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 9, 2013	
NAVI	DEA BIOPHARMACEUTICALS, INC.	
(Exact n	ame of registrant as specified in its charter)
Delaware	001-35076	31-1080091
(State or other jurisdiction	(Commission	(IRS Employer
of incorporation)	File Number)	Identification No.)
425 Metro Place North, Suite 450, Dublin, Ohio		43017
(Address of principal executive offices)		(Zip Code)
Registrant's telephone number, including area code	(614) 793-7500	
, , ,		
(Former name	or former address, if changed since last re	nort)
(1 office hame	of former address, if changed since last re	poru,
Check the appropriate box below if the Form 8-K filing any of the following provisions (see General Instruction)		filing obligation of the registrant under
☐ Written communications pursuant to Rule 425 und	er the Securities Act (17 CFR 230.425)	
$\hfill \square$ Soliciting material pursuant to Rule 14a-12 under t	he Exchange Act (17 CFR 240.14a-12)	
\square Pre-commencement communications pursuant to R	tule 14d-2(b) under the Exchange Act (17	CFR 240.14d-2(b))
\square Pre-commencement communications pursuant to R	tule 13e-4(c) under the Exchange Act (17 C	CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

On September 9, 2013, Navidea Biopharmaceuticals, Inc. (the "Company") entered into a manufacturing services agreement (the "Services Agreement") with OSO BioPharmaceuticals Manufacturing, LLC ("OsoBio"). Pursuant to the terms of the Services Agreement, OsoBio will provide contract pharmaceutical development, manufacturing, packaging and analytical services for the Company's Lymphoseek® (technetium Tc 99m tilmanocept) Injection product ("Lymphoseek"). During the term of the Services Agreement OsoBio will be the primary supplier of manufacturing services for Lymphoseek. In consideration for these services, the Company will pay a unit pricing fee set forth in the Services Agreement. In addition, the Company will pay OsoBio a fee for regulatory support services described in the Services Agreement.

The foregoing description of the terms of the Services Agreement is qualified in its entirety by reference to the complete text of the Services Agreement, a copy of which is attached hereto as Exhibit 10.1 and which is incorporated herein in its entirety by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number

Exhibit Description

10.1

Manufacturing Services Agreement, dated September 9, 2013, by and between Navidea Biopharmaceuticals, Inc. and OSO BioPharmaceuticals Manufacturing, LLC (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the United States Securities and Exchange Commission).

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.

Navidea Biopharmaceuticals, Inc.

Date: September 12, 2013

By: /s/ Brent L. Larson

Brent L. Larson, Executive Vice President and

Chief Financial Officer

MANUFACTURING SERVICES AGREEMENT

This MANUFACTURING SERVICES AGREEMENT ("Agreement") is made this 9th day of September 2013, by and between OSO BioPharmaceuticals Manufacturing, LLC ("OsoBio"), with a place of business at 4401 Alexander Blvd., Albuquerque, NM 87107, USA and Navidea Biopharmaceuticals, Inc. ("Navidea"), having its principal place of business at 425 Metro Place North, Suite 450, Dublin, Ohio 43017, USA.

- A. OsoBio provides contract pharmaceutical development, manufacturing, packaging, analytical, and sales and marketing services to the pharmaceutical industry.
- B. Navidea has certain technology relating to the certain pharmaceutical products and wants OsoBio to assist in the formulation, filling, packaging and testing on such products as provided in this Agreement and the attachments hereto.
- C. Navidea desires to engage OsoBio to provide certain services to Navidea in connection with the processing of Navidea's Product (defined below); and OsoBio desires to provide such services pursuant to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth below, the parties agree as follows:

ARTICLE 1 DEFINITIONS

The following terms have the following meanings in this Agreement:

- 1.1 "Affiliate(s)" means any corporation, firm, partnership or other entity which controls, is controlled by or is under common control with a party. For purposes of this definition, "control" shall mean the ownership of at least fifty percent (50%) of the voting share capital of such entity or any other comparable equity or ownership interest.
- 1.2 "API" means the active pharmaceutical ingredient used in the manufacture of the Product.
- 1.3 "Applicable Laws" means all laws, ordinances, rules and regulations within the Territory applicable to the Processing of the Product or any aspect thereof and the obligations of OsoBio or Navidea, as the context requires under this Agreement, including, without limitation, (i) all applicable federal, state and local laws and regulations of each Territory; (ii) the U.S. Federal Food, Drug and Cosmetic Act, and (iii) the Good Manufacturing Practices promulgated by the Regulatory Authorities, as amended from time to time ("GMPs").

- "Batch" means a specific quantity of a Product comprising a number of units of Product mutually agreed upon between the parties, and that (a) is intended to have uniform character and quality within specified limits, and (b) is Processed according to a single manufacturing order during the same cycle of Processing. Unless otherwise mutually agreed by both parties, Batch size shall mean the targeted range of units used in the validation process, [*] vials.
- 1.5 "Calendar Quarter" means a period of three (3) consecutive months commencing on January 1, April 1, July 1 or October 1 of any calendar year.
- 1.6 "Calendar Year" means the period from January 1 to December 31 of each year.
- 1.7 "Certificate of Analysis" or "CofA" means a certificate providing details about the quality and conformance to applicable quality assurance requirements relating specifically to the result of testing a representative sample drawn from the specific batch or lot of material it is purported to represent.
- 1.8 "Change Order" shall have the meaning set forth in Section 4.5(a).
- 1.9 "Commencement Date" means the first date upon which a Regulatory Authority approves OsoBio as a manufacturer of one of the Products; provided that such date shall not be earlier than the date that a Regulatory Authority has granted marketing clearance for the Product.
- 1.10 "Confidential Information" is as defined in Section 11.2.
- 1.11 "Contract Year" means each consecutive twelve (12) month period beginning on the Commencement Date.
- 1.12 "Navidea Materials" shall have the meaning set forth in Article 12.
- 1.13 "Defective Product" shall have the meaning set forth in Section 5.2.
- 1.14 "Delayed Approval Fee" shall have the meaning set forth in Section 7.4.
- 1.15 "Dispute" shall have the meaning set forth in Section 18.9.
- 1.16 "Effective Date" means the date this Agreement was fully executed.
- 1.17 "Facilities" means OsoBio's facilities located in Albuquerque, New Mexico, as set forth below:

Manufacturing and Microbial Testing:

4272 Balloon Park Rd NE Albuquerque, NM 87109 **Analytical Testing:** 4200 Balloon Park Rd NE Albuquerque, NM 87109 Inspection, Testing, Packaging and Storage:

4401 Alexander Blvd NE Albuquerque, NM 87107 **Stability Testing:** Not applicable to OsoBio.

[*]

- 1.18 "FDA" means the United States Food and Drug Administration, and any successor agency thereto.
- 1.19 "Firm Commitment" shall have the meaning set forth in Section 4.2.
- 1.20 "Intellectual Property" means all intellectual property (whether or not patented), including without limitation, patents, patent applications, know-how, trade secrets, copyrights, trademarks, designs, concepts, technical information, manuals, standard operating procedures, instructions or specifications.
- 1.21 "Minimum Requirement" shall have the meaning set forth in Section 4.1.
- 1.22 "OsoBio Materials" shall have the meaning set forth in Article 12.
- 1.23 "Process" or "Processing" shall mean the compounding, filling, producing, packaging and labeling of the Raw Materials into Product in accordance with the Specifications and the terms and conditions set forth in the Quality Agreement.
- 1.24 "Processing Date" means the day on which the Product is to be first Processed by OsoBio.
- 1.25 "Product" means the product identified by the Specifications which may include unlabeled lyophilized vialed product and labeled kits of finished Lymphoseek® product.
- 1.26 "Purchase Order" shall have the meaning set forth in Section 4.3.
- 1.27 "Raw Materials" means all raw materials, supplies, components, labeling and packaging necessary to manufacture and ship the Product in accordance with the Specifications, as provided in Exhibit A, but not including the API.
- 1.28 "Regulatory Approval" shall have the meaning set forth in Section 7.4.
- 1.29 "Regulatory Authority" means any governmental regulatory authority within the Territory involved in regulating any aspect of the development, manufacture, market approval, sale, distribution, labeling, and packaging or use of the Product.

- 1.30 "Release of Product to Navidea" means the posting of all documents required for final Product release by Navidea. Posting is done by OsoBio via a mutually agreed mechanism (i.e. secure electronic portal). This includes, but is not limited to, relevant CofA's, Batch records, and samples provided by OsoBio to Navidea. For purposes of clarity, OsoBio does not perform final product release.
- 1.31 "Review Period" shall have the meaning set forth in Section 5.1.
- 1.32 "Rolling Forecast" shall have the meaning set forth in Section 4.2.
- 1.33 "Sample" shall have the meaning set forth in Section 5.1.
- 1.34 "Specifications" means the Product specifications set forth on Exhibit A, and any procedures, requirements, standards, quality control testing, or any provisions of the Service Agreements that would impact Product quality.
- 1.35 "Term" shall have the meaning set forth in Section 15.1.
- 1.36 "Territory" shall mean the United States of America, those countries regulated by the European Medicines Agency (EMA), and any other country that the parties agree in writing to add to this Agreement from time to time.
- 1.37 "Unit Pricing" shall have the meaning set forth in Section 7.1.
- 1.38 "Validation Batches" shall mean each Batch of Product manufactured by OsoBio which is necessary to support the validation portion of Navidea's NDA submission to the FDA.

ARTICLE 2 VALIDATION, PROCESSING & RELATED SERVICES

- 2.1 <u>Validation Services</u>. OsoBio shall perform the qualification, validation and stability services described in $\underline{\text{Exhibit A}}$, and $\underline{\text{Exhibit B}}$ of this Agreement.
- 2 . 2 <u>Supply and Purchase of Product.</u> During the Term, OsoBio shall be the primary supplier of manufacturing services for the Product and shall Process the Products in accordance with the Specifications, the Applicable Laws and the terms and conditions of this Agreement. Navidea shall purchase the Product from OsoBio in accordance with the terms and conditions of this Agreement.
- 2.3 Other Related Services. OsoBio shall provide other services upon terms and conditions agreed to by the parties in writing from time to time.

ARTICLE 3 MATERIALS

- API. Navidea shall supply to OsoBio for Processing, at Navidea's sole cost, the API and applicable reference standards in quantities sufficient to meet Navidea's requirements for each Product as further set forth in Article 4. Prior to delivery of any of the API or reference standard to OsoBio for Processing, Navidea shall provide to OsoBio a copy of the API Material Safety Data Sheet ("MSDS"), as amended, and any subsequent revisions thereto. Navidea shall supply the API, reference standards, and Certificate of Analysis F.C.A. (Incoterms 2010) the **Facilities** no later than sixty (60) days before the scheduled Processing Date upon which such API will be used by OsoBio. Upon receipt of the API, OsoBio shall conduct testing of the API according to the specifications as agreed to by both parties. OsoBio shall use the API solely and exclusively for Processing under this Agreement.
- 3 . 2 <u>Raw Materials.</u> OsoBio shall be responsible for procuring, purchasing, inspecting and releasing adequate Raw Materials, at OsoBio's cost, as necessary to meet the Firm Commitment, unless otherwise agreed to by the parties in writing. Raw materials may be purchased only from qualified suppliers. Navidea will be responsible for all costs associated with qualification of a supplier of a Raw Material designated by Navidea not previously qualified by OsoBio. Unless a particular Raw Material can be replaced with the same raw material from another supplier, OsoBio shall not be liable for any delay in delivery of Product if (i) OsoBio is unable to obtain, in a timely manner, a particular Raw Material necessary to Process the Product, and (ii) OsoBio placed orders for such Raw Materials promptly following receipt of Navidea's Firm Commitment.
- 3 . 3 Artwork and Packaging. Navidea shall provide or approve, prior to the procurement of applicable components, all artwork, advertising and packaging information necessary to Process the Product. Such artwork, advertising and packaging information is and shall remain the exclusive property of Navidea, and Navidea shall be solely responsible for the content thereof. Such artwork, advertising and packaging information or any reproduction thereof may not be used by OsoBio following the termination of this Agreement, or during the Term of this Agreement in any manner other than solely for the purpose of performing its obligations hereunder.
- 3 . 4 <u>Reimbursement for Materials</u>. In the event of (i) a Specification change for any reason, (ii) termination or expiration of this Agreement (other than a termination by Navidea under Section 15.2); or (iii) obsolescence of any Raw Material, Navidea shall bear the cost of any unused Raw Materials, provided that OsoBio purchased such Raw Materials in quantities consistent with the first six months of Navidea's Rolling Forecast and any minimum purchase obligations required by the Raw Material supplier.

ARTICLE 4 MINIMUM COMMITMENT, PURCHASE ORDERS & FORECASTS

- 4.1 <u>Minimum Requirement.</u> During the term of the Agreement Navidea shall purchase from OsoBio a minimum of [*] of its annual requirements for Product.
- 4.1.1 In the event that annual quantities do not exceed [*] Batches in Calendar Year for which Navidea qualifies an additional contract manufacturer, the minimum requirement of this Section 4.1 will be waived for said Calendar Year.
- 4.1.2 In the event (a) OsoBio fails to deliver Product for more than two consecutive Calendar Quarters for which such Product had been ordered and firm Purchase Order accepted by OsoBio in accordance with the requirements of Section 4.2 and such failure shall not be attributable to (i) any failure of performance by Navidea of any of its obligations under this agreement or (ii) force majeure, or (b) without limiting any rights under Section 15.2(a), OsoBio otherwise fails to cure any of its other material noncompliance with the terms of this Agreement within 180 days of formal notification of such non-complaince, Navidea shall be released from the minimum requirement of this Section 4.1 for the remainder of the Term.
- 4.1.3 At the end of each calendar year Navidea shall provide a statement of compliance with this Section 4.1 as outlined in Exhibit D.
- Forecast and Purchase Order. On or before the first (1st) day of each Calendar Quarter, beginning at least one (1) Calendar 42 Quarter prior to the anticipated Commencement Date, Navidea shall furnish to OsoBio a written twelve (12) month rolling forecast of the quantities of Product that Navidea intends to order from OsoBio during such period ("Rolling Forecast"). The first six (6) months of such Rolling Forecast shall constitute a firm and binding commitment to order for the quantities of Product specified therein ("Firm Commitment") and the following six (6) months of the Rolling Forecast shall be non-binding, good faith estimates. Navidea shall submit with the Rolling Forecast a binding, non-cancelable purchase order for the Firm Commitment portion of the Processing, which specifies the actual number of Batches to be Processed, the approximate number of vials in each Batch, and the specific requested delivery dates for each Batch ("Purchase Order"). Navidea shall submit each Purchase Order to OsoBio at least ninety (90) days in advance of the Processing Date requested in the Purchase Order, OsoBio shall notify Navidea in writing of acceptance each Purchase Order within ten (10) days of receipt; provided that OsoBio shall not be permitted to reject any Purchase Order unless such Purchase Order is not consistent with the terms of this Section 4.2 (i.e., not consistent with the applicable Firm Commitment amount or the ninety (90)-day lead time). If within the ten (10)-day period after receipt of a Purchase Order OsoBio does not provide its notice of acceptance or rejection to Navidea, then the Purchase Order shall be deemed to be accepted. In the event of a conflict between the terms of any Purchase Order and this Agreement, this Agreement shall control unless OsoBio has accepted such conflicting terms in the written notice of acceptance referenced in the preceding sentences. Notwithstanding the foregoing, OsoBio shall use commercially reasonable efforts to supply Navidea with quantities of Product which are in excess of the quantities specified in the Firm Commitment, subject to OsoBio's other supply commitments and manufacturing and equipment capacity. Except as otherwise provided in this Section 4.2, no modification or amendment to this Agreement shall be effected by or result from the receipt, acceptance, signing or acknowledgement of any party's purchase orders, quotations, invoices, shipping documents or other business forms containing terms or conditions in addition to or different from the terms and conditions set forth in this Agreement.

- 4 . 4 <u>OsoBio's Cancellation of Purchase Orders</u>. In the event Navidea refuses or fails to make scheduled deliveries of the API as provided in Section 3.1, OsoBio reserves the right to cancel all, or any part of, a Purchase Order upon written notice to Navidea and OsoBio shall have no further obligations or liability with respect to such Purchase Order.
- 4.5 <u>Unplanned Delay or Elimination of Processing</u>. OsoBio shall use diligent efforts to meet the Purchase Orders; provided that the foregoing shall not limit OsoBio's obligation to deliver Product on the delivery date specified in the relevant Purchase Order, nor Navidea's remedies in the event of a breach of such obligation under the terms and conditions of this Agreement. OsoBio shall provide Navidea with as much advance notice as possible (and will use its best efforts to provide at least fifteen (15) days advance notice where possible) if OsoBio determines that any Processing will be delayed or eliminated for any reason.

ARTICLE 5 TESTING: SAMPLES: RELEASE

- Sample; Testing; Acceptance. Prior to delivering any shipment of Product, OsoBio shall provide Navidea with a certificate of 5.1 conformance and, additionally, in cases where OsoBio has performed any analytical testing of the Product, a Certificate of Analysis, in each case certifying that the Product conforms in all material respects to the Specifications and Applicable Laws. Navidea shall notify OsoBio within thirty (30) days following delivery of Product (or, in the case of any nonconformity not reasonably susceptible to discovery upon receipt of the Product, within 30 days after discovery thereof by Navidea, but in no event after the expiration date of the Product) to Navidea if Navidea has determined that such Product does not conform to Specifications or Applicable Laws and shall provide OsoBio a sample of such non-conforming Product. OsoBio shall have 10 days to advise Navidea in writing if it disagrees with Navidea's claimed nonconformity. If OsoBio agrees that the Batch is non-conforming, OsoBio shall, at its option, promptly re-perform the services in accordance with this Article, or credit Navidea's account for the invoiced price for such Product. If OsoBio does not agree with Navidea's determination that such Product fails to meet the Specifications or Applicable Laws, then after reasonable efforts to resolve the disagreement, either party may submit a sample of such Product to a mutually agreed upon independent third party laboratory to determine whether the Product meets the Specifications and Applicable Laws. The independent party's results shall be final and binding. In the event that such evaluation determines that the Product does not conform to the Specifications or Applicable Laws, OsoBio shall credit Navidea's account for the invoiced price of such Product. Unless otherwise agreed to by the parties in writing, the costs associated with such testing and review shall be borne by the non-prevailing party.
- 5.2 <u>Replacement of Defective Product</u>. In accordance with the terms set forth in this Agreement, OsoBio shall, at its option, either (i) replace, at its sole expense, all Product that does not comply with the Specifications ("Defective Product") or (ii) credit Navidea's account for the invoiced price of such Defective Product. The obligation of OsoBio to replace Defective Product in accordance with the Specifications or credit Navidea for such defective product shall be Navidea's sole and exclusive remedy under this agreement for Defective Product and is in lieu of any other warranty, express or implied.

5 . 3 <u>Supply of Material for Replacement Product</u>. In the event OsoBio replaces Defective Product pursuant to Section 5.2, above, Navidea shall supply OsoBio with sufficient quantities of the API at its sole cost as necessary for OsoBio complete such replacement, notwithstanding Liability in Section 16.1.

ARTICLE 6 DELIVERY

- 6.1 <u>Delivery.</u> OsoBio shall tender the Product for shipment, F.C.A. (Incoterms 2010) the Facility promptly following the Release of Product to Navidea. Risk of loss or damage to the Product shall remain with OsoBio until the Product is loaded on the carrier's vehicle at the Facility, whereupon title and risk of loss or damage shall transfer to Navidea. Navidea shall be responsible for all costs associated with shipment of the Product. Navidea shall designate carriers to ship the Product and then designate the priority of such qualified carriers to OsoBio.
- 6 . 2 Failure to Take Delivery. If Navidea or its designated agent fails to take delivery by the scheduled delivery date, or within 2 weeks of OsoBio's release to Navidea, whichever is later, Navidea shall be invoiced on the last day of each month for the stored Product and reasonable administration and storage costs. For each such Batch, or portion of a Batch, of undelivered Product, Navidea agrees that: (i) Navidea has made a fixed commitment to purchase such Product, (ii) risk of ownership for such Product passes to Navidea, (iii) such Product shall be on a bill and hold basis for legitimate business purposes, (iv) if no delivery date is determined at the time of billing, OsoBio shall have the right to ship the Product to Navidea within four months after billing, and (v) Navidea will be responsible for any decrease in market value of such Product that relates to factors and circumstances outside of OsoBio's control. Within five (5) days following a written request from OsoBio, Navidea shall provide OsoBio with a letter confirming items (i) through (v) of this Section for each Batch of undelivered Product.

ARTICLE 7 PRICING AND PAYMENT

7.1 <u>Pricing.</u> Navidea shall pay to OsoBio the unit pricing set forth on <u>Exhibit B</u> ("Unit Pricing") for all Product. In addition, Navidea shall pay OsoBio for certain regulatory support services as set forth on <u>Exhibit B</u>. In the event Navidea requests any other services, OsoBio shall provide a written quote of the fee for such additional services and Navidea shall advise OsoBio whether it wishes to have such additional services performed by OsoBio.

- Price Increase. OsoBio may implement an increase in the Unit Pricing for the Product once annually in accordance with the total percentage change in the Producer Price Index, Pharmaceutical Preparations (Series ID PCU325412325412) as published by the U.S. Department of Labor, Bureau of Labor Statistics ("PPI") over the twelve (12) month period preceding the date of such price increase, provided, however that, notwithstanding the actual change in the PPI, if OsoBio's cost for any Raw Material changes by more than five percent (5%), OsoBio shall modify the Unit Pricing to account for such cost differential. In the event of an increase tied to a change in OsoBio's cost of Raw Materials, OsoBio shall provide Navidea copies of invoices evidencing the increased cost of such Raw Materials. Notwithstanding the foregoing, OsoBio shall not increase the Unit Price more frequently than once in any twelve (12) month period and may not increase the Unit Price for any undelivered Product that is the subject of a Purchase Order issued within the preceding twelve (12) months.
- 7 . 3 <u>Taxes; Duty.</u> All taxes, duties and other amounts assessed on the Raw Materials, API or the Product prior to or upon sale to Navidea are the responsibility of Navidea, and Navidea shall reimburse OsoBio for any such taxes, duties or other expenses paid by OsoBio.
- 7.4 <u>Product Approval</u>. Notwithstanding the terms set forth above, Navidea shall use its commercially reasonable efforts to expedite and obtain all regulatory approvals necessary for OsoBio to commence production at the Facility ("Regulatory Approvals").
- 7.5 <u>Payment Terms.</u> OsoBio shall invoice Navidea for all Product upon shipment of the Product pursuant to Section 6.1, and payment for such invoices shall be due within thirty (30) days after the date of such invoice. Each such invoice shall, to the extent applicable, identify the Purchase Order number, quantities, Unit Price, freight charges, and the total amount to be remitted by Navidea. Navidea shall pay all undisputed invoices within 30 days of the date of the invoice. Any undisputed amounts not paid by Navidea when due under this Agreement, shall accrue interest at the rate of one and one-half percent (1½%) per month until paid in full.

ARTICLE 8 CHANGES TO SPECIFICATIONS

All Specifications and any changes thereto agreed to by the parties from time to time shall be in writing, dated and signed by the parties. No change in the Specifications shall be implemented by OsoBio, whether requested by Navidea or required by any Regulatory Authority, until the parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in fees associated with such change. OsoBio shall respond promptly to any request made by Navidea for a change in the Specifications, and both parties shall use commercially reasonable, good faith efforts to agree to the terms of such change in a timely manner. As soon as possible after a request is made for any change in Specifications, OsoBio shall notify Navidea of the fees associated with such change. Navidea shall pay all fees associated with such agreed upon changes.

ARTICLE 9 QUALITY & REGULATORY MATTERS

9.1 <u>Quality Agreement</u>. This Agreement hereby incorporates the Quality Agreement between OsoBio and Navidea dated 11 April, 2013 as attached to this Agreement as <u>Exhibit C</u>. The Quality Agreement shall in no way determine liability or financial responsibility of the parties for the responsibilities set forth therein. In the event of a conflict between the terms of this Agreement and the Quality Agreement, this Agreement shall control except with respect to matters relating to compliance with GMPs and related regulations, in which case, the Quality Agreement will control.

- 9.2 <u>Regulatory Compliance</u>. Navidea shall be solely responsible for all permits and licenses required by any Regulatory Authority with respect to the Product under this Agreement, including any product licenses, applications and amendments in connection therewith. OsoBio will be responsible to maintain all permits and licenses required by any Regulatory Authority with respect to the Facility or the Processing of the Product. Each party intends and commits to cooperate to satisfy all Applicable Laws relating to their activities under this Agreement.
- 9.3 Regulatory Authority Inspection. OsoBio hereby agrees to advise Navidea promptly, but not later than within two business days, of any proposed or, scheduled or unannounced inspection of the Product or Processing by any Regulatory Authority and will, to the extent not prohibited by Applicable Law, permit Navidea to be present during any such inspection. If Navidea is not present during such an inspection, OsoBio shall promptly provide a report of the results of the inspection to Navidea.
- Audit. Navidea or its designated representative shall have the right during normal business hours, and upon reasonable notice to OsoBio, to inspect and audit in a reasonable manner those portions of the Facilities in which Processing is conducted in order to ensure OsoBio's compliance with its obligations under this Agreement.
- Recall. In the event OsoBio believes a recall, field alert, Product withdrawal or field correction may be necessary with respect to any Product provided under this Agreement, OsoBio shall immediately notify Navidea in writing. OsoBio will not act to initiate a recall, field alert, Product withdrawal or field correction without the express prior written approval of Navidea, unless otherwise required by Applicable Laws or upon advice of legal counsel. In the event Navidea believes a recall, field alert, Product withdrawal or field correction may be necessary with respect to any Product provided under this Agreement, Navidea shall immediately notify OsoBio in writing and OsoBio shall provide all necessary cooperation and assistance to Navidea. Navidea shall bear the cost of, and shall reimburse OsoBio for expenses incurred in connection with, any recall, field alert, Product withdrawal or field correction related to the Product unless such recall, field alert, Product withdrawal or field correction is caused primarily by OsoBio's breach of its obligations under this Agreement or Applicable Laws or its negligence or willful misconduct, in which case, such cost shall be borne by OsoBio. For purposes hereof, such cost shall be limited to reasonable, actual and documented administrative costs incurred by Navidea for such recall, withdrawal or correction, and replacement of the Defective Product to be recalled, in accordance with Article 5.

ARTICLE 10 REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 <u>OsoBio</u>. OsoBio represents, warrants and covenants to Navidea that:

- A. At the time of delivery of the Product as provided in Section 6.1, such Product will conform to and will have been Processed in conformance with the Specifications and Applicable Laws.
- B. It has all necessary authority and all right, title and interest in and to any Intellectual Property necessary to Process the Product or that is otherwise required to perform its obligations under this Agreement.
- C. It will comply with the Quality Agreement and all Applicable Laws during its performance under this Agreement and its use of any materials or API provided by Navidea under this Agreement.
- D. It will obtain and maintain for each Facility all permits, licenses and approvals required for OsoBio to Process and supply all Products in compliance with the terms of this Agreement and all Applicable Laws.
- E. It will not ship the Product if the batch record for a particular Batch of Product indicates that the Product does not comply with the Specifications or Applicable Laws, or if the Product has expired.
- F. Prior to releasing any Batch of Product, it will review all Product specific validation records and confirm that the Product is in compliance with Applicable Laws.
- G. All Products delivered to Navidea shall (1) **comply with the specifications and be produced in accordance with current Good Manufacturing Practices**; (2) be free and clear of any and all encumbrances, liens, security interests or other third party claims; and (3) not be adulterated or misbranded within the meaning of the U.S. Food, Drug and Cosmetic Act or any similar law or regulation of applicable Regulatory Authorities.
- H. It has not been debarred by the FDA or other Regulatory Authorities, and has not been convicted of a crime that could lead to such debarment.
- I. It will not employ, contract with or retain any person directly or indirectly to perform services under this Agreement if such a person is debarred by the FDA under 21 U.S.C. § 335(a) or disqualified as described in 21 C.F.R. §312.170. In the event that OsoBio becomes aware of or receive notice of the debarment or disqualification of any person providing services to under this Agreement, then OsoBio agrees to notify Navidea immediately.
- 10.2 <u>Navidea</u>. Navidea represents and warrants to OsoBio that:
- A. The Navidea-supplied API will comply with all applicable Specifications, will have been produced in compliance with the Applicable Laws;
- B. It has all necessary authority and all right, title and interest in and to any Intellectual Property related to each Product or that is otherwise required to perform its obligations under this Agreement;

- C. All artwork and packaging provided by Navidea to OsoBio under Section 3.3 shall comply with all Applicable Laws;
- D. It has provided all safe handling instructions, health and environmental information and material safety data sheets applicable to the Product or to the API, except as disclosed to OsoBio in writing by Navidea in sufficient time for review and training by OsoBio prior to delivery;
- E. All Product delivered to Navidea by OsoBio will be held, used and/or disposed of by Navidea in accordance with all Applicable Laws; and
- F. It will comply with all Applicable Laws applicable to Navidea's performance under this Agreement and its use of any materials or Products provided by OsoBio under this Agreement.
- G. It will not release the Product if the batch record for a particular Batch of Product indicates that the Product does not comply with the Specifications or Applicable Laws.
- H. Prior to releasing any Batch of Product, it will review all Product specific validation records and confirm that the Product is in compliance with Applicable Laws.
- 10.3 <u>Mutual</u>. Each party hereby represents and warrants to the other party that:
- A. <u>Existence and Power.</u> Such party (1) is duly organized, validly existing and in good standing under the laws of the state in which it is organized, (2) has the power and authority and the legal right to own and operate its property and assets, and to carry on its business as it is now being conducted, and (3) is in compliance with all requirements of Applicable Laws, except to the extent that any noncompliance would not materially adversely affect such party's ability to perform its obligations under the Agreement;
- B. <u>Authorization and Enforcement of Obligations</u>. Such party (1) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (2) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder.
- C. <u>Execution and Delivery</u>. This Agreement has been duly executed and delivered on behalf of such party, and constitutes a legal, valid, binding obligation, enforceable against such party in accordance with its terms;
- D . <u>No Consents.</u> All necessary consents, approvals and authorizations of all Regulatory Authorities and other persons required to be obtained by such party in connection with the Agreement have been obtained; and
- E. <u>No Conflict</u>. The execution and delivery of this Agreement and the performance of such party's obligations hereunder (1) do not conflict with or violate any requirement of Applicable Laws; and (2) do not materially conflict with, or constitute a material default or require any consent under, any material contractual obligation of such party.

10.4 <u>Limitations</u>. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE 10 ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 11 CONFIDENTIAL INFORMATION

- Mutual Obligation. OsoBio and Navidea agree that they will not disclose the other party's Confidential Information (defined below) to any third party without the prior written consent of the other party except as required by law, regulation or court or administrative order (including without limitation the Securities Act of 1933, the Securities Exchange Act of 1934, and the regulations promulgated thereunder); provided, however, that prior to making any such legally required disclosure, the party making such disclosure shall give the other party as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances. Notwithstanding the foregoing, each party may disclose the other party's Confidential Information to any of its Affiliates that (A) need to know such Confidential Information for the purpose of performing under this Agreement, (B) are advised of the contents of this Article, and (C) agree to be bound by the terms of this Article. Each receiving party shall use the disclosing party's Confidential Information solely for the purpose of carrying out the receiving party's obligations under this Agreement.
- 11.2 <u>Definition.</u> As used in this Agreement, the term "Confidential Information" includes all such information furnished by OsoBio or Navidea, or any of their respective representatives or Affiliates, to the other or its representatives or Affiliates, whether furnished before, on or after the date of this Agreement and furnished in any form, including but not limited to written, verbal, visual, electronic or in any other media or manner. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other Intellectual Property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either party, or any of their respective representatives, containing or based in whole or in part on any such information furnished by the other party or its representatives. Notwithstanding the foregoing, Navidea Confidential Information shall include the Process, all Master Batch Records, and all Production Batch Records related to the manufacture and release of the Product. Confidential Information also includes the existence of this Agreement and its terms, provided that Navidea may disclose the existence of this Agreement and its terms to a third party and/or the third party's advisors in connection with an investment in Navidea, acquisition of or merger with Navidea, loan to Navidea, licensing transaction related to the Product or other commercial agreement related to the sale, marketing or distribution of the Product, provided that Navidea requires said third party to enter into a confidentiality agreement on terms no less restrictive than those contained herein and that Navidea also remains responsible for any disclosure by said third party.

- 1 1 . 3 <u>Exclusions</u>. Notwithstanding Section 11.2, Confidential Information does not include information that (A) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, or (B) is already known by the receiving party at the time of disclosure as evidenced by the receiving party's written records, or (C) becomes available to the receiving party on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis, or (D) was or is independently developed by or for the receiving party without reference to the Confidential Information, as evidenced by the receiving party's written records.
- 11.4 <u>No Implied License</u>. The receiving party will obtain no right of any kind or license under any Intellectual Property rights of a disclosing party by reason of this Agreement. All Confidential Information will remain the sole property of the party disclosing such information or data.
- Return of Confidential Information. Upon termination of this Agreement, the receiving party shall, upon request, promptly return within thirty (30) days all such information, including any copies thereof, and cease its use or, at the request of the disclosing party, shall promptly destroy the same and certify such destruction to the disclosing party; except for a single copy thereof, which may be retained for the sole purpose of determining the scope of the obligations incurred under this Agreement.
- 11.6 Survival. The obligations of this Article 11 will terminate five (5) years from the expiration of this Agreement.

ARTICLE 12 INTELLECTUAL PROPERTY

12.1 Rights in Materials. All OsoBio Materials, including without limitation, all improvements, developments, derivatives or modifications to the OsoBio Materials, shall be owned exclusively by OsoBio. All Navidea Materials, including, without limitation, all improvements, developments, derivatives or modifications to the Navidea Materials shall be owned exclusively by Navidea. For purposes hereof, "OsoBio Materials" means all OsoBio proprietary information, intellectual property, and developments (including, all patents, patent applications, know-how, inventions, designs, concepts, improvements, technical information, manuals, instructions or specifications), owned, licensed or used by OsoBio in developing, formulating, manufacturing, filling, processing or packaging of liquid solutions or pharmaceuticals and the packaging equipment, processes or methods of packaging, or any improvements to any of the foregoing, including any container, pouch, vial, ampoule or other form of liquid container developed by OsoBio. For purposes hereof, "Navidea Materials" means all proprietary information, intellectual property and developments owned, developed, licensed or used by Navidea relating to the API and Product, including, without limitation, patents, patent applications, know-how, inventions, designs, concepts, improvements, technical information, trademarks or trade names.

12.2 <u>Inventions</u>. If OsoBio or its agents or employees make any invention, improvement or modification (whether or not patentable) to the Product or the use thereof (exclusive of methods of Processing) in the course of providing services under this Agreement, OsoBio shall promptly disclose such invention, improvement or modification to Navidea and assign and/or cause its agents or employees to assign all rights, title and interest in such invention, improvement or modification to Navidea. OsoBio shall execute such further documents and take such further actions as are reasonable or necessary to fully vest in Navidea such rights, title and interest.

ARTICLE 13 INDEMNIFICATION

- 13.1 <u>Indemnification by OsoBio</u>. **Subject to the limitation of liability provisions of Section 16,** OsoBio shall indemnify and hold harmless Navidea, its Affiliates, and their respective directors, officers, employees and agents ("Navidea Indemnitees") from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees) in connection with any suit, demand or action by any third party ("Losses") arising out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement or (B) any gross negligence or willful misconduct by OsoBio, except to the extent that any of the foregoing arises out of or results from any Navidea Indemnitee's negligence, willful misconduct or breach of this Agreement.
- 13.2 <u>Indemnification by Navidea</u>. Navidea shall indemnify and hold harmless OsoBio, its Affiliates, and their respective directors, officers, employees and agents ("OsoBio Indemnitees") from and against all Losses arising out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement; (B) any manufacture, sale, promotion, distribution, use of or exposure to the Product or any Navidea-supplied API, or third-party sourced diluent, incorporated into the Product including, without limitation, product liability or strict liability; (C) Navidea's exercise of control over the Processing of the Product to the extent that Navidea's instructions or directions violate Applicable Law; (D) any actual or alleged infringement or violation by the API or Product of any third party Intellectual Property rights provided by Navidea; or (F) any gross negligence or willful misconduct by Navidea, except to the extent that any of the foregoing arises out of or results from any OsoBio Indemnitee's gross negligence, willful misconduct or breach of this Agreement.
- 1 3 . 3 <u>Indemnification Procedures.</u> All indemnification obligations in this Agreement are conditioned upon the party seeking indemnification: (A) promptly notifying the indemnifying party of any claim or liability of which the party seeking indemnification becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, however, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying party of any of its obligations hereunder except to the extent the indemnifying party is prejudiced by such failure; and (B) reasonably cooperating with the indemnifying party in the defense of any such claim or liability (at the indemnifying party's expense). The indemnifying party may, in its sole discretion, assume and conduct the legal defense of the indemnified person in, and the settlement of, any suit that could result in claims under this Section 13.3; provided, however, that the indemnifying party will not, in defense of any such suit, except with the consent of the indemnified person, consent to the entry of any judgment or enter into any settlement which does not include, as an unconditional term thereof, the giving by the claimant or plaintiff to the indemnified person of a release from all liability in respect thereof. If the indemnifying party assumes the defense and settlement of a suit, the indemnified person may elect to participate in, but not control, such defense and settlement through counsel of its choosing and at its own expense.

ARTICLE 14 INSURANCE

During the Term, each party shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance: (i) with respect to OsoBio only, Commercial General Liability insurance with per-occurrence and general aggregate limits of not less than [*]; (ii) Products and Completed Operations Liability Insurance with per-occurrence and general aggregate limits of not less than [*]; (iii) Workers' Compensation and Employer's Liability Insurance with statutory limits for Workers' Compensation and Employer's Liability insurance limits of not less than [*]; (iv) with respect to OsoBio only, Professional Services Errors & Omissions Liability Insurance with per claim and aggregate limits of not less than [*] covering sums that OsoBio becomes legally obligated to pay as damages resulting from claims made by Navidea for errors or omissions committed in the conduct of the services outlined in the Agreement; and (v) with respect to Navidea only, All Risk Property Insurance, including transit coverage, in an amount equal to full replacement value covering Navidea's property while it is at the Facility. In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire Term and for a period of not less than three (3) years following the termination or expiration of this Agreement. Upon request of a party, the other party shall furnish evidence of insurance for the above noted policies applicable to such other party. Each insurance policy that is required under this Article 14 shall be obtained from an insurance carrier with an A.M. Best rating of at least A- VII.

ARTICLE 15 TERM AND TERMINATION

1 5 . 1 Term. This Agreement shall commence on the Effective Date and shall continue until December 31, 2016, unless earlier terminated under Section 15.2 below (the "Term"). After December 31, 2016, this Agreement shall automatically renew for additional two (2) year periods, unless written notice of intent to cancel the agreement is provided by either party at least twelve (12) months prior to the expiration of the initial term or any.

15.2 <u>Termination by Either Party.</u>

(a) <u>Material Breach</u>. Either party may terminate this Agreement effective upon sixty (60) days prior written notice to the other party, if the other party commits a material breach of this Agreement and fails to cure such breach by the end of such sixty (60) day period; provided, however, that failure to pay all undisputed invoices under this Agreement within ninety (90) days after such payments are due (as set forth in Section 8.5) shall constitute cause for immediate termination of this Agreement, or at OsoBio's discretion, OsoBio shall be relieved of any further obligation to perform under this Agreement until all outstanding payments are brought current.

- (b) <u>Bankruptcy</u>. Either party may terminate this Agreement effective upon written notice to the other party, if the other party becomes insolvent or admits in writing its inability to pay its debts as they become due, files a petition for bankruptcy, makes an assignment for the benefit of its creditors or has a receiver, trustee or other court officer appointed for its properties or assets.
- 15.3 <u>Duties Upon Termination</u>. In the event of any termination, other than a termination by either party as a result of a material breach by the other, OsoBio shall complete delivery of any Product in accordance with any Purchase Order open as of the date notice of termination is given hereunder. In the event of any termination, OsoBio shall promptly, after completion of any deliveries required by the immediately preceding sentence, return to Navidea (i) any remaining inventory of API or other materials received from Navidea or Navidea's suppliers, (ii) all packaging components paid for by Navidea, (iii) all remaining inventories of the Product; and (iv) any Product or material being stored for Navidea, at Navidea's expense. OsoBio shall have no obligation to return the foregoing until all outstanding invoices to Navidea have been paid in full.

ARTICLE 16 LIMITATIONS OF LIABILITY

- 16.1 OSOBIO'S LIABILITY FOR ANY AND ALL CLAIMS FOR LOST, DAMAGED OR DESTROYED API OR OTHER NAVIDEA-SUPPLIED MATERIALS, WHETHER OR NOT SUCH API OR NAVIDEA-SUPPLIED MATERIALS ARE INCORPORATED INTO FINISHED PRODUCT OR DEFECTIVE PRODUCT SHALL BE LIMITED TO [*].
- 16.2 OSOBIO'S TOTAL LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED THE TOTAL FEES PAID BY NAVIDEA TO OSOBIO FOR THE SERVICES OR BATCH OF PRODUCT GIVING RISE TO SUCH LIABILITIES, CLAIMS, OR OBLIGATIONS.
- 16.3 NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL LOSSES, DAMAGES, COSTS OR EXPENSES OF ANY NATURE WHATSOEVER ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION, LOSS OF REVENUES, PROFITS OR DATA, OR PENALTIES ARISING UNDER THIRD PARTY CONTRACTS, WHETHER IN CONTRACT OR TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 16.3 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER ARTICLE 13, OR DAMAGES AVAILABLE FOR BREACHES OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 11.

ARTICLE 17 NOTICE

All notices and other communications hereunder shall be in writing and shall be deemed given: (A) when delivered personally; (B) when delivered by facsimile transmission (receipt verified); (C) when received or refused, if mailed by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered if sent by express courier service,

to the parties at the following addresses (or at such other address for a party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof):

To Navidea: Navidea Biopharmaceuticals, Inc.

425 Metro Place North, Suite 450

Dublin, OH 43017 Attn.: President

Facsimile: (614) 793-7522

With a copy to: Navidea Biopharmaceuticals, Inc.

425 Metro Place North, Suite 450

Dublin, OH 43017 Attn.: CFO

Facsimile: (614) 793-7522

To OsoBio: OSO BioPharmaceuticals Manufacturing, LLC

4401 Alexander Blvd. NE Albuquerque, NM 87107 Attn: President/CEO Facsimile: (505) 923-1611

With a copy to: OSO BioPharmaceuticals Manufacturing, LLC

4401 Alexander Blvd. NE Albuquerque, NM 87107 Attn: Contracts Manager Facsimile: (505) 923-1611

ARTICLE 18 MISCELLANEOUS

1 8 . 1 <u>Entire Agreement; Amendments</u>. This Agreement, including the attachments, Project Plans and any amendments thereto, constitutes the entire understanding between the parties and supersede any contracts, agreements or understanding (oral or written) of the parties with respect to the subject matter hereof. No term of this Agreement may be amended or modified except upon written agreement signed by a duly authorized officer of each party, unless otherwise expressly provided in this Agreement.

- 18.2 <u>Captions</u>. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement
- 18.3 <u>Further Assurances</u>. The parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.
- 18.4 <u>No Waiver</u>. Failure by either party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.
- 1 8 . 5 <u>Severability</u>. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.
- 18.6 <u>Independent Contractors</u>. The relationship of the parties is that of independent contractors, and neither party will incur any debts or make any commitments for the other party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the parties the relationship of joint ventures, co-partners, employer/employee or principal and agent.
- 18.7 <u>Successors and Assigns.</u> This Agreement will be binding upon and inure to the benefit of the parties, their successors and permitted assigns. Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other party, except that either party may, without the other party's consent, assign this Agreement to an Affiliate or to a successor to substantially all of the business or assets of the assigning company.
- 18.8 <u>Governing Law.</u> This Agreement shall be governed by and construed under the laws of the State of Delaware, excluding its conflicts of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.
- 18.9 Alternative Dispute Resolution. If any dispute arises between the parties relating to this Agreement, including the breach, termination or validity thereof ("Dispute"), such Dispute shall be presented to the respective presidents or senior executives of OsoBio and Navidea for their consideration and resolution. All negotiations pursuant to the preceding sentence will be confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. If such parties cannot reach a resolution of the Dispute, then such Dispute shall be finally resolved by binding alternative dispute resolution in accordance with the then existing Rules for Non-Administered Arbitration of the CPR Institute for Dispute Resolution, 366 Madison Avenue, New York, NY 10017 ("CPR Rules") by three independent and impartial arbitrators, of whom each party shall designate one, with the third arbitrator appointed as provided in the CPR Rules. The arbitration shall be governed by the Federal Arbitration Act, 9 U.S.C. §§1 et seq. and judgment upon the award rendered by the arbitrator(s) may be entered by any court having jurisdiction thereof, subject, however, to the right of a party to appeal such award under the CPR Arbitration Appeal Procedure. .. Arbitration shall be conducted in the jurisdiction of the defendant party. Each party is required to continue to perform its obligations under this Agreement pending final resolution of any dispute arising out of or relating to this Agreement, unless to do so would be impossible or impracticable under the circumstances, and provided that the provisions of this Section 18.9 shall not be deemed to be a waiver of any right of termination under Section 15.2. Notwithstanding anything in this Section 18.9 to the contrary, the parties shall be entitled to seek at any time during a Dispute injunctive relief or other equitable remedies with respect to any Dispute from any court of competent jurisdiction.

- 18.10 <u>Prevailing Party.</u> In any dispute resolution proceeding between the parties in connection with this Agreement, tribunal shall have the authority to award and apportion costs, including reasonable attorneys' fees and other costs incurred by the parties, taking into account the circumstances of the case, the conduct of the parties during the proceeding, and the result.
- 18.11 <u>Counterparts.</u> This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.
- 18.12 <u>Publicity.</u> Neither party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other party's express prior written consent, except as required under applicable law or by any governmental agency, in which case the party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.
- 18.13 <u>Survival</u>. The rights and obligations of the parties under Articles 11 (Confidential Information), 12 (Intellectual Property), 13 (Indemnification), 14 (Insurance) to the extent expressly stated therein, 16 (Limitations of Liability), 17 (Notice), 18 (Miscellaneous), and Section 15.3 (Duties Upon Termination), shall continue notwithstanding expiration or termination of this Agreement.
- 18.15 <u>Force Majeure</u>. Except as to payments required under this Agreement, neither party shall be liable in damages for, nor shall this Agreement be terminable or cancelable (except as provided in this Section 18.15) by reason of, any delay or default in such party's performance hereunder, if such default or delay is caused by events beyond such party's reasonable control including, but not limited to, acts of God, regulation or law or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or storm, labor disturbances, epidemic, or failure of suppliers, public utilities or common carriers; provided however, that the party seeking relief hereunder shall promptly notify the other party of such cause(s). A party that invokes this section shall use all commercially reasonable endeavors to reinstate its ongoing obligations to the other; provided that if the cause(s) shall continue unabated for one hundred eighty (180) days, then the party that has not invoked this Section to excuse its delay or nonperformance may terminate this Agreement, subject to the duties set forth in Section 15.3.

18.16 <u>No Strict Construction.</u> The language used in this Agreement will be deemed to be the language chosen by the parties to express their mutual intent, and no rules of strict construction will be applied against any party.

IN WITNESS WHEREOF, the parties have caused their duly authorized representative to execute this Agreement effective as of the date first written above.

OsoBio		Navidea	
OSO	BioPharmaceuticals Manufacturing, LLC	Navidea Biopharmaceuticals, Inc.	
By:	/s/ Milton Boyer	By: /s/ Brent L. Larson	
Name	: Milton Boyer	Name: Brent L. Larson	
Its:	President	Its: EVP & CFO	
		•	

 $\underline{Confidential\ Treatment} - Asterisked\ material\ has\ been\ omitted\ and\ filed\ separately\ with\ the\ Securities\ and\ Exchange\ Commission\ pursuant\ to\ a\ request\ for\ confidential\ treatment.$

EXHIBIT A SPECIFICATIONS

SPECIFICATION FOR LYMPHOSEEK VIAL, 250MCG

Characteristic	Specification (Limits)	Test Method
[*]	[*]	[*]
[*]	[*]	<u>[*]</u>
[*]	[*]	<u>[*]</u>
[*]	[*]	[*]
[*]	*	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*] [*] [*] [*] [*] [*] [*]
[*]	[*]	[*]
[*]	[*]	[*]
	[*] [*] [*] [*] [*] [*] [*] [*] [*] [*]	[*] [*]
		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*] [*] [*] [*]	[*] [*] [*]	[*] [*] [*]
[*]	<u> *</u>	<u>[*]</u>
a raa		
^a <u>[*]</u> <u>b [*]</u>		
<u>v [*]</u>		
<u>c</u> _[*]		
<u>d</u> [*]		
	22	

 $\underline{Confidential\ Treatment} - Asterisked\ material\ has\ been\ omitted\ and\ filed\ separately\ with\ the\ Securities\ and\ Exchange\ Commission\ pursuant\ to\ a\ request\ for\ confidential\ treatment.$

EXHIBIT B UNIT PRICING, FEES

UNIT PRICING				
Product	Dosage Form	Initial Unit Price		
Lymphoseek Vial, 250mcg	Lyophilized, multi-dose vial	<u>[*]</u> 1		
¹ Unit pricing is based upon a [*] unit Batch	size			
	ADDITIONAL FEES			
Annual Product Maintenance Fee Includes: Annual Product Reviews Copies of Documents (Routine – Batch respecific) Notification of Updates to Drug Master In Product Licenses Navidea Complaints Does not Include: Rest of World (ROW) filings or additions CMC Services after 1st filing All additional countries Additional Annual filings with respect to changes to fee initiated or required by Navidea Labeling Changes requested by Navidea	File (DMF) al countries after 1st filing al, CBE or Prior Approval acilities and equipment	Payable upon the Effective Date and once annually, on the anniversary date of this Agreement and continuing following termination of this Agreement until all Product Processed under this Agreement has expired.		
Items excluded will be billed @ [*] to [*] pe	r hour plus any actual external or material	resources and mutually agreed and approved in		

writing by both parties.

EXHIBIT C FORM OF QUALITY AGREEMENT

(To be appended upon execution of QAA for execution copies of Supply Agreement)

EXHIBIT D

STATEMENT OF COMPLIANCE FOR MINIMUM QUANITIES OF LYMPLHOSEEK SOURCED BY NAVIDEA BIOPHARMACEUTICALS, INC.

The quantities purchased in calendar year 20_ represent a minimum of [*] of the annual requirements of Product purchased by avidea from all sources.
igned:
Jame:
litle:
Pate:
25