporate entity, has the power to direct or cause the direction of the management and policies of such corporation or non-corporate entity, as applicable.
- (d) “API” means the active pharmaceutical ingredient for the Product.
- (e) “Certificate of Analysis” means, for each batch of Product produced, a document prepared by Service Provider setting forth the measured and observable characteristics of Product from the batch, and confirming that such batch meets the Specifications.

Each Certificate of Analysis shall include: (a) a listing of tests performed by or on behalf of Service Provider, test date(s), and test results, and a certification of the accuracy of each of the foregoing; and (b) a reference to or inclusion of the related Certificate of Compliance. The Parties shall from time to time agree upon a format or formats for the Certificate of Analysis to be used under this Agreement.

- (f) “Certificate of Compliance” means, for each batch of Product produced, a document prepared by Service Provider: (a) listing the manufacturing date, unique batch number, and quantity of Product in such batch, and (b) certifying that such batch was manufactured in accordance with cGMPs and all Applicable Laws. The Parties shall from time to time agree upon a format or formats for the Certificate of Compliance to be used under this Agreement.
- (g) “Client Intellectual Property” means all Intellectual Property and embodiments thereof owned by or licensed to Client as of the Effective Date or developed by or on behalf of Client other than in connection with this Agreement.
- (h) “Commercialization” means, with respect to a Product, activities directed to obtaining pricing and reimbursement approvals, carrying out post-marketing studies, and marketing, promoting, distributing, importing, exporting, offering for sale or selling a Product.
- (i) “Confidential Information” means all information disclosed by the Disclosing Party (or on such Party’s behalf) to the Receiving Party, whether directly or indirectly, in writing, orally, electronically or by drawings or inspection of equipment, products, facilities, software or other property of the Disclosing Party, including, but not limited to, any information, regardless of form, proprietary to or maintained in confidence by the Disclosing Party, including, without limitation, any information, technical data or know-how, formulae, manufacturing, discoveries, ideas, inventions, software, equipment, designs, drawings, specifications, techniques, processes, research, development, business plans or opportunities, business strategies, marketing plans, future projects or products, sales data, procedures, and information relating to prices, finances, costs, suppliers, service providers, customers and employees. For clarity, the Service Provider Intellectual Property and Process Inventions are deemed to be the Confidential Information of Service Provider, and the Client Intellectual Property and Product Inventions are deemed to be the Confidential Information of Client.
- (j) “Force Majeure” means all incidences beyond the reasonable control of either Party and which have a material adverse effect on the ability of such Party to perform under this Agreement, including, but not limited to: failure of power or other utility or sanitary supplies; fire; flood; earthquake; explosion; pandemics; riot; civil insurrection or unrest; terrorist activity; war and the regulations of any governmental, national or trans-national authority.
- (k) “cGMPs” means the then-current good manufacturing practices required by the FDA, as defined in 21 C.F.R. Parts 210 and 211 and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable laws or regulations applicable to the manufacture and testing of pharmaceutical materials in jurisdictions outside the U.S., as they may be updated from time to time. cGMPs shall include applicable quality guidelines promulgated under the International Conference on Harmonization.

- (l) “Governmental Entity” means any arbitrator, court, judicial, legislative, administrative or regulatory agency, commission, department, board or bureau or body or other governmental authority or instrumentality or any person or entity exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government, whether foreign, federal, state, provincial, local or other (including without limitation any domestic or foreign governmental regulatory authority involved in the regulation of or granting of approvals for the manufacture, storage, sale, distribution, reimbursement and/or pricing of a pharmaceutical product such as the United States Food and Drug Administration (“FDA”)).
- (m) “Intellectual Property” means all intellectual property, whether or not patented, including without limitation, data, ideas, information, technology, tangible materials, methods, processes, know-how, trade secrets, designs, concepts, technical information, manuals, standard operating procedures, instructions, formulations, specifications, developments, inventions and improvements.
- (n) “Invention” means any Intellectual Property developed by Service Provider solely or jointly in connection with a PSA.
- (a) “Label”, “Labeled” or “Labeling” means all labels and other written, printed or graphic matter upon (i) the Product or any container or wrapper utilized with the Product or (ii) any written material accompanying the Product, including without limitation, package inserts.
- (b) “Latent Defect” means a defect in Manufacture that is not discoverable upon a reasonable inspection of the Product including, but not limited to, loss of stability, separation or discoloration.
- (c) “Losses” shall mean all claims, losses, judgments, obligations, liens, fines, penalties, amounts paid in settlement, liabilities, damages, costs and expenses, including reasonable legal fees, and other costs of defense.
- (d) “Manufacture” and “Manufacturing” and other forms of such words, when used in connection with the Product, shall refer to the manufacturing, processing, handling, packaging, labeling, storage, disposal and quality control testing (including in-process, release and stability testing) of the Product and the API, raw materials and components used in connection therewith.
- (e) “Manufacturing Facility” or “Facility” shall mean Service Provider’s facilities.
- (f) “Manufacturing Specifications” shall mean the written specifications for the Product, including but not limited to its testing and production, as agreed with the Client.
- (g) “Packaging” means all primary containers and secondary packaging, including cartons, shipping cases and other like matter used in packaging or accompanying the Product.
- (h) “Packaging Specifications” shall mean all of the written requirements for the Labeling and Packaging of the Product, as agreed with the Client.
- (i) “Product” has the meaning ascribed to it in the applicable PSA.

- (j) “Product Invention” means any Invention resulting from the Services that relies on Client’s Confidential Information or is specific to the Product.
- (k) “Process Invention” means any Invention other than Product Inventions, including, without limitation, (i) analytical methods, processes, information and technology relating to developing, formulating, manufacturing, filling, processing, packaging, analyzing or testing pharmaceutical products; (ii) generally the Services design processes, procedures and techniques, computer technical expertise and software programs; and (iii) any Invention that relies on Summit’s Confidential Information.
- (l) “Regulatory Approval” means, in relation to the Product, the registrations, authorizations and approvals of any Governmental Entity that are required to be obtained prior to the marketing, distribution or sale of the Product, to the extent applicable.
- (m) “Regulatory Requirements” means (a) applicable cGMP, in effect at the particular time, issued or required by the FDA and other Governmental Entity for the methods to be used in, and the facilities and controls to be used for, the manufacture of drugs or pharmaceutical products, and (b) any laws, rules, guidelines, regulations and standards of Governmental Entities that apply to any manufacturing, shipment or activities or facilities at which any of the manufacturing activities hereunder are performed.
- (n) “Quality Agreement” means a written agreement between the Parties which describes certain quality and regulatory responsibilities relating to the manufacture and release for sale of the Product by Service Provider to Client.
- (o) “SOPs” means the standard operating procedures or policies of the Service Provider in effect during the Term of this Agreement, unless otherwise mutually agreed and described in writing.
- (p) “Specifications” means, with respect to a Product, the Manufacturing Specifications and the Packaging Specifications.
- (q) “Service Provider Intellectual Property” means all Intellectual Property and embodiments thereof owned by or licensed to Summit as of the Effective Date or developed by or on behalf of Summit other than in connection with this Agreement.
- (r) “Third Party Claim” shall mean any suit, proceeding, claim or demand asserted by a third Party against an Indemnitee, as defined herein.
- (s) “Unit” shall mean a single completed and packaged tube, bottle, spray unit or other container of the Product ready for distribution and fully compliant with all Specifications and Applicable Laws.

## 2. SERVICES

- (a) Project. The Service Provider shall provide services from time to time to the Client as may be requested by the Client and agreed to by the Service Provider (the “Services”). The scope and nature of such Services shall be described in individual project scope agreements or statements of work (each, a “Project Scope Agreement” or “PSA”). When signed by both Parties, these PSAs form an integral part of the MSA and are incorporated herein by reference. Each particular Project Scope Agreement shall: (i) state that such PSA is subject to the terms and conditions of this Master Services Agreement and is

incorporated by reference herein; (ii) describe the details of the Services for each specific project to be performed by the Service Provider, including such matters as scope of work, compensation, billing schedule and payment terms; and (iii) be signed by authorized representatives of each Party hereto (with each PSA being referred to hereinafter as a "Project").

- (b) Performance. Service Provider shall use commercially reasonable efforts, care and attention to perform the Services for the Client. The Service Provider will perform the Services in a timely and professional manner.
- (c) Service Provider's Compliance with Laws, Standards. Service Provider represents and warrants the following:
- (i) Service Provider shall perform the Services (and the receipt, processing, handling and storage of all materials required to perform the Services) in accordance with (A) a detailed project proposal approved in writing by the Client and included in the applicable PSA; (B) cGMPs, unless otherwise explicitly agreed in the applicable PSA), and all Applicable Laws; (C) SOPs; and (D) the reasonable instructions of the Client to the extent consistent with the PSA.
- (ii) If the Services include manufacturing, the Product upon release to the Client (A) will meet the Specifications, (B) will have been manufactured, stored and shipped in accordance with Applicable Laws, Labeling and Specifications, (C) will not be defective in materials or workmanship, and at the time of release to Client, shall be in good, usable and merchantable condition for the uses set forth in the Labeling and (D) will not be adulterated or misbranded within the meaning of the Act (clauses (A) through (D), collectively, the "Warranty"). Manufacturing facilities used by the Service Provider in manufacturing the Product shall have been inspected by FDA and shall conform, and shall continue to conform throughout the Term (as hereinafter defined), in all material respects to Applicable Laws governing such facilities. The Service Provider shall have good title to the Product and deliverables supplied by Service Provider hereunder and shall pass such title to the Client, free and clear of all security interests, liens, or other encumbrances of any kind or character.
- (d) Client's Compliance with Laws, Standards. Client represents and warrants that Client conduct its activities, including, without limitation, use, storage, handling, shipment and Commercialization of the Product, in accordance, in all material respects, with Applicable Laws.
- (e) Materials and Resources. Except for Client-supplied materials and as otherwise set forth in the applicable PSA, the Service Provider is responsible for obtaining all active ingredients, excipients, supplies and raw materials, labor, development and production support, including all personnel and labor, necessary to progress and complete the tasks in the applicable PSA.
- (f) Client-Supplied Materials. The Client shall retain title to all Client-supplied materials (including API and delivery devices, as the case may be) at all times while in the Service Provider's possession or under the Service Provider's control, and the Service Provider shall only use or permit the use of the Client-supplied materials to perform the Services for the Client and shall not transfer the Client-supplied materials to any third party. The Service Provider shall test samples of the Client-supplied materials that it receives in

accordance with Service Providers standard operating procedures. The Client shall be responsible for ensuring that the Client-supplied materials meet the applicable specifications, comply with Applicable Laws and are appropriate for use with respect to the Product and Services; Service Provider makes no representations or warranties with respect to Client-supplied materials. In the event that the Service Provider obtains the Client-supplied materials at the Client's written request, the Client shall reimburse the Service Provider for the actual out-of-pocket expenses incurred by the Service Provider for such items in such amount as agreed to by the Client in advance and in writing (except as otherwise explicitly agreed in the applicable PSA).

(g) Revisions to Project. Should changes to a particular PSA become necessary or desirable, such changes will only be made following discussion and written agreement between the Client and the Service Provider; provided, however, that the Service Provider shall use reasonable efforts to accommodate the Client's requests for changes. The Service Provider will submit a written proposal to the Client in the event a revision of a Project will result in a revision in the price of the Project. The Service Provider has no obligation to perform and the Client has no obligation to pay for any additional or modified Services absent written agreement by the Parties with respect thereto.

(h) Product Acceptance, Rejection and Recall.

(i) Service Provider shall not be responsible for quality damages occurring due to improper storage of Products after the Products are released to the Client or Client's designee, except to the extent caused by Service Provider's negligence, willful misconduct or breach of this Agreement.

(ii) If a shipment of Product or any portion thereof fails to conform to the Specifications or the Warranty provided by Service Provider herein upon shipment to Client, then Client shall have the right to reject such nonconforming shipment of Product or the non-conforming portion thereof, as the case may be. Client shall give written notice to Service Provider of its rejection hereunder, specifying the grounds for such rejection, within fifteen (15) business days of Client's (or its designee's) receipt thereof; provided, however, that in the event such defect is a Latent Defect or was not obvious and could not be readily discovered from a physical inspection of the Product shipment, Client may give written notice to Service Provider of its rejection of such shipment within five (5) business days after Client's discovery of such non-conformance, specifying the grounds for such rejection. The non-conforming shipment of the Product, or the non-conforming portion thereof, shall be returned to Service Provider or disposed of by Client at Service Provider's election, in each case at Service Provider's expense, after resolution of any dispute regarding such rejection in accordance with this Agreement. At Client's option, Service Provider shall manufacture, supply and deliver replacement Product as soon as possible at Service Provider's expense (including as to the cost of shipping, insurance and Client-supplied materials) or Service Provider shall promptly provide a refund or credit to Client for the full amount paid by Client for such Product, including the costs of shipping, insurance and Client-supplied materials.

(iii) If Service Provider and Client do not agree on whether the Product conformed to the Specifications or the Warranty provided by Service Provider herein within thirty (30) days after Client's written notice of rejection, the matter will be submitted to an independent testing laboratory acceptable to both Parties for its review and

determination. The Parties will agree on the analytical methods and procedures for testing, and an inter-laboratory methods transfer process will be implemented at the laboratory to ensure acceptable test methods are applied. The determination of such independent laboratory will be binding on both Parties. The costs of the independent laboratory shall be borne by the Party against which the determination of the laboratory is made (i.e., if the laboratory decides the Product failed to meet Specifications upon shipment by Service Provider, then Service Provider shall be responsible for such costs; otherwise Client shall be). If the Product is determined not to conform to the Specifications or the Warranty provided by Service Provider herein when shipped by Service Provider (whether by agreement of the Parties or by the independent laboratory), then Service Provider shall have the obligations with respect to the non-conforming Product set forth in this Section 2(h) and, if requested by Client, shall manufacture, supply and deliver replacement Product as soon as possible. If the Product is determined to conform to the Specifications, then Client shall accept and pay for the Product in accordance with the terms hereof.

- (i) Shipping. The Product will be shipped to Client or its designee FCA the Manufacturing Facility (Incoterms 2020), at which time title and risk of loss will pass to Client, using a carrier selected by Client.
- (j) Product Recall.
  - (i) In the event that either Party should become aware of information that may require a recall of any Product supplied under this Agreement, such Party shall inform the other Party in writing within twenty-four (24) hours of becoming aware of such information. In the event of any recall of the Product as suggested, requested, or required by any governmental authority or Client, or any recall to which both Parties agree in writing, Client shall oversee and handle all physical aspects relating to any withdrawal or recall of the Product sold by Client, its Affiliates, distributors, or customers. Service Provider shall cooperate with Client and provide assistance to Client, as reasonably requested, in conducting such recall, including providing all pertinent records that Client may reasonably request to assist in effecting such action.
  - (ii) With respect to any withdrawal or recall caused by the negligence, mistake, fault, error or omission of Service Provider, Service Provider shall reimburse or credit Client, upon Client's consent, for any costs and expenses reasonably incurred by Client in connection with the recall, including, without limitation, replacing the Product at Client's option (which replacement of Product shall be paid for by Client at the Supply Price in effect at the time the rejected Product was purchased, unless Client is entitled to a credit or reimbursement in accordance with Section 2(h) (ii) for such Product being replaced, in which case Service Provider shall be responsible for the cost of such replacement Product). In all other circumstances, Client shall be responsible for the costs and expenses of such withdrawal or recall and shall reimburse or credit Service Provider, upon Service Provider's consent, for all costs and expenses reasonably incurred by Service Provider in connection with the recall.
- (k) Product Complaints. Either Party shall immediately notify the other Party in writing should it become aware of any defect or condition that renders any lot(s) of Product supplied by Service Provider to Client in violation of any law or regulation of any jurisdiction where the Product is sold. The Parties shall share with each other all data on confirmed, lot-specific Product complaints, including, but not limited to, complaints

or information regarding performance and/or allegations or reports of any negative effect from the use or misuse of such affected lot of Product, as soon as such data is available. Each Party will provide reasonable assistance to the other in resolving customer complaints. However, Client shall have sole responsibility and authority to interact directly with its customers and regulatory authorities in the resolution of such complaints. The Parties' obligations with respect to Regulatory Requirements, adverse drug reactions and drug withdrawals shall be set forth in the Quality Agreement for the Product.

- (l) Regulatory Inspections. The Service Provider agrees to permit representatives of the FDA or any other relevant regulatory or governmental authority to access at any reasonable time during normal business hours relevant records, information (and where applicable make copies of the same), personnel and facilities that are relevant to the Product. The Service Provider will advise the Client as soon as reasonably possible of any proposed regulatory inspection relating to any particular Product, the Services or this Agreement and shall keep the Client informed about the results and conclusions of each such regulatory inspection or audit, including actions taken by Service Provider to remedy conditions cited in such inspection or audit.
- (m) Inspection by the Client. During the term of the relevant PSA, the Service Provider will permit the Client to inspect the Manufacturing Facility (including relevant records and information and where applicable make copies of the same) once per calendar year (or more frequently for cause) to ensure compliance with cGMPs and this Agreement. Such inspection shall occur during normal business hours at times mutually agreeable to the Client and the Service Provider. Client shall ensure that Client personnel will conduct each such inspection so as to cause minimum interference to the normal operation of Service Provider's facilities. Such inspections may involve the transfer of Confidential Information and shall be subject to the terms of Section 4 below.
- (n) Disclosures. The Service Provider shall provide all information to the Client requested by the Client to comply with any disclosure requirements of Applicable Law.
- (o) Cooperation. To the extent such services are included in the PSA, Service Provider shall reasonably cooperate with and provide assistance to Client, at Client's request and expense, in connection with the preparation, submission and maintenance of applications and other filings to the applicable Governmental Entities to obtain and maintain Regulatory Approvals for the Product. Service Provider shall promptly provide Client upon request with all information in Service Provider's control and part of the deliverables under the applicable PSA that is necessary for Client to apply for, obtain, and maintain Regulatory Approvals for the Product, including information relating to its facilities, processes, methodology, raw materials and intermediates or the equipment used in the manufacture of the Product. Further, Service Provider agrees, at Client's request and expense, to execute, acknowledge and deliver such further instruments, and take such other actions, within a reasonable time after receiving such request, which may be necessary to assist in the filing for, preparation, submission or maintenance of such Regulatory Approvals.
- (p) Records. Service Provider shall maintain complete and accurate batch records, laboratory data, reports and other technical records relating to the Product in accordance with SOPs. Such information shall be maintained for the minimum period required by Applicable Laws or, if longer, the Quality Agreement, provided that Service Provider shall not destroy any such information without first providing Client at least thirty (30)

days prior written notice thereof and the opportunity to take possession of such information, at Client's expense.

- (q) Regulatory Compliance. Service Provider shall obtain and maintain all permits and licenses with respect to operation of its facilities required by any Governmental Entity in each jurisdiction in which Service Provider performs Services.

### 3. COMPENSATION AND EXPENSES.

- (a) Fees. Subject to the terms and conditions hereof, the Client shall pay the supply price, compensate the Service Provider the fees and reimburse the Service Provider for expenses incurred in performing the Services in accordance with each PSA.
- (b) Payment. Unless otherwise agreed in the PSA, payment is due within fifteen (15) days following the date of each invoice.

### 4. CONFIDENTIALITY AND INTELLECTUAL PROPERTY

- (a) Each Party (the "Receiving Party") may be provided with or otherwise have access to Confidential Information of the other Party (the "Disclosing Party"), its customers, suppliers, licensors, business partners and/or other third parties, whether directly or indirectly, in writing, orally, electronically or by drawings or inspection of equipment, products, facilities, software or other property. The Receiving Party agrees not to disclose any Confidential Information of the Disclosing Party to third parties or to use any Confidential Information for any purpose other than performance of its obligations or exercise of its rights pursuant to this Agreement, without prior written consent of the Disclosing Party.
- (b) Confidential Information does not include information that: (i) is or later becomes available to the public through no breach of the Agreement by the Receiving Party; (ii) is obtained by the Receiving Party from a third party who had the legal right to disclose the information to the Receiving Party; (iii) is already in the possession of the Receiving Party without obligation of confidentiality at the time of disclosure by the Disclosing Party; (iv) is developed independently by the Receiving Party without use of the Disclosing Party's Confidential Information; or (v) is required to be disclosed by law, government regulation, or court order, provided that if the Receiving Party discloses the Confidential Information pursuant to Section 4(b)(v) hereof, the Receiving Party shall give the Disclosing Party reasonable advance, written notice sufficient to permit the Disclosing Party to contest such requirement of disclosure, take all reasonable and lawful actions to avoid and/or minimize the extent of such disclosure, and cooperate with the Disclosing Party, at the Disclosing Party's cost, if the Disclosing Party wishes to seek a protective order or other equitable relief.
- (c) Neither Party shall make any press release or other public announcement regarding the existence or terms of this Agreement without the prior written consent of the other Party, except as necessary to comply with Applicable Laws (including securities regulations). Notwithstanding anything to the contrary in this Agreement, either Party may disclose this Agreement on a reasonable need-to-know basis to actual and potential investors, acquirers, lenders, licensees or collaborators under reasonable conditions of confidentiality under the circumstances.

- (d) The obligations set forth in this Section 4 shall survive the termination or expiration of this Agreement or a PSA for any reason and are in addition to, not in lieu of, any other obligations regarding the Confidential Information contained in any other agreement.
- (e) All Client Intellectual Property and Product Inventions will be the sole and exclusive property of Client. Service Provider will, and hereby does, at no cost, assign to Client any and all Product Inventions. If Client requests and at Client's expense, Service Provider will execute any and all applications, assignments or other instruments and give testimony which shall be necessary to apply for and obtain letters of patent or any other intellectual property rights of the U.S. or of any foreign country with respect to the Product Inventions and Client shall reimburse Service Provider for reasonable out of pocket expenses incurred. Client hereby grants to Service Provider a royalty-free, non-transferable license (without right to sublicense) to use such Client Intellectual Property and Product Inventions solely to the extent necessary to perform the Services during the Term.
- (f) All Service Provider Intellectual Property and Process Inventions will be the sole and exclusive property of Service Provider. Service Provider hereby grants to Client a perpetual, irrevocable, world-wide, royalty-free, non-exclusive license (with the right to grant sublicenses through multiple tiers) for Client to use Service Provider Intellectual Property and Process Inventions that are incorporated in the Product or other deliverables provided by Service Provider solely to the extent necessary for Client to develop and seek regulatory approval for the Product and, in the case of any such subject matter that is incorporated into a regulatory submission for the Product or covered by a patent, to produce and commercialize the Product. The terms of any license to any other Service Provider Intellectual Property and Process Inventions for production and commercialization of a Product will be set forth in a new or amended PSA or other relevant, legal agreement executed between the Parties (e.g., commercial supply agreement) on commercially reasonable terms promptly following Client's request. Service Provider will not incorporate any Intellectual Property owned by any third party that has not been properly licensed or purchased by Service Provider or Client into any Product or deliverable under this Agreement.

## 5. DEBARMENT

Service Provider represents and warrants to Client that:

- (a) Service Provider is not now nor will Service Provider, during the Term of this Agreement, be debarred or disqualified pursuant to the FDCA ("Debarred"), be excluded from participating in a federal health care program ("Excluded"), and that Service Provider has never been convicted of a felony under federal law for conduct relating to the development or approval of a drug product or relating to a drug product ("Drug Felony");
- (b) Service Provider will not use any employee, independent contractor or other representative that is Debarred, Excluded, or has been convicted of a Drug Felony, in any capacity in connection with the performance of the Services provided hereunder; and
- (c) If Service Provider or any employee, independent contractor or other representative is subsequently Debarred, Excluded, or convicted of a Drug Felony, or is charged with or

under investigation for any of the foregoing, Service Provider will immediately notify Client of such action in writing.

## 6. RETURN AND DESTRUCTION OF MATERIALS

Upon termination of this Agreement, the Service Provider and Client agree to arrange the return or destruction of all materials and tangible embodiments of the Confidential Information pertinent to the Client's Product in the Service Provider's possession, as well as any unused Client-supplied materials (including API and delivery devices, as the case may be), in a commercially reasonable manner.

## 7. TERM AND TERMINATION

- (a) This Agreement shall be effective as of the Effective Date of this Agreement and shall continue through the completion of all Services under any and all Project Scope Agreements, unless earlier terminated in accordance with this Section (the "Term"). The term for any particular Project shall be set forth in the PSA to the extent it can be estimated at the inception of the Project; otherwise, the term for any Project starts upon signature by both Parties of the applicable PSA and ends on the completion of all Services related to such Project.
- (b) Either the Client or Service Provider may terminate this Agreement or a Project Scope Agreement effective immediately upon written notice to the other Party if the other Party makes an assignment for the benefit of its creditors, the other Party files a voluntary petition under federal or state bankruptcy or insolvency laws, a receiver or custodian is appointed for the other Party's business, or proceedings are instituted against the other Party under federal or state bankruptcy or insolvency laws that have not been stayed or dismissed within sixty (60) days.
- (c) Each Party hereto (the "Non-Breaching Party") shall be entitled to terminate this Agreement, or any particular PSA, by written notice to the other Party (the "Breaching Party") in the event that the Breaching Party is in default of any of its material obligations under this Agreement (or a particular Project) and, in the case of a default that can be remedied, fails to remedy such default within sixty (60) days after receipt of written notice thereof by the Non-Breaching Party. Any such notice shall specifically state: (i) the nature of the breach; (ii) the desired cure; and (iii) that the Non-Breaching Party intends to terminate this Agreement (or a particular Project, identifying the particular Project in such notice) in the event that the Breaching Party fails to remedy the default.
- (d) Client shall be entitled to terminate this Agreement, or any particular PSA, without cause upon at least thirty (30) days prior written notice to Service Provider.
- (e) Upon termination of this Agreement or a particular PSA, Service Provider will cooperate with the Client, as reasonably requested by the Client, to provide for the orderly cessation or completion of the applicable Project(s), and the Client shall pay Service Provider for the actual work completed to the date of termination, together with any reasonable expenses incurred or to be incurred from non-cancelable agreements, costs of cancellation of cancelable agreements, and termination /cancellation fees and other fees set forth in the PSA. In the event of termination by Service Provider pursuant to Section 7(b) or 7(c) above, the Service Provider may, at its option complete the manufacturing of purchase orders accepted by the Service Provider prior to the effective date of

termination. In the event of termination by Client pursuant to Section 7(b), 7(c) or 7(d) above, the Client may, at its option, require Service Provider to complete the manufacturing of purchase orders accepted by the Service Provider prior to the effective date of termination. The termination or expiration of this Agreement or any PSA shall not relieve any of the Parties of their obligations to the other in respect to maintaining confidentiality, indemnification, compensation for Services performed and appropriate reporting of any data obtained. Termination or expiration of this Agreement or any PSA shall not affect: (i) the Client's obligation to pay for Services performed by the Service Provider or expenses reasonably incurred by the Service Provider for which the Service Provider is entitled to reimbursement under this Agreement or a PSA, including without limitation payment for Product delivered after the effective date of termination; or (ii) the Parties' obligations under paragraphs 2(h), 2(i), 2(j), 2(m), 2(n), 4, 6, 7, 8, 9 and 10 hereof, which shall survive termination or expiration of this Agreement.

## 8. INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

- (a) The Client agrees to indemnify, defend and hold harmless the Service Provider, its Affiliates and their respective officers, directors, employees, and agents (each, a "Representative") from any and all Losses incurred by any of them relating to a Third Party Claim arising from or relating to:
- (i) Any breach of any obligation by the Client under this Agreement or a PSA, or of any representation or warranty of the Client under this Agreement or a PSA or any act, or omission of the Client in connection with its obligations under this Agreement or a PSA;
  - (ii) Any claim that the Product infringes or violates the intellectual property rights of a third party;
  - (iii) the negligence, recklessness or willful misconduct of, or breach of a statutory duty by Client or its agents in connection with this Agreement; or
  - (iv) Client's development, studies, regulatory submissions, use, storage, handling, shipment or Commercialization of, or with respect to, the Product.

The Client shall have no liability under this Section 8(a) for items that are Service Provider's responsibility pursuant to Section 8(b) below.

- (b) The Service Provider agrees to indemnify, defend and hold harmless the Client and its Representatives from any and all Losses incurred by any of them relating to a Third Party Claim arising from or relating to:
- (i) Any breach of any obligation by the Service Provider under this Agreement or a PSA, or of any representation or warranty of the Service Provider under this Agreement or a PSA or any act, or omission of the Service Provider in connection with its obligations under this Agreement or a PSA;
  - (ii) Any claim that any work performed by Service Provider hereunder infringes or violates the intellectual property rights of a third party; or
  - (iii) the negligence, recklessness or willful misconduct of, or breach of a statutory duty by Service Provider or its agents in connection with this Agreement.

The Service Provider shall have no liability under this Section 8(b) for items that are Client's responsibility pursuant to Section 8(a) above.

(c) Any Party seeking indemnification under this Article 8 (the "Indemnitee") shall: (a) promptly notify the indemnifying Party (the "Indemnitor") of the applicable claim; (b) provide the Indemnitor sole control over the defense and/or settlement thereof; and (c) at the Indemnitor's request and expense, provide full information and reasonable assistance to Indemnitor with respect to such claim. Without limiting the foregoing, Indemnitee, at its own expense, shall have the right to participate with counsel of its own choosing in the defense and/or settlement of any such claim. The indemnification under this Article 8 shall not apply to amounts paid in settlement of any claim if such settlement is effected without the consent of the Indemnitor. Indemnitor shall not settle any such claim or otherwise consent to an adverse judgment in such claim if the same materially diminishes the rights or interests of the Indemnitee without the express written consent of such Indemnitee, which consent shall not be unreasonably withheld.

(d) NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL LOSSES OR DAMAGES, INCLUDING, BUT NOT LIMITED TO, LOSS OF REVENUES, PROFITS OR DATA, LOST BUSINESS, LOST INFORMATION OR OTHER PECUNIARY LOSS, SUFFERED OR INCURRED BY A PARTY ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN ANY EVENT, UNDER NO CIRCUMSTANCES WILL SERVICE PROVIDER BE LIABLE FOR ANY LOSS, COST, EXPENSE OR DAMAGE ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT IN AN AMOUNT EXCEEDING THE SUM OF THE FEES ACTUALLY PAID BY CLIENT TO SUMMIT UNDER THIS AGREEMENT, EVEN IF CLIENT PARTY HAS BEEN ADVISED OF THE CLAIM OR POTENTIAL CLAIM. THE FOREGOING LIMITATIONS ON DAMAGES AND LIABILITY UNDER THIS SECTION 8(d) SHALL NOT APPLY WITH RESPECT TO A PARTY'S WILLFUL MISCONDUCT (INCLUDING, IN THE CASE OF SERVICE PROVIDER, WILLFUL FAILURE TO SUPPLY PRODUCT IN ACCORDANCE WITH THIS AGREEMENT), GROSS NEGLIGENCE, BREACH OF ARTICLE 4 OR OBLIGATION TO INDEMNIFY THE OTHER UNDER SECTIONS 8(a) OR 8(b) HEREOF IN CONNECTION WITH A LIABILITY TO A THIRD PARTY.

EXCEPT AS SPECIFICALLY SET FORTH IN THIS AGREEMENT, THERE ARE NO WARRANTIES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, WITH RESPECT TO THE SERVICES OR ANY DELIVERABLES, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE OR NONINFRINGEMENT.

(e) Each Party shall obtain and maintain, during the Term and for six (6) years thereafter, comprehensive general liability insurance, including product liability and/or clinical trial insurance, as the case may be, commensurate with levels standard and customary in the pharmaceutical industry and with projects of the nature and scope described in this Agreement. Such liability insurance shall be maintained on an occurrence basis to provide such protection after expiration or termination of the policy itself or this

Agreement. Each Party shall furnish to the other Party on request certificates issued by the insurance company setting forth the amount of the liability insurance.

## 9. FORCE MAJEURE

- (a) Notification. If either Party is affected by a Force Majeure, it shall forthwith notify the other Party in writing of the nature and extent thereof.
- (b) Forgiveness of Performance. Neither Party shall be deemed to be in breach of this Agreement, or otherwise liable to the other, by reason of any delay in performance, or non-performance of any of its obligations hereunder to the extent that such delay or non-performance is due to any Force Majeure of which it has notified the other Party in writing and the time for performance of such obligation shall be extended for the period that such Force Majeure shall continue.
- (c) Continuation of Force Majeure. In the event that such Force Majeure continues for a period in excess of sixty (60) days and the affected Party is unable to fulfill its obligations hereunder beyond such period of sixty (60) days, the unaffected Party shall be entitled to suspend its performance of its obligations under this Agreement until such time as the affected Party is able to fulfill its obligations. The Parties agree to undertake discussions with a view to reaching some other mutually acceptable and reasonable arrangement for alleviating the effects of such Force Majeure, which may include the termination of this Agreement.

## 10. MISCELLANEOUS

- (a) This Agreement may not be assigned by either Party, nor may any right or obligation be delegated by either Party without the prior written consent of the other Party hereto; provided, however, that either Party may assign this Agreement, without the other Party's consent, to an Affiliate or by way of merger or sale of all or substantially all of the Party's assets related to this Agreement. This Agreement will inure to the benefit of and be binding on all permitted successors and assigns. Service Provider may not subcontract all or substantially all of the Services without Client's prior written consent.
- (b) The relationship created by this Agreement shall be that of independent contractor, and the Service Provider shall have no authority to bind or act as agent for the Client or its employees for any purpose.
- (c) This Agreement, together with the Project Scope Agreements, constitutes the entire agreement between the Client and the Service Provider with respect to the subject matter of this Agreement. In the event of any conflict between the terms of the MSA and any PSA, the PSA shall govern and control.
- (d) This Agreement may not be modified in any respect by any verbal statement, representation, or agreement made by any employee, officer, or representative of the Client, or by any written documents unless it is signed by an officer of the Client and by the Service Provider.
- (e) The Service Provider hereby agrees that each provision herein shall be treated as a separate and independent clause, and the unenforceability of any one clause shall in no way impair the enforceability of any of the other clauses of the Agreement. Moreover,

if one or more of the provisions contained in this Agreement shall for any reason be held to be unenforceable at law, the Parties shall in good faith negotiate a replacement for each such provision that is consistent with their original intent, and the remaining provisions of this Agreement shall remain in full force and effect. The Parties hereby further agree that the language of all parts of this Agreement shall in all cases be construed as a whole according to its fair meaning and not strictly for or against either of the Parties.

- (f) This Agreement will be governed by, construed, and enforced in accordance with the laws of the State of New York without giving effect to the conflicts of laws principles of any jurisdiction. Client and Service Provider each irrevocably and unconditionally submit to the jurisdiction of any Federal or State court sitting in the State of New York, County of New York, accept for itself and in respect of its property the non-exclusive jurisdiction of such courts, and waive the right to trial by jury in any action, suit, or proceeding of any kind or nature in any court to which they become parties relating to the transactions contemplated by this Agreement.
- (g) This Agreement and any amendment hereto may be executed in any number of counterparts, each of which when executed and delivered shall be deemed to be an original and all of which counterparts taken together shall constitute but one and the same instrument. The exchange of copies of this Agreement or amendments thereto and of executed signature pages by facsimile transmission or by email transmission in portable document format (.pdf), or similar format, shall constitute effective execution and delivery of such instrument(s) as to the Parties and may be used in lieu of the original Agreement or amendment for all purposes. Signatures of the Parties transmitted by facsimile or by email in portable document format (.pdf), or similar format, shall be deemed to be their original signatures for all purposes.
- (h) Any notice or report required or permitted to be given or made under this Agreement or any PSA by either Party shall be in writing and delivered to the other Party at its address indicated on Exhibit B hereto (or to such other address as a Party may specify by like notice) by courier or by registered or certified airmail, postage prepaid, or by email; provided, however, that all email notices shall be promptly confirmed, in writing, by courier or by registered or certified airmail, postage prepaid. All notices shall be effective as of the date received by the addressee.

*[signature page follows]*

IN WITNESS WHEREOF, the Parties have executed this Agreement effective as of the Effective Date.

CLIENT:

**OPIANT PHARMACEUTICALS, INC**

By: \_\_\_/s/ Dr. Roger Crystal \_\_\_\_\_  
Name: Dr. Roger Crystal

Title: Chief Executive Officer

SERVICE PROVIDER:

**SUMMIT BIOSCIENCES INC.**

By: \_\_\_/s/ Ted Marcuccio \_\_\_\_\_  
Ted Marcuccio  
Chief Business Officer

EXHIBIT A

PROJECT SCOPE AGREEMENT



*Quality, Integrity and Passion*

**Development, Manufacturing and Stability Program for  
Opioid Antagonist Nasal Spray (revision 03)**

*Prepared For*

**Opiant Pharmaceuticals, Inc.**



July 22, 2020

***Confidential Business Information***  
***Property of Summit Biosciences Inc.***  
***Authorized Use Only***

**Project**

This Project Scope Agreement (PSA) is between Opiant Pharmaceuticals, Inc. (Opiant or Client), with an address of 233 Wilshire Blvd, Suite 280, Santa Monica, CA 90401, and Summit Biosciences Inc. (Summit), with an address of 1513 Bull Lea Road, Lexington, KY. This PSA provides an estimate for the services to be performed by Summit for Opiant.

In consideration for an estimated project cost of approximately \$6.545 million, Summit will provide services related to product and method development, validation, GMP manufacturing and stability of an opioid antagonist nasal spray product as described more fully on Appendix A and Appendix B.

**Summit's Specialized Capabilities for this Project*****Expertise and Regulatory Experience with Spray Drug Development***

Summit personnel have over 18 years of experience developing and manufacturing multiple nasal spray drug products, which includes extensive interaction with the FDA. This experience includes the development and qualification of analytical methods used to measure and characterize nasal spray drug products, which is critically important for gaining FDA approval.

Summit's extensive interaction with the FDA can be leveraged to help meet non-published FDA expectations and to avoid pitfalls related to the development of nasal drug products. The recent experience of completing the vast number of studies and tasks required for new and generic nasal spray products can be used to add significant value to the program.

***Unique Infrastructure***

Summit operates an FDA and EU approved and DEA registered cGMP manufacturing facility specifically designed to produce nasal spray drug products. Based on FDA, EU and DEA feedback over the years, the facility and manufacturing process have been designed to control Critical Quality Attributes (CQAs) of the drug product. Summit manufactures both generic and branded nasal spray products for development, clinical testing and commercial sale in the US, Europe, and elsewhere.

Summit has installed and qualified all of the analytical instrumentation required to characterize nasal spray drug products as specified in FDA guidance documents. Summit scientists have gained extensive experience using this instrumentation while characterizing multiple products during release, stability and bioequivalence testing. Summit has a fully equipped microbiology laboratory for testing raw materials, environmental samples and finished products.

***COVID-19 Emergency Management Plan***

Summit is classified as a Critical Infrastructure Industry by the Dept of Homeland Security, and as such is expected to remain operational during the current pandemic. Summit has put in place a business continuity plan for mitigating the impact of highly infectious agents including SARS-CoV-2. This continuity plan outlines Summit's strategy in preparing for, responding to, and recovering from a highly infectious (respiratory) disease outbreak such as COVID-19 or Pandemic Flu. The plan defines the response leadership team, communication strategies, and

includes current procedures, policies and enhanced hygiene requirements throughout all operations. Evolving information from CDC or other governmental agencies is monitored regularly and any new recommendations or requirements are integrated into Summit policies. Policies and requirements are reviewed daily with staff, and refresher training is conducted as needed on pertinent topics. While the overall impact of the pandemic is uncertain and cannot be predicted, Summit remains committed to the safety of employees, Clients and visitors, and to continuing to deliver outstanding service to our Clients.

### ***Focused Project Management***

Summit will appoint a Project Manager with development, validation and manufacturing experience and expertise related to nasal spray drug products to manage the tasks, budget and timeline to assure:

1. High quality, on-time delivery of objectives
2. Proactive, focused customer service
3. Application of our vast experience and expertise in nasal drug development to help speed development objectives.

### **Terms and Conditions**

1. **Initiation of Work** - Services will not be initiated until a purchase order number, a signed copy of this proposal, or an email from a duly authorized representative of Client referencing the proposal number and authorized value is received. Additionally, the Project Deposit and Materials Deposit must be received prior to initiating work.
2. **Scope Change** - Information provided to Summit subsequent to the effective date may change the scope or nature of this project and may result in mutually agreed changes to the estimates provided herein and amendments to this proposal. Any changes in the scope of this project may be addressed in an amendment to this proposal. The pricing for any such scope changes will be at the current Summit hourly or flat rate pricing in effect when such scope changes are signed.
3. **Development Stage & cGMP** – Tasks will be phased in as appropriate for the stage of development (Development vs. GMP) and agreed to in advance by Client and Summit.
4. **Customs Fees** – Any customs duty and/or taxes payable will be charged to Client.
5. **Shipping** – Pass through costs may include out of country telephone transaction charges, express mail/courier shipment costs and freight.
6. **Travel** – Any project-related travel of Summit scientific staff and time spent outside the company at the request of Client will be subject to additional charges and will require pre-approval by Client.
7. **Materials and Supplies** – Unless otherwise specified in the proposal, Client will be invoiced for the cost of all project materials and supplies purchased by Summit (such as pumps, vials, reagents, reference standards, filters, tubing, labels, etc.) plus a handling charge.
8. **Subcontracted Services** – Unless otherwise specified in the proposal, Client will be invoiced for the cost of all subcontracted services necessary to complete the project plus a handling charge.

9. **Storage** – Storage will be invoiced monthly based on volume and storage requirements of the product (DEA controlled vs. non-controlled).
10. **Reports and Documentation** – Summit will provide one draft for each requested document in an agreed upon format. Additional drafts of batch records, protocols, or reports required for format changes will incur an additional cost at standard hourly rates.
11. **Invoicing and Payment** – Summit shall invoice and Client shall pay the fees, costs, expenses and deposits as set forth on Appendix A.
12. **Variables and Additions** – The parties recognize that unusual, unique and unexpected problems, requirements, or developments may arise which require additional unanticipated work. The following is not an exhaustive list of such variables which, if incurred, may require the performance of additional work outside the scope of that described in the proposal:
- Unusual physical or chemical characteristics that are discovered during stability.
  - Formulations, technologies, processes or analytical methodologies represented as meeting USP, GMP and/or Summit standards that do not meet requirements.
  - Identification and quantification of impurities and/or degradation products (not included in the standard assay qualification).
  - Additional analytical work due to customer request, out of specification results and/or analysis of samples placed on hold.
  - **Data Rates** – Delivery of supporting documentation related to batch manufacturing (i.e. room monitoring data, Purified Water System qualification testing data, requalification or certification data, etc.) will incur an additional cost at standard hourly rates.
  - **Regulatory Support** – Regulatory support, including client submissions and activities which result in direct contact between Summit and any regulatory agency will incur a charge at the regulatory support hourly rate.

In the event that any of these variables or others exists or occurs, they will be promptly identified by Summit in a Project Change Order, and the cost thereof presented to Client. The additional work will proceed when the modified scope of work is agreed to and signed by Client and Summit.

**Master Services Agreement**

This PSA is subject to the terms and conditions of that Master Services Agreement (“MSA”) between Client and Summit with an Effective Date of July 1, 2020, and is incorporated by reference therein. The terms and conditions in the MSA, together with this PSA, will govern the arrangement between the parties for this program.

By signing this PSA, Client authorizes Summit to begin ordering project materials and performing one or more of the activities detailed herein. The levels of effort and cost reflected in this PSA are estimates only and are, therefore, subject to change upon the receipt and review of additional information. Additional documentation to drive the various requirements of the services to be provided will be prepared by Summit and signed by Summit and Client.

**Approvals**

PROPOSAL BY:

ACCEPTED BY:

**Summit Biosciences Inc.****Opiant Pharmaceuticals, Inc.**

\_\_\_\_\_/s/ Greg Plucinski\_\_\_\_\_      \_\_\_\_/s/ Dr. Roger Crystal\_\_\_\_\_

Signature

Signature

Printed Name: Greg Plucinski

Printed Name: Dr. Roger Crystal

Title: President &amp; COO

Title: Chief Executive Officer

Date: July 22, 2020

Date: July 22, 2020

**Appendix A**

**[Intentionally Deleted]**

**Appendix B**

**[Intentionally Deleted]**

**EXHIBIT B**

**CONTACT ADDRESSES**

If to Service Provider:

Summit Biosciences Inc.  
Coldstream Research Campus  
1513 Bull Lea Road  
Lexington, KY 40511  
Attention: Ted Marcuccio

If to Client:

Opiant Pharmaceuticals, Inc.  
233 Wilshire Blvd., Suite 280  
Santa Monica, CA 90401  
Attention: General Counsel