Exhibit 10.1

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

**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.

1. OsoBio provides contract pharmaceutical development, manufacturing, packaging, analytical, and sales and marketing services to the pharmaceutical industry.
2. 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.
3. 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. "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.
2. “API” means the active pharmaceutical ingredient used in the manufacture of the Product.
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”).



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1. "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.
2. "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.
3. “Calendar Year” means the period from January 1 to December 31 of each year.
4. “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.
5. “Change Order” shall have the meaning set forth in Section 4.5(a).
6. “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.
7. "Confidential Information" is as defined in Section 11.2.
8. “Contract Year” means each consecutive twelve (12) month period beginning on the Commencement Date.
9. “Navidea Materials” shall have the meaning set forth in Article 12.
10. “Defective Product” shall have the meaning set forth in Section 5.2.
11. “Delayed Approval Fee” shall have the meaning set forth in Section 7.4.
12. “Dispute” shall have the meaning set forth in Section 18.9.
13. "Effective Date" means the date this Agreement was fully executed.
14. “Facilities” means OsoBio’s facilities located in Albuquerque, New Mexico, as set forth below:

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**Manufacturing and Microbial Testing:** **Inspection, Testing, Packaging and Storage:**

4272 Balloon Park Rd NE 4401 Alexander Blvd NE

Albuquerque, NM 87109 Albuquerque, NM 87107

**Analytical Testing:** **Stability Testing:**

4200 Balloon Park Rd NE Not applicable to OsoBio.

Albuquerque, NM 87109

[\*]

1. “FDA” means the United States Food and Drug Administration, and any successor agency thereto.
2. “Firm Commitment” shall have the meaning set forth in Section 4.2.
3. “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.
4. “Minimum Requirement” shall have the meaning set forth in Section 4.1.
5. “OsoBio Materials” shall have the meaning set forth in Article 12.
6. "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.
7. "Processing Date" means the day on which the Product is to be first Processed by OsoBio.
8. “Product" means the product identified by the Specifications which may include unlabeled lyophilized vialed product and labeled kits of finished Lymphoseek® product.
9. “Purchase Order” shall have the meaning set forth in Section 4.3.
10. “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.
11. “Regulatory Approval” shall have the meaning set forth in Section 7.4.
12. "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.

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1. “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.
2. “Review Period” shall have the meaning set forth in Section 5.1.
3. “Rolling Forecast” shall have the meaning set forth in Section 4.2.
4. “Sample” shall have the meaning set forth in Section 5.1.
5. “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.
6. "Term" shall have the meaning set forth in Section 15.1.
7. “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.
8. “Unit Pricing" shall have the meaning set forth in Section 7.1.
9. “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**

1. Validation Services. OsoBio shall perform the qualification, validation and stability services described in Exhibit A, and Exhibit B of this Agreement.

2 . 2 Supply and Purchase of Product. 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.

1. Other Related Services. OsoBio shall provide other services upon terms and conditions agreed to by the parties in writing from time to time.

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**ARTICLE 3**

**MATERIALS**

3.1 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 Raw Materials. 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 Reimbursement for Materials. 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.

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