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) August 16, 2013

NAVIDEA BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-35076	31-1080091
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer 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 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 (see General Instruction A.2. below):

☐ 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))

Item 1.01. Entry into a Material Definitive Agreement.

On August 16, 2013, Navidea Biopharmaceuticals, Inc. (the "Company") entered into a manufacturing services agreement (the "Services Agreement") with PETNET Solutions, Inc. ("PETNET"). Pursuant to the terms of the Services Agreement, PETNET will provide manufacturing and distribution services for the Company's product, 2-[2-(fluoro-18F)-6-(methylamino)-3-pyridinyl]-5-benzofuranol, identified as [18F]NAV4694 ("NAV4694"). Accordingly, PETNET will implement production processes and quality control methods for the preparation and testing of NAV4694. PETNET will also establish production equipment, quality control equipment, equipment qualification and standard operating procedures. In consideration for the manufacturing and distribution services, the Company will pay PETNET a technology transfer fee, site qualification and implementation fees, production fees, and infrastructure and equipment fees. NAV4694 is an investigational beta-amyloid PET imaging agent, which is currently being evaluated in Phase 2 and 3 clinical trials evaluating subjects with signs or symptoms of cognitive impairment such as Mild Cognitive Impairment and Alzheimer's disease.

The Services Agreement commenced on August 16, 2013, and will continue in effect for an initial term of three years (the "Initial Term"), unless earlier terminated as provided in the Services Agreement. Thereafter, the Services Agreement will automatically renew for additional one year terms, unless either party thereto gives written notice to the other at least sixty days prior to the end of the Initial Term, or any subsequent extension, that it wishes not to renew 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 8.01 Other Events.

On August 20, 2013, the Company issued a press release announcing that the Centers for Medicare & Medicaid Services (CMS) has issued a Healthcare Common Procedure Coding System (HCPCS) Pass-Through "C Code" for Lymphoseek (technetium Tc 99m tilmanocept) Injection. The Company anticipates that the billing code, which will become effective on October 1, 2013, will streamline the billing and reimbursement process for hospital providers who use Lymphoseek and support its fair and equitable reimbursement. Lymphoseek was approved by the U.S. Food and Drug Administration (the "FDA") in March, 2013, for use in lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma.

On August 21, 2013, the Company issued a press release announcing that it had signed the Services Agreement with PETNET, which grants PETNET the right to manufacture NAV4694 for the Company. Under the terms of the Services Agreement, PETNET will initially manufacture NAV4694 clinical trial material at select U.S. radiopharmacies, with the possibility of expanding into additional PETNET locations next year.

On August 21, 2013, the Company issued a second press release announcing the award of a Small Business Innovation Research (SBIR) grant from the National Institute On Aging (NIA) of the National Institutes of Health (NIH) in connection with the Company's Phase 3 clinical program for NAV4694. The SBIR grant has the potential to provide up to $1.8 million in support, if fully funded, through the conclusion of the Phase 3 clinical study. Funding for the approved first stage of the grant ($259,000) is intended to provide support for initiation activities of the Phase 3 clinical program. Funding of the second stage of the grant is contingent upon meeting specific aims related to the first stage of the grant, such as institutional review board approval of the Phase 3 protocol, clinical site contracting and investigator training. The Company announced the initiation of the Phase 3 program in June 2013.

On August 22, 2013, the Company issued a press release announcing that it has reached agreement with the FDA for two special protocol assessments (SPA) for the Company's pivotal Phase 3 program with NAV5001 as an aid in the differential diagnosis of Parkinsonian Syndromes from non-Parkinsonian tremor. NAV5001 is an investigational imaging agent used to visualize dopamine transporters (DAT) in the brain using single photon emission tomography (SPECT) imaging. The SPAs are written agreements between the Company, as the program's sponsor, and the FDA regarding the design, endpoints and statistical analysis for the two, pivotal Phase 3 clinical trials to be used in support of a potential NAV5001 New Drug Application. The international, open-label, pivotal NAV5001 Phase 3 program consists of two similar clinical trials that will run in parallel and enroll approximately 550 total subjects who exhibit early stage tremor. Each Phase 3 trial was the subject of a SPA with the FDA. The primary endpoint of both studies is to evaluate the relative diagnostic efficacy of the NAV5001 SPECT images compared with the diagnosis made by neurologists and that established by a consensus panel of three movement disorder specialists as the 'Standard of Truth'. In one study, each subject will undergo SPECT imaging with NAV5001 only. In the second study, subjects will undergo SPECT imaging with both NAV5001 and an alternative SPECT agent, ioflupane, in a cross-over comparison design

A copy of the complete text of the Company's August 20, 2013 press release, first August 21, 2013 press release, second August 21, 2013 press release, and August 22, 2013 press release, is attached as Exhibit 99.1, 99.2, 99.3, and 99.4, to this Current Report on Form 8-K, respectively, and each is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	*Exhibit Description*
10.1	Manufacturing Services Agreement, dated August 16, 2013, by and between Navidea Biopharmaceuticals, Inc. and PETNET Solutions, Inc. (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).
99.1	Navidea Biopharmaceuticals, Inc. press release dated August 20, 2013, entitled "Navidea Biopharmaceuticals Announces Centers for Medicare & Medicaid Services (CMS) Issuance of Lymphoseek® Reimbursement Pass-Through C Code, Effective as of October 1, 2013."
99.2	Navidea Biopharmaceuticals, Inc. press release dated August 21, 2013, entitled "Navidea Biopharmaceuticals Signs Manufacturing Agreement with Siemens' PETNET Solutions for NAV4694 Beta-amyloid Imaging Agent."
99.3	Navidea Biopharmaceuticals, Inc. press release dated August 21, 2013, entitled "Navidea Awarded NIH SBIR Grant for NAV4694 Beta-Amyloid Imaging Agent Phase 3 Clinical Program Aimed at Alzheimer's Disease."
99.4	Navidea Biopharmaceuticals, Inc. press release dated August 22, 2013, entitled "Navidea Biopharmaceuticals Announces Agreement with FDA on Special Protocol Assessments for NAV5001 Phase 3 Program."

The Private Securities Litigation Reform Act of 1995 (the Act) provides a safe harbor for forward-looking statements made by or on behalf of the Company. Statements contained or incorporated by reference in this Current Report on Form 8-K, which relate to other than strictly historical facts, such as statements about the Company's plans and strategies, expectations for future financial performance, new and existing products and technologies, anticipated clinical and regulatory pathways, and markets for the Company's products are forward-looking statements within the meaning of the Act. The words "believe," "expect," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date hereof. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, the Company's continuing operating losses, uncertainty of market acceptance of its products, reliance on third party manufacturers, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on limited product line and distribution channels, competition, limited marketing and manufacturing experience, risks of development of new products, regulatory risks and other risks detailed in the Company's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and other filings with the United States Securities and Exchange Commission. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

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: August 22, 2013

By:/s/ Brent L. Larson

Brent L. Larson, Executive Vice President and
Chief Financial Officer

Exhibit 10.1

Execution Copy

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

Between

Navidea Biopharmaceuticals, Inc.

And

PETNET Solutions, Inc.

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 (this "Agreement") is made as of this 16th day of August, 2013 (the "Effective Date") by and between Navidea Biopharmaceuticals, Inc., a corporation organized under the laws of the State of Delaware, with its principal place of business at 425 Metro Place North, Suite 450, Dublin, Ohio 43017-1367 ("NAVIDEA") and PETNET Solutions, Inc., a Tennessee corporation, having its principal place of business at 810 Innovation Drive, Knoxville, TN 37932 ("PETNET"). NAVIDEA and PETNET are referred to herein individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, PETNET is a leading company in the business of manufacturing and distributing radiopharmaceuticals, including radiopharmaceuticals used for positron emission tomography ("PET") imaging and individual unit dose radiopharmaceuticals through its network of radiopharmacies and cyclotron-based PET manufacturing facilities; and

WHEREAS, NAVIDEA is conducting Phase II and III human clinical trials to determine the drug safety and efficacy of the Product (as defined in Section 1.1 hereof) as specified under U.S. Food and Drug Administration ("FDA") regulations (collectively, the "Trials") at locations that perform PET imaging ("Authorized Trial Sites" as defined in Exhibit A), and in connection therewith desires PETNET to provide manufacturing and distribution services as more specifically set forth in the Scope of Work attached hereto as Exhibit A and made a part of this Agreement (the "SOW").

NOW, THEREFORE, in consideration of the mutual covenants hereinafter expressed, the Parties hereby agree as follows:

1. **Services**

1.1 Scope of Work

NAVIDEA has requested and PETNET has agreed to provide, from certain of the facilities listed in the SOW (the "Facilities") manufacturing and distribution services (the "Services") with respect to NAVIDEA'S product, 2-[2-(fluoro- ^{18}F)-6-(methylamino)-3-pyridinyl]-5-benzofuranol, identified as [^{18}F]NAV4694, as more particularly described in the SOW attached hereto (the "Product"). PETNET shall use commercially reasonable efforts to carry out the Services in a professional and workman-like manner, consistent with cGMP and/or industry standards for the manufacturing of PET products. All Products delivered by PETNET hereunder shall be manufactured in accordance with all applicable laws and regulations, including those promulgated by the FDA.

1.2 Personnel

Each Party shall assign a project manager to: (i) oversee performance of qualification activities; and (ii) be the primary contact person for communication between the Parties. PETNET will identify additional qualified personnel at each of the Facilities to assist in the aforementioned activities.

2. **Financial Terms**

2.1 Payment

PETNET will be paid for the Services performed in accordance with the terms of this Agreement, as set forth on Exhibit C (the "Financial Terms").

2.2 Changes

It is understood between both Parties that, during any project of this nature, unforeseen events may occur, including, but not limited to, termination of any further activity due to unacceptable results, significant reevaluation due to marginal results, changes in the scope or timing of any activity, or closure of PETNET Facilities. Either Party will promptly notify the other Party of any such unforeseen events before proceeding further with the rendering of the Services. Both Parties agree that changes, including any changes in costs, will be described in writing, and that the approval of each revision is required by both Parties before proceeding.

3. **Invoicing & Payment**

3.1 Invoicing and Payment Terms

PETNET shall invoice NAVIDEA for the Technology Transfer Fee and Site Qualification Fees according to the Payment Schedule set forth in Exhibit C and monthly for all Production Fees for Product produced and delivered to NAVIDEA hereunder as set forth in the Financial Terms. NAVIDEA shall pay all amounts on invoices duly issued by PETNET under this Agreement within thirty (30) days after receipt thereof. All invoices and payments required to be paid hereunder shall be in U.S. Dollars.

Invoices shall be sent to the following address:

Navidea Biopharmaceuticals, Inc.
425 Metro Place North, Suite 450
Dublin, OH 43017-1367

Attn: Accounts Payable

accountspayable@navidea.com

3.2 Late Payments

A service charge of one and one-half percent (1 ½%) per month shall be charged by PETNET on any portion of NAVIDEA's outstanding balance that is not paid by the due date. In the event that NAVIDEA's invoices remain past due in excess of 30 days, or if PETNET otherwise reasonably deems itself insecure, PETNET will no longer be required to extend such payment terms. Without limiting its other remedies, PETNET may require cash terms and/or other assurances of payment, and/or may suspend service to NAVIDEA until such time as all NAVIDEA invoices are paid in full.

4. **Production and Delivery**

4.1 Batch Production

PETNET will produce the Product in Batches and will dispense the Batches into doses for delivery to Authorized Trial Sites. A "Batch" shall mean the amount of Product produced in one operation of PETNET'S production equipment, containing at least one dose suitable for release and distribution for use in the Trials. The manufacture of Batches will be allocated among the Facilities in such manner as the Parties mutually agree is reasonable and appropriate based upon, among other things: the dates of qualification of the Facilities; the location of the sites; the estimated transportation times between Facilities and Authorized Trial Sites; the resources available at any given Facility; and the enrollment patterns of the Authorized Trial Sites.

4.2 Product Ordering

Doses of the Product will be available from the Facilities according to a production schedule to be established by PETNET and NAVIDEA for each Facility from time to time. ***Under no circumstances will the Product be available at any Facility prior to 12:00 P.M. (local time) unless otherwise agreed in writing by PETNET***. NAVIDEA or its Authorized Trial Sites may order Doses by delivering a purchase order in a form reasonably satisfactory to PETNET ("Order") specifying the Trial Site to which such Doses are to be delivered, the number of Doses, the scheduled times for injection of each Dose, and the size of each Dose (in mCi calibrated to injection time). NAVIDEA will place orders for Doses no later than thirty-six (36) hours before the Product is to be delivered. If orders are placed later than thirty six (36) hours before the Product is to be delivered, PETNET may, but shall not be obligated to, produce the Product in its sole discretion. In the event that an Explora One synthesis module and associated equipment installed at a Facility to perform the Services is used for production of a radiopharmaceutical other than [^{18}F]NAV4694, PETNET will ensure that such use does not unreasonably delay or interfere with production of [^{18}F]NAV4694.

4.3 Product Delivery

PETNET will deliver Doses to the Authorized Trial Sites. Delivery will be made by PETNET to a common carrier chosen by PETNET in its reasonable discretion, and risk of loss shall pass to NAVIDEA upon delivery to the carrier. NAVIDEA shall bear one hundred percent (100%) of all shipping costs and shall reimburse PETNET accordingly as invoiced each month.

4.4 Raw Materials and Components

(a) NAVIDEA shall provide to PETNET, at no cost to PETNET, all quantities of (i) NAVIDEA's chemical compound, NAV4614, the chemical precursor to the Product (the "Precursor"), required to perform the Services and (ii) NAVIDEA's chemical compound, the chemical reference standard, NAV4694RS, for the Product (the "Reference Standard"), required to perform the Services; and further may provide to PETNET, at no cost to PETNET, any other raw materials or components for use in the manufacture of Products (collectively, "NAVIDEA Materials"), as more fully described in Exhibit D. PETNET acknowledges and agrees that the NAVIDEA Materials shall be the sole and exclusive property of NAVIDEA.

(b) PETNET may only use NAVIDEA Materials and Product for the benefit of NAVIDEA and in furtherance of this Agreement, and shall not use either NAVIDEA Materials or Product produced by it hereunder for any other purpose.

4.5 Obsolete Inventory

Any NAVIDEA Materials, waste by-products, testing supplies, stability samples, work-in-process, and finished goods rendered obsolete or expired at the expiration, revision or termination of this Agreement or of the Services shall be either destroyed or disposed of by PETNET or shipped to NAVIDEA, freight collect, for destruction by NAVIDEA, at NAVIDEA' direction. NAVIDEA shall bear one hundred percent (100%) of all destruction costs related to said obsolete inventory, whether destroyed or disposed of by PETNET or NAVIDEA. The destruction by either Party shall be in accordance with all applicable laws and regulations. PETNET shall provide NAVIDEA with all manifests and other applicable evidence of proper destruction as may be requested by NAVIDEA or as required by applicable law.

4.6 Acquired Equipment

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5. **Compliance**

5.1 NAVIDEA's Responsibility

(a) NAVIDEA shall obtain and maintain all regulatory approvals required to conduct the Trials. NAVIDEA represents and warrants to PETNET that all Trials will be conducted under a valid and existing Investigational New Drug Application for the Product (the "IND") filed with the FDA allowing for the conduct of the Trials, and that no notice or other communication has been received from the FDA that would prevent the conduct of the Trials. Without limiting the generality of the foregoing, NAVIDEA shall:

(i) Submit to the FDA regulatory documentation which is necessary for including the PETNET Facilities in the IND;

(ii) Obtain regulatory approvals needed for conducting human clinical trials, including Institutional Review Board approvals or Radioactive Drug Research Committee approvals as may be required;

(iii) Provide PETNET with a copy of the FDA approval to proceed letter for the [^{18}F]NAV4694 IND.

(iv) Maintain regulatory documentation for the Product and the Trials;

(v) Develop all clinical protocols for the Trials;

(vi) Oversee and monitor the Trials in accordance with FDA regulations; and

(vii) Within 36 hours of receipt, provide to PETNET any subsequent regulatory notices relating to the quality of Product produced at a Facility or affecting the Specifications of the Product being used in the Trials or which may otherwise affect PETNET's provision of the Services.

(viii) Submit all other Regulatory documentation related to the IND for [^{18}F]NAV4694 IND including but not limited to IND Amendments, IND Safety Reports, Annual Reports, etc.

(b) NAVIDEA shall be responsible for maintaining such records and making such reports as may be required by the FDA and any other applicable regulatory agency with respect to the Trials and shall make copies of sections relevant to PETNET's activities under this Agreement available to PETNET upon request.

(c) Copies of all complaints concerning the Product that may be received or originated by NAVIDEA or otherwise coming to the attention of NAVIDEA, including any adverse drug experience reports from the Authorized Trial Sites, shall be promptly forwarded to PETNET.

(d) Because of FDA regulation of the Trials, the Facilities will be listed appropriately in the IND documents filed with the FDA. NAVIDEA will provide the opportunity, prior to submission to FDA, for PETNET to review and comment on relevant portions of NAVIDEA's FDA submissions that include documentation on Facilities.

(e) Prior to PETNET's receipt and testing, and as a condition precedent of any testing work by PETNET pursuant to this Agreement, NAVIDEA shall provide to PETNET the applicable Material Safety Data Sheet ("MSDS") containing written or printed material concerning a hazardous chemical which is prepared in accordance with the regulations promulgated by the Occupational Safety & Health Administration, or any successor entity thereto, for the Product, the Precursor, the Reference Standard, and all components necessary for the manufacture of Product.

(f) NAVIDEA warrants and certifies to PETNET that no person involved with this Agreement or any SOW has been debarred, is under investigation, or convicted of crimes pursuant to Sections 306(a) and (b) of the Food, Drug and Cosmetic Act and under the U.S. Generic Drug Enforcement Act of 1992, 21 U.S.C. §§335(a) and (b), as amended. NAVIDEA agrees to notify PETNET as soon as practicable upon NAVIDEA's learning of the occurrence of any such debarment, conviction, investigation or inquiry relating to a potential debarment, of any person involved with this Agreement or any SOW and agrees that said person shall be immediately prohibited from participating in this Agreement or any SOW.

5.2 PETNET's Responsibility

(a) PETNET shall maintain all original documents involving the manufacture and control for the Product, its raw materials, drug substance, and package components, including, without limitation, inventory records, testing procedures and specifications, master and lot manufacturing instructions, data from testing and inspections, and original records of experimental work performed to establish capability to manufacture and test the Product. Additionally, after withdrawing Doses and samples needed for testing, PETNET shall maintain for a period of thirty (30) days, the bulk vial from all Batches (the "Retains"). PETNET shall store these original records and Retains in a safe and organized manner so that they may be provided upon request to NAVIDEA or to the FDA or other federal, state or locally regulatory agency. PETNET shall deliver Retains and copies of all records created under the Services to NAVIDEA at costs upon receipt of a written request from NAVIDEA

(b) PETNET shall be responsible for, and shall take all steps necessary for, passing any applicable government inspection of the Facilities by the FDA or other federal, state or local regulatory agency. All manufacturing, packaging, storage, cleaning, and analytical methods and processes of the Product or its components must be qualified by PETNET in accordance with the methods set forth in the IND Qualification procedures and reports will be provided to NAVIDEA upon request. Following qualification of a process and or process change, PETNET shall notify NAVIDEA of such qualification and, upon request, deliver a copy of the qualification report to NAVIDEA.

(c) PETNET shall perform all work under this Agreement and any SOW in conformity with all applicable federal, state and local laws and regulations including, without limitation, the Food, Drug and Cosmetic Act and the regulations promulgated pursuant thereto, as amended from time to time, including 21 CFR 212 (PET Drug cGMP Regulations).

(d) Copies of all complaints concerning the Product that may be received or originated by PETNET or otherwise coming to the attention of PETNET, including any adverse drug experience reports from Authorized Trial Sites, shall be promptly forwarded to NAVIDEA. PETNET shall provide to NAVIDEA, within 24 hours of receipt, any regulatory notices relating to the quality of Product produced at a Facility or affecting the Specifications of the Product being used in the Trials or which may otherwise affect PETNET's provision of the Services.

(e) PETNET warrants and certifies to NAVIDEA that no person performing Services pursuant to this Agreement or any SOW has been debarred, is under investigation, or convicted of crimes pursuant to Sections 306(a) and (b) of the Food, Drug and Cosmetic Act and under the U.S. Generic Drug Enforcement Act of 1992, 21 U.S.C. §§335(a) and (b), as amended. PETNET agrees to notify NAVIDEA as soon as practicable upon PETNET' learning of the occurrence of any such debarment, conviction, investigation or inquiry relating to a potential debarment, of any person performing services pursuant to this Agreement or any SOW and agrees that said person shall be immediately prohibited from performing Services under this Agreement or any SOW.

5.3 Compliance Audit

(a) NAVIDEA shall have the right, upon not less than 30 days' prior written notice to PETNET and its sole expense, to once every twelve (12) months during the Term conduct a compliance audit of PETNET and each of the Facilities directly related to the manufacturing, laboratory, packaging, storage, testing, shipping or receiving of the Product; *provided, however*, that such audit(s) shall be conducted between the hours of 9:00 am and 5:00 pm local time and in such a manner as to not unreasonably interfere with the operations at the Facilities, and NAVIDEA' representatives shall comply with PETNET's customary procedures for such audits at the Facilities.

(b) NAVIDEA shall be responsible for communicating with any governmental or regulatory authority concerning the Product, and PETNET shall provide NAVIDEA with reasonable assistance NAVIDEA may require to assist it in such communications. PETNET shall have no such communications specifically related to the Product, except to the extent that they relate to PETNET's Facilities or manufacturing activities under this Agreement with respect to the Product, in which case PETNET shall be solely responsible for such communications and any required follow-up actions. Notwithstanding the foregoing, nothing in this Section 5.3(b) shall be deemed to restrict either Party's independent right to communicate with any governmental or regulatory authority. NAVIDEA shall have the right to challenge any order of a regulatory or governmental activity affecting its Product, and PETNET will be permitted to participate in such challenge at its sole discretion.

5.4 Recall

In the event (a) any government authority of any country should issue a request, directive or order that the Product supplied by PETNET to NAVIDEA be recalled, or (b) a court of competent jurisdiction orders such a recall, or (c) the Parties reasonably determine after consultation with each other that the Product should be recalled (each of the foregoing (a) to (c), a "Recall"), the Parties shall take all appropriate corrective action and shall cooperate fully with one another in connection therewith. Unless otherwise mutually agreed, NAVIDEA shall be responsible for coordinating all activity associated with such Recall. NAVIDEA shall be responsible for all Recall expenses pertaining thereto incurred by NAVIDEA or PETNET. For purposes of this Agreement, Recall expenses shall include, but not be limited to, the expenses of notification and destruction or return of the recalled Product, as well as NAVIDEA's and PETNET's out-of-pocket costs incurred in connection therewith.

6. **Confidentiality**

6.1 Confidential Information

(a) For purposes of this Agreement, Confidential Information means (i) designs, specifications, know-how, processes, formulae, costs, financial data, marketing plans and customer lists and, (ii) information that is marked "confidential", "proprietary" or some other similar marking or information that is disclosed verbally that is designated in writing as "confidential" within five (5) days of its disclosure, or (iii) information that a reasonable person would consider to be the confidential information of the disclosing Party based on the nature of the information or the circumstances surrounding its disclosure. The Confidential Information of a Party ("Discloser") acquired by the other Party ("Recipient") under this Agreement or any SOW shall not be disclosed to any third party without the prior written authorization from Discloser. Recipient shall use the Confidential Information only for the purpose of fulfilling its obligations or exercising its rights under this Agreement. Recipient represents and warrants that it has obtained or will obtain agreements with its employees and agents (including subcontractors) to maintain the confidentiality of all Confidential Information as provided herein. Notwithstanding the foregoing, either Party may disclose Joint Process Inventions to a third party bound by a confidentiality agreement containing provisions at least as stringent as this Section 6 so long as Discloser is given 30 days notice of the contemplated disclosure and may prevent such disclosure if it reasonably identifies said third party as a competitor.

(b) The obligations of Recipient with regard to Confidential Information shall continue for a period of five (5) years from the date that such Confidential Information is acquired by Recipient, except with respect to Confidential Information that is a trade secret, as defined by applicable law, in which case the obligations of Recipient shall remain in effect for the greater of such five (5) year period or for as long as such information retains its status as a trade secret, as determined by applicable law.

(c) The obligations of Recipient regarding the confidentiality and nondisclosure of Confidential Information as provided in this section shall not apply to information that:

(i) is already known to Recipient without prior disclosure from Discloser, as shown by Recipient's prior written records;

(i i) Recipient can demonstrate by written records was developed for or by Recipient, independent of any Confidential Information of the Discloser;

(iii) becomes publicly available through no fault of Recipient; or

(iv) is received from a third party that has the legal right to disclose it to Recipient.

6.2 Compelled Disclosure

The confidentiality obligations contained in this Section 6 shall not apply to the extent that Recipient is required to disclose information by law, order or regulation of a governmental agency or a court of competent jurisdiction; provided that (a) if Recipient shall, to the extent not prohibited by applicable law or court order, notify Discloser in writing immediately so that Discloser, at its sole option and expense, may seek a protective order or other appropriate remedy or waive compliance with the provisions of this Section 6; (b) if Discloser elects to seek a protective order or other appropriate remedy, Recipient shall cooperate with, and not object to, any such actions; and (c) if a protective order or other remedy is not obtained or Discloser waives compliance with the provisions of this Section 6, Recipient shall furnish only that portion of Discloser's Confidential Information which Recipient reasonably believes is legally required to be disclosed.

6.3 Irreparable Harm

Recipient acknowledges that the disclosure of Confidential Information without Discloser's expressed permission may cause Discloser irreparable harm and that the breach or threatened breach of nondisclosure provisions of this Agreement may entitle Discloser to seek injunctive relief from a court of competent jurisdiction, in addition to any other legal remedies that may be available.

6.4 Publicity

The terms and conditions contained herein shall be held in strict confidence by the Parties hereto, and neither Party shall publicly disclose, directly or indirectly, any of the terms or conditions of this Agreement unless such disclosure is required by law, order or regulation of a governmental agency or a court of competent jurisdiction, and is in compliance with Section 6.2 or is otherwise consented to by the nondisclosing Party. Any announcement or other publicity relating to the transactions contemplated hereby, and the method of the release of such publicity, must be approved in writing, in advance, by both Parties hereto, which approval shall not be unreasonably withheld.

7. **Intellectual Property Rights**

7.1 Certain Definitions

As used in this Agreement, the following terms have the following meanings:.

(a) "Documentation" means any written or electronic record embodying the NAVIDEA Technology, including the Specifications or the Methods.

(b) "Intellectual Property Right(s)" means, individually or collectively, (i) ideas, inventions, improvements, or discoveries, Know-How (whether patentable or not), (ii) works of authorship copyright applications and copyrights (including, without limitation, documentation, reports, materials, writings, designs, computer software), processes methods, techniques and any (iii) Patent Rights, (iv) trade secrets, or (v) other intellectual property right pertaining to any of the foregoing.

(c) "Know-How" means unpatented technical and other information which is not known to the public, including without limitation, information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, information relating to material, inventions, methods, models, assays, research plans, procedures, designs for experiments and tests and results of experimentation and testing including results of research or development together with processes including manufacturing processes, specifications, techniques, chemical, pharmacological, toxicological, clinical, analytical and quality control data, trial data, case report forms, data analyses, reports or summaries and information contained in submissions to and information from ethical committees and regulatory authorities including documents (which shall include paper, notebooks, books, files, ledgers, records, tapes, discs, diskettes, CD-ROM and any other media on which Know-How can be permanently stored) containing Know-How. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, and/or a development related to the item, is (or remains) not known to the public.

(d) "Maintained" means, with respect to any Intellectual Property Right, that a Party owns a transferable interest or has a license to practice such Intellectual Property Right and has the ability to grant the other Party access, a license or a sublicense (as applicable) to practice such Intellectual Property Right.

(e) "NAVIDEA Technology" means all Intellectual Property Rights that are owned or Maintained by NAVIDEA on the Effective Date or during the Term, including without limitation the Specifications, the Methods, and the Documentation, excluding Joint Process Inventions.

(f) "Methods" means the radiochemistry synthesis methods Maintained by NAVIDEA to produce the Product and to demonstrate that Batches of the Product meet the Specifications.

(g) "Patent Rights" means the rights and interests in and to any and all issued patents and pending patent applications (including inventor's certificates and utility models) in any country worldwide, including any and all provisionals, non-provisionals, substitutions, continuations, continuations-in-part, divisionals and other continuing applications, supplementary protection certificates, renewals, and all letters patent on any of the foregoing, and any and all reissues, re-examinations, extensions, confirmations, registrations and patents of addition of any of the foregoing.

(h) "PETNET Technology" means all Intellectual Property Rights that are Maintained by PETNET on the Effective Date or during the Term, excluding Joint Process Inventions.

(i) "Specifications" means the specified manufacturing instructions, analytic tests and acceptance criteria further described in Exhibit B, as it may be modified by NAVIDEA from time to time.

7.2 Ownership and Publication of Results

(a) All data and information, including raw data and case report forms, generated as a result of the Trials, will be the property of NAVIDEA and may be freely utilized by NAVIDEA in any manner desired, subject to restrictions set out in Section 7.2(c) below.

(b) Any information regarding the Trials, including the name and location of the Authorized Trial Sites, shall be treated in confidence by PETNET as the Confidential Information of NAVIDEA, except that PETNET may disclose or use information in accordance with Article 5.2 and 5.3 above.

(c) NAVIDEA shall have the right to use, copy, publish and distribute as it sees fit any of the results of the Trials; provided, however, that NAVIDEA may not use the name of PETNET or its employees or representatives for any public or commercial purpose, including advertising, promotional or sales literature or product labeling without the prior written consent of PETNET, unless required by governmental order, law or regulation.

7.3 Ownership of Intellectual Property

(a) As between the Parties, all PETNET Technology is and shall be the exclusive property of PETNET and may be freely used by PETNET, subject to the terms and conditions of this Agreement. Except as provided in Section 7.3(c), all improvements, enhancements, modifications or derivatives to the PETNET Technology ("PETNET Technology Inventions") shall be the exclusive property of PETNET. To the extent NAVIDEA has any Intellectual Property Rights in and to any PETNET Technology Inventions, NAVIDEA hereby assigns and transfers the same to PETNET absolutely and free of any third party claims or interests. NAVIDEA shall execute such deeds or documents and do such things as are necessary to transfer ownership of the PETNET Technology Inventions to PETNET and to facilitate the filing of patent applications for Patent Rights or other registrations of Intellectual Property Rights in the name of PETNET at PETNET's reasonable expense. All PETNET Technology and PETNET Technology Inventions shall be deemed the Confidential Information of PETNET. Notwithstanding anything in this Agreement to the contrary, to the extent PETNET Technology Inventions are utilized in the manufacture, preparation, distribution and/or use of the Product as manufactured by PETNET, PETNET hereby grants NAVIDEA a non-exclusive, non-transferable, perpetual, royalty free worldwide license to make, distribute or use or have made, distributed or used Product under such PETNET Technology Inventions.

(b) As between the Parties, all NAVIDEA Technology is and shall be the exclusive property of NAVIDEA and may be freely used by NAVIDIEA, subject to the terms of this Agreement, including, without limitation, Section 7.4 below. Except as provided in Section 7.3(c), all inventions that are improvements, enhancements, modifications or derivatives of the NAVIDEA Technology ("NAVIDEA Technology Inventions") shall be the exclusive property of NAVIDEA. To the extent PETNET has any Intellectual Property Rights in and to any NAVIDEA Technology Inventions, other than the license grant set forth in Section 7.4 below, PETNET hereby assigns and transfers the same to NAVIDEA absolutely and free of any third party claims or interests. PETNET shall execute such deeds or documents and do such things as are necessary to transfer ownership of the NAVIDEA Technology Inventions to NAVIDEA and to facilitate the filing of patent applications for Patent Rights or other registrations of Intellectual Property Rights in the name of NAVIDEA at NAVIDEA's reasonable expense. All NAVIDEA Technology and NAVIDEA Technology Inventions shall be deemed the Confidential Information of NAVIDEA.

(c) Except as otherwise set forth in this Section, any process inventions conceived of jointly by the Parties shall be jointly owned ("Joint Process Inventions"), and may be freely used by the Parties subject to any underlying PETNET Intellectual Property Rights and any underlying NAVIDEA Intellectual Property Rights and subject to the terms and conditions of this Agreement. Whether a process-related invention is a Joint Process Invention shall be governed by United States patent law governing joint inventorship. The Parties shall promptly notify each other if they believe they have conceived of a Joint Process Invention. The Parties shall then discuss whether a patent application or applications should be filed for the Joint Process Invention. The Parties acknowledge that "time is of the essence" when deciding whether to file a patent application and agree to act in good faith in making a determination as to how to proceed.

(i) If the Parties wish to jointly pursue patent protection and/or jointly own any resulting patents for Joint Process Inventions, the Parties shall work together to obtain patent protection and shall equally split the costs of patent prosecution and maintenance unless explicitly agreed in writing otherwise. The Parties shall decide which Party will take the lead in patent prosecution ("Lead Party"). The Lead Party shall keep the other Party informed of developments in the patent prosecution and maintenance and shall seek the advice and input of the non-Lead Party in making substantive decisions regarding patent prosecution and maintenance. The Parties shall work together in making substantive decisions, developing a prosecution strategy and in selecting appropriate outside counsel, if necessary. Both Parties shall jointly own, by having an undivided equal joint interest therein, any patent issuing on any Joint Process Invention ("Joint Patent"). Each Party shall provide all information and execute and file all documents and instruments necessary to memorialize and record such joint ownership with all applicable patent offices and government agencies, including any affidavits, declarations, or assignments. Subject to any underlying Intellectual Property Rights of the other Party and subject to the terms and conditions of this Agreement, each Party shall have full use of any Joint Patents for its own purposes including (subject to the foregoing) the right to license or assign its rights to any Joint Patent without obligation or accounting to the other Party.

(ii) If one of the Parties ("Non-prosecuting Party") decides it does not want to, or no longer wants to pursue patent protection (including any interferences, reissue proceedings, re-examinations, and post-grant reviews) for a Joint Process Invention and/or does not want to maintain a patent or application for a Joint Process Invention or to file any subsequent application claiming priority thereto (including any continuation, continuation-in-part, divisional, reissue, PCT application, or foreign counterpart applications), and provides timely written notification of such decision, the other Party ("Prosecuting Party") shall have the option of pursuing patent protection or maintaining patents or applications for the Joint Process Invention on its own. The Prosecuting Party shall bear the entire cost of patent prosecution and/or maintenance and shall be the sole owner of the patent applications, patents and patent rights unless agreed to in writing otherwise. The non-prosecuting Party shall cooperate with the Prosecuting Party including providing, at the Prosecuting Party's reasonable expense, all necessary information and input and executing, and causing such Non-prosecuting Party's employees, consultants, and contractors to execute, any necessary documents and instruments, including affidavits, declarations, and assignments. The Prosecuting Party shall have the final say on all matters related to patent prosecution and maintenance and may but shall not be obligated to notify the Non-prosecuting Party of developments regarding the patent prosecution or seek the Non-prosecuting Party's input. Subject to any underlying Intellectual Property Rights of the other Party and subject to the terms and conditions of this Agreement, the Non-prosecuting Party shall have a non-exclusive, fully paid-up, world-wide, perpetual license to any resulting patents covering the Joint Process Invention. This license shall be non-transferrable and non-licensable except to Affiliates of the Non-prosecuting Party.

(iii) Neither Party shall disclose to its sublicensee(s) or any other third party any confidential PETNET Intellectual Property Rights or confidential NAVIDIEA Intellectual Property Rights (as applicable) of the other Party that underlies the Joint Process Inventions.

(d) In the event that either Party reasonably believes that a third party may be infringing any Joint Patent, then such Party shall promptly notify the other Party in writing, identifying the alleged infringer and the alleged infringement complained of and furnishing the information upon which such determination is based. PETNET shall, at its expense, have the first right, but not the obligation, through counsel of its choosing, to take any measures it deems appropriate to prevent or stop any such infringement. PETNET shall keep NAVIDEA promptly apprised of all enforcement actions taken by PETNET in connection with any such enforcement action, including providing NAVIDEA with drafts of briefs and filings in connection therewith and allowing adequate time for review and comment by NAVIDEA whenever possible. PETNET shall reasonably consider all such NAVIDEA comments, and shall obtain NAVIDEA's written consent before entering into any settlement with the infringing third party, which consent shall not be unreasonably withheld, conditioned or delayed. Upon reasonable request by PETNET, NAVIDEA shall give PETNET all reasonable information and assistance, and, if necessary for PETNET to prosecute any legal action, join in the legal action as a party at PETNET's expense. In the event PETNET fails within thirty (30) days following notice of such infringement to take commercially appropriate steps to prevent or stop such infringement, or earlier notifies NAVIDEA in writing of its intent not to do so, then NAVIDEA shall have the right, at its expense, but not the obligation, to do so. NAVIDEA shall keep PETNET promptly apprised of all enforcement actions taken by NAVIDEA in connection with any such enforcement action, including providing PETNET with drafts of briefs and filings in connection therewith and allowing adequate time for review and comment by PETNET whenever possible. NAVIDEA shall reasonably consider all such PETNET comments, and shall obtain PETNET's written consent before entering into any settlement with the infringing third party, which consent shall not be unreasonably withheld, conditioned, or delayed. Upon reasonable request by NAVIDEA, PETNET shall give NAVIDEA all reasonable information and assistance in connection with such suit for infringement. Any damages or other amounts collected by either PETNET or NAVIDEA as the result of a legal action under this Section 7.3(d) shall be allocated first to reimburse the Party prosecuting such action for its costs and expenses in making such recovery, with any remainder of damages that are attributable to infringement to be shared equally by the Parties.

(e) In the event that a third party asserts, as a defense or as a counterclaim in any infringement action, or in a declaratory judgment action or similar action or claim before any court, tribunal, administrative agency, or patent office, that any Joint Patent is invalid or unenforceable, then the Party participating in such action shall promptly give written notice to the other Party. PETNET shall have the first right, but not the obligation, at its sole cost and expense through counsel of its choosing, to respond to such defense or defend against such counterclaim (as applicable) unless NAVIDEA is pursuing the applicable infringement action or is the named defendant, in which case NAVIDEA shall have the first right. The Party controlling such response or defense (the "Controlling Party") shall keep the other Party (the "Other Party") promptly apprised of all actions taken by the Controlling Party in connection with any such response or defense, including providing the Other Party with drafts of briefs and filings in connection therewith, allowing adequate time for review and comment by the Other Party whenever possible, and the Controlling Party shall reasonably consider all such comments. The Controlling Party shall obtain the written consent of the Other Party prior to settling or, otherwise compromising such defense or counterclaim, which consent shall not be unreasonably withheld or delayed. If the Controlling Party determines not to respond to such defense or defend against such counterclaim (as applicable), it shall notify the Other Party of the same in sufficient time to allow the Other Party to respond or defend (as applicable). The Other Party shall have the right, but not the obligation, to respond to such defense or defend against such counterclaim at its sole cost and expense through counsel of its choosing. If the Other Party determines to respond to such defense or defend against such counterclaim, it shall obtain the written consent of the former Controlling Party prior to settling or otherwise compromising such defense or counterclaim, which consent shall not be unreasonably withheld or delayed. Upon reasonable request by a Party, the other Party shall give the requesting Party, at the requesting Party's expense, all reasonable information and assistance in connection with the defense to actions specified under this Section.

7.4 Limited Licenses

NAVIDEA hereby grants to PETNET a non-exclusive, non-transferable (except as set forth in Section 12), royalty-free license, with the right to sublicense under any Intellectual Property Rights of NAVIDEA relating directly or indirectly to the NAVIDEA Technology or NAVIDIEA Technology Inventions, to make, have made, use and distribute NAVIDEA Materials and the Product solely for the purpose of manufacturing and distributing the Product and performing the Services as set forth in this Agreement. NAVIDEA hereby grants to PETNET the right to use and reference all applicable regulatory filings, production contracts and drug master files and other regulatory documents solely for the purpose of performing its obligations set forth in this Agreement. Except as specifically provided herein, PETNET shall have no other rights to intellectual property of NAVIDEA for the duration of the Trials and thereafter.

8. **Warranties and Disclaimer**

(a) Each Party hereby represents and warrants that:

(i) It is a corporation duly organized, validly existing and in good standing under applicable state law.

(ii) This Agreement has been duly executed and delivered by it and constitutes the legal, valid and binding obligation of such Party, enforceable against it in accordance with its terms, except as the same may be limited by bankruptcy, insolvency, moratorium, reorganization or other laws of general applicability relating to or affecting the enforcement of creditor's rights and general principles of equity.

(iii) The execution, delivery and performance of this Agreement do not and will not (A) violate or conflict with, result in a breach of, constitute a material default (or an event which, with or without notice or lapse of time or both, would constitute a default) under any material contract to which it is a party or by which it is bound; (B) violate any applicable law; or (C) violate or conflict with any provision of its certificate of incorporation and by-laws or comparable organizational documents.

(iv) It has not been debarred, suspended or excluded under any laws or regulations promulgated by FDA or any equivalent law. It does not and will not employ, contract with or retain any person to perform activities under this Agreement if such person is debarred, suspended or otherwise excluded by governmental authorities.

(v) It has the requisite corporate power and authority to carry on its business as it is now being conducted and is duly licensed or qualified to do business in each jurisdiction in which the nature of the business conducted by it or the character or location of the properties owned or leased by it makes such licensing or qualification necessary.

(b) NAVIDEA hereby represents and warrants that NAVIDEA Technology and NAVIDEA Technology Inventions used in the performance of this Agreement does not infringe, misappropriate or otherwise violate any Intellectual Property Rights of any third party.

(c) THE REPRESENTATIONS AND WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT ARE THE PARTIES' ONLY REPRESENTATIONS AND WARRANTIES WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT AND ARE MADE EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WHICH ARE HEREBY DISCLAIMED, INCLUDING ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, NON-INFRINGEMENT OR OTHERWISE. THE PARTIES AGREE THAT IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM BREACH OF THIS AGREEMENT.

9. **Force Majeure**

Each of the Parties hereto shall be excused from the performance of its obligations hereunder to the extent performance of this Agreement is prevented by force majeure and such excuse shall continue as long as the condition constituting such force majeure continues; provided, however, if such delay continues in excess of eight (8) weeks, this Agreement may be terminated upon written notice by the effected Party to the other Party. Neither Party shall be obligated to pay or refund any amount stated in Exhibit C upon early termination due to force majeure.

For purposes of this Agreement, "force majeure" is defined as follows:

Causes beyond the control of NAVIDEA or PETNET, which are not attributable to any legal violation, negligence, breach or default by either Party, including acts of God, new statutes, regulations or other changes of laws of any government, civil commotion, strikes, shortages of raw materials, terrorism, unavailability of necessary equipment, substantial damage to or destruction of production facilities or material by fire, earthquake or storm, epidemics and failure of public utilities or common carriers or any other cause beyond the reasonable control of the Party affected thereby.

10. **Indemnification**

10.1 Indemnification by PETNET

(a) PETNET agrees to indemnify, defend and hold harmless NAVIDEA and its affiliates, as well as the officers, directors, employees and agents of each (collectively "NAVIDEA Indemnitees"), against any third party claims, losses or damages (including reasonable attorney's fees and disbursements paid or incurred by any of them) suffered or incurred by any NAVIDEA Indemnitee resulting from (i) the personal injury (including death) or damage to tangible personal property to the extent caused by PETNET's negligence or willful misconduct in the performance of the Services; or (ii) any intentional misconduct on the part of PETNET; *provided*, that in no event shall PETNET be required to indemnify NAVIDEA to the extent of claims, losses or damages arising on account of (or to the extent aggravated by reason of) the negligence or willful misconduct of NAVIDEA Indemnitees.

(b) NAVIDEA agrees to provide PETNET with prompt notice of any claim by any NAVIDEA Indemnitee for indemnification under Section 10.1(a) (a "NAVIDEA Claim"). In the event of any NAVIDEA Claim, PETNET shall manage and control the defense and settlement of any and all actions, proceedings, and suits with respect thereto, and shall have the right to select and engage counsel of its own choice. Any NAVIDEA Indemnitee may also participate in the defense with counsel of its own choosing at its own expense. The NAVIDEA Indemnitees shall reasonably cooperate at PETNET's reasonable cost in the defense of any and all such actions, proceedings, and suits. No NAVIDEA Indemnitee shall be entitled to compromise or settle any claim, loss, or damage that is or may be the subject of indemnification under Section 10.1(a) without the prior written approval of PETNET, and PETNET shall have no obligation to indemnify any NAVIDEA Indemnitee that is so compromised or settled.

10.2 Insurance by PETNET

PETNET shall maintain in full force and effect during the term of this Agreement, at its sole cost and expense, the following insurance: (i) Products Liability Insurance coverage in the minimum amount of Five Million ($5,000,000) Dollars per occurrence with an annual aggregate amount of Ten Million ($10,000,000) Dollars; (ii) Commercial General Liability insurance with bodily injury and property damage with minimum limits of Five Million ($5,000,000) per occurrence, with an annual aggregate limit of Ten Million ($10,000,000); and (iii) Worker's Compensation and Occupational Disease Disability insurance as required by the laws of the state(s) in which the Services are to be performed.

10.3 Indemnification by NAVIDEA

(a) NAVIDEA agrees to indemnify, defend and hold harmless PETNET, and its affiliates, as well as the officers, directors, employees and agents of each (hereafter collectively referred to as "PETNET Indemnitees"), against any third party claims, losses or damages (including reasonable attorney's fees and disbursements paid or incurred by any of them) suffered or incurred by any PETNET Indemnitee resulting from (i) any clinical trials, ownership, testing, use, application, consumption, distribution, marketing or sale of the Product; (ii) any intentional misconduct on the part of NAVIDEA; (iii) any claim that the NAVIDEA Technology, NAVIDEA Technology Inventions, NAVIDEA Materials or Product ((A) as specified in the NDA or (B) any other written specifications or written instructions provided by NAVIDEA to PETNET or (C) as delivered to PETENT) infringes Intellectual Property Right of a third party; or (iv) any failure by NAVIDEA to honor NAVIDEA's financial obligations to any subcontractor of NAVIDEA; *provided*, that in no event shall NAVIDEA be required to indemnify PETNET to the extent of claims, losses or damages arising on account of (or to the extent aggravated by reason of) the negligence or willful misconduct of PETNET Indemnitees.

(b) PETNET agrees to provide NAVIDEA with prompt notice of any claim by any PETNET Indemnitee for indemnification under Section 10.3(a) (a "PETNET Claim"). In the event of any PETNET Claim, NAVIDEA shall manage and control the defense and settlement of any and all actions, proceedings, and suits with respect thereto, and shall have the right to select and engage counsel of its own choice. Any PETNET Indemnitee may also participate in the defense with counsel of its own choosing at its own expense. The PETNET Indemnitees shall reasonably cooperate at NAVIDEA' reasonable cost in the defense of any and all such actions, proceedings, and suits. No PETNET Indemnitee shall be entitled to compromise or settle any claim, loss, or damage that is or may be the subject of indemnification under Section 10.3(a) without the prior written approval of NAVIDEA, and NAVIDEA shall have no obligation to indemnify any PETNET Indemnitee that is so compromised or settled.

10.4 Insurance by NAVIDEA

NAVIDEA shall maintain in full force and effect during the term of this Agreement, at its sole cost and expense, the following insurance: (i) Products Liability Insurance coverage in the minimum amount of Five Million ($5,000,000) Dollars per occurrence with an annual aggregate amount of not less thanTen Million ($10,000,000) Dollars; and (ii) Commercial General Liability insurance with bodily injury and property damage with minimum limits of One Million ($1,000,000) per occurrence and a commercial umbrella policy with a per-occurrence limit of not less than Five Million ($5,000,000) dollars.

10.5 Certificates of Insurance

Each Party shall provide to the other certificates of insurance evidencing the insurance required hereunder, upon written request, and will provide at least thirty (30) days prior written notice to the other Party prior to any cancellation of such coverage or material change in such coverage.

11. Term; Termination; Effect

11.1 Term

This Agreement shall commence on the Effective Date and shall have an initial term of three (3) years ("Initial Term"), unless earlier terminated as provided herein. Thereafter, this Agreement shall automatically renew for additional one year terms ("Extended Term"), unless either Party gives written notice at least sixty (60) days prior to the end of the Initial Term, or any subsequent extension, that it wishes not to renew. The Initial Term and any subsequent extensions shall be referred to collectively as the "Term".

11.2 Breach

In addition to any other rights a Party may have in law or equity, either Party may terminate this Agreement, or the SOW, upon written notice to the other Party, if the other Party materially breaches this Agreement, or the SOW, and such breach is not cured within thirty (30) days from notice of such breach. Each Party agrees to use all reasonable efforts to correct said breach and provide satisfactory evidence of corrective actions in a timely manner. Failure to cure the breach within such 30-day period shall entitle the non-breaching Party to terminate this Agreement, or any SOW, immediately by written notice to the breaching Party. Upon early termination for cause, the non-breaching Party shall have no obligation to pay or refund any amount stated in Exhibit C to the breaching Party.

11.3 Termination Without Cause

Upon any notice by NAVIDEA or PETNET pursuant to Section 2.2, either Party may terminate this Agreement, or any SOW, for any reason and without cause, upon sixty (60) days' prior written notice to the other, *except* that PETNET shall have no right to terminate without cause until six (6) months after the Effective Date. If PETNET elects to terminate this Agreement without cause during the Initial Term, PETNET shall refund to NAVIDEA an amount equal to the Site Qualification Fees set forth in Exhibit C, pro-rated over the remaining balance of the Initial Term. NAVIDEA shall receive no refund of any fees if it elects to terminate without cause at anytime, or if PETNET so elects during any Extended Term.

11.4 Effect of Termination

In the event of termination of this Agreement or any SOW for any reason:

(a) NAVIDEA and PETNET agree to discuss, cooperate and coordinate termination of activities being conducted by PETNET.

(b) NAVIDEA shall pay, in accordance with Section 3.1, for all Batches supplied by PETNET up to date of termination. PETNET shall return or destroy all NAVIDEA Materials in accordance with the provisions of Section 4.5.

(c) A reasonable plan of action for cessation of activities will be agreed to by both Parties to ensure an orderly cessation of on-going tasks and activities in order to comply with the legal responsibilities of the Parties according to applicable local, federal and/or state laws, regulations and ordinances.

(d) PETNET will provide NAVIDEA with a copy of all records relating to the performance of the Services and all periodic/final reports and/or records, in any case as required by applicable provisions of this Agreement.

11.5 Survival

Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of either Party prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of this Agreement or by their nature should survive the termination or expiration of this Agreement, including pursuant to Sections 5 through 8 and 10 through 18 hereof.

12. **Assignment and Subcontracting**

This Agreement shall not be assigned or transferred by either Party, in whole or in part, by operation of law or otherwise, without the prior written consent of the other Party, and any attempt to make such assignment without such consent shall be null and void, provided, however this Agreement may be assigned to an affiliate or a successor in interest by operation of law or otherwise, provided, however, such successor agrees in writing to be bound by the terms of this Agreement. PETENT shall have the right to subcontract with a third party to perform delivery services under this Agreement without the prior written consent of NAVIDEA. PETNET may not engage any other third party to perform Services under this Agreement without the prior written consent of NAVIDEA.

13. **Notice**

Any notice required hereunder shall be effective upon receipt and may be served by either Party on the other by: (i) personal delivery, (ii) post prepaid, national courier, (iii) national postal service via registered or by certified mail, or (iv) by facsimile or e-mail (receipt verified); in each case to the address noted below:

If to PETNET:

Siemens Medical Solutions USA, Inc.
Attention: Legal Department
810 Innovation Drive
Knoxville, TN 37932
Fax: +1.865.218.2760

If to NAVIDEA:

Navidea Biopharmaceuticals, Inc.
425 Metro Place North Suite 450
Dublin, OH 43017
Attention: Thomas Tulip, President and Chief Business Officer
Telephone:978 655-2670
Fax: 978 655-2671

14. **Independent Contractor**

The relationship created by this Agreement shall be strictly that of independent contractor, and no partnership or joint venture exists or shall be implied between the Parties hereto. Neither Party is hereby constituted an agent or legal representative of the other Party for any purpose whatsoever and neither Party is granted any right or authority hereunder to assume or create any obligation, express or implied, or to make any representation, warranties or guarantees, except as are expressly granted or made in this Agreement.

15. **Governing Law**

The validity, interpretation and effect of this Agreement shall be governed by and construed under the laws (other than the conflict of laws rules) of the State of Delaware.

16. **Survivability**

In the event that any term or provision of this Agreement shall violate any applicable statute, ordinance, or rule of law in any jurisdiction in which it is used, or otherwise be unenforceable, such provision shall be ineffective to the extent of such violation without invalidating any other provision hereof.

17. **Counterparts**

This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same original. Signatures to this Agreement may be delivered by facsimile, by electronic mail (e.g., a ".pdf" file) or by any other electronic means that is intended to preserve the original appearance of the document, and such delivery will have the same effect as the delivery of the paper document bearing the actual, hand-written signatures.

18. **Entire Agreement**

The Parties hereto acknowledge that this Agreement and the Exhibits hereto set forth the entire agreement and understanding of the Parties and except as set out herein, supersedes all prior written or oral agreements or understandings with respect to the subject matter hereof. No modification of any of the terms of this Agreement, or any amendments thereto, shall be deemed to be valid unless in writing and signed by the Party against whom enforcement is sought. No course of dealing or usage of trade shall be used to modify the terms and conditions herein. The captions or headings herein are solely for convenience and have no effect on the meaning or interpretation of this Agreement.

* ***Signatures appear on following page*** *

SIGNATURES

IN WITNESS WHEREOF, the Parties have each caused this Agreement to be executed by their duly authorized officers as of the Effective Date.

NAVIDEA BIOPHARMACEUTICALS, INC.

By: /s/ Thomas H. Tulip
Thomas H. Tulip, President

PETNET SOLUTIONS, INC.

By: /s/ Christoph Zindel
Christoph Zindel
Chief Executive Officer

And

By: /s/ Brian Malone
Brian Malone
Chief Financial Officer

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

Scope of Work

1. NAVIDEA has selected the [*] Facilities listed in paragraph 2 below to begin producing the Product in support of its Trials [*].

2. The Facilities of PETNET located in the following metropolitan areas shall be qualified in accordance with paragraph 7 below:

    - o [*]
    - o [*]
    - o [*]

- o [*]

3. PETNET will implement the production processes and quality control methods for the preparation and testing of the Product at the Facilities. The Parties will use commercially reasonable efforts to meet the schedule below for site qualification. As a condition of PETNET's commitment to this schedule, NAVIDEA agrees to provide PETNET with: (1) [*]. In the event NAVIDEA fails to provide [*], the Parties shall make an equitable adjustment to the schedule below (*e.g.* an additional day to qualify each Facility for each day that passes after [*]), and this Agreement shall be modified, in writing accordingly.

    - · [*]
    - · [*]
    - · [*]

4. PETNET shall establish production equipment, quality control equipment, equipment qualification and standard operating procedures ("SOPs"). The quality control equipment and processes will provide the necessary analytical data on each production batch of Product as described in Exhibit B.

5. PETNET's duties under paragraphs 2, 3, and 4 will be performed in compliance with cGMP regulations specified in 21 CFR 212 ("cGMP").

6. A PETNET operator shall be qualified ("Qualified Operator") for each Facility before making the Product. For purposes of this Agreement, a Qualified Operator shall have performed three successful qualification runs with full analytical testing as defined in Exhibit B. All batch records and analytical results will be forwarded to NAVIDEA upon completion.

7. Each Facility shall be qualified before making the Product. For purposes of this Agreement, Facility qualification shall consist of three successful qualification runs with full analytical testing as defined in Exhibit B. All batch records and analytical results will be forwarded to NAVIDEA upon completion. The Parties will use commercially reasonable efforts to obtain a batch production of at least 1 Ci of final product as measured at end of synthesis.

8. Prior to the qualification runs and at NAVIDEA's option and sole expense, a compliance audit based on cGMP requirements will be performed by NAVIDEA of each Facility. NAVIDEA shall notify PETNET at least 14 calendar days in advance of any such compliance audit. Any deficiencies will be addressed, and documentation of the resolution of the issues will be forwarded to NAVIDEA upon request. Such audits will be in addition to those compliance audits described in Section 5.3(a) of the Agreement.

9. Product labels shall be essentially in the form shown in Exhibit A, Attachment 1. Prior to use, PETNET shall submit labels to NAVIDEA for approval. Approved labels will be included in appropriate IND filings.

10. If analytical tests show unsatisfactory results, the manufacturing procedure will be investigated by PETNET to identify the source of the problem. PETNET will propose an appropriate modification to be implemented to correct the manufacturing process. PETNET shall implement such correction in consultation with NAVIDEA.

11. Navidea shall provide PETNET with a list of sites that have met regulatory requirements to receive Product ("Authorized Trial Sites"). PETNET shall provide Product only to Authorized Trial Sites.

12. PETNET shall prepare Product for the Trials according to the appropriate SOPs. Product release shall be performed by qualified PETNET personnel. Doses will be dispensed by qualified PETNET personnel. Doses and shields will be labeled with approved labels. .

13. PETNET will provide copies of batch records and analytical test results to NAVIDEA upon release of a Batch and within four (4) days of completion of sterility testing of the Batch.

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, Attachment 1

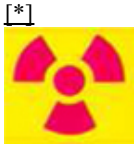
SHIELD LABEL

[^{18}F]NAV4694
[Pharmacy name and location]
Batch # _____
Calibration @ EOS*:
Date _____ Time _____
Activity Concentration:
_____ mCi in _____ mL @ EOS
Expires: Date _____ Time:_____

Subject No. _____

Sterile Solution for Intravenous Administration
Caution: New drug – Limited by Federal Law to Investigational Use

Each mL contains __ mCi of [^{18}F]NAV4694 at EOS.
Contains: [*]
Store upright in shielded container at 2° – 30°C.
Do not use if cloudy or contains particulate matter.
[*]



CAUTION: RADIOACTIVE MATERIAL

Syringe Label

[^{18}F]NAV4694
Rx #_____ Date/Time(@EOS):_____
[^{18}F]NAV4694: _____mCi@dosing
Time (@dosing):_____
Patient ID:_____

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

Specifications, Analytical Tests and Acceptance Criteria

Test	Acceptance criteria	Method reference
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

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EXHIBIT C

Financial Terms

1. In consideration for PETNET providing the selected qualified Facilities to produce the Product in support of the Trials, NAVIDEA shall pay the following non-refundable (except as set forth in Section 11.3) Technology Transfer and Site Qualification Fees to PETNET:

   Technology Transfer Fee:

   - **[*]**

   Site Qualification Fees:

   [*]

   - [*]:
     - o [*]
     - o [*]
     - o [*]
     - o [*]

2. PETNET will provide NAVIDEA an estimated total [*] of Product from the Facilities (the "Product Volume") for the Trials over the Initial Term. In exchange for PETNET's commitment to produce the Product Volume, NAVIDEA shall pay PETNET the following nonrefundable monthly production fees:

   Production Fees:

   - **[*]**

     plus

   - **$[*]** of Product supplied to NAVIDEA.

3. In addition to the price per Batch set forth in paragraph 2 of this Exhibit C, NAVIDEA will reimburse PETNET for all actual freight charges for transportation of Doses of Product from a Facility to the specified Trial Site.

4. The Site Qualification and Production Fees shall apply to each additional Facility selected for production beyond the minimum required in Exhibit A.

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

Payment Schedule

PETNET shall invoice Navidea according to the following schedule:

Technology Transfer Fee

- [*]
- [*]
- [*]

[*]

Site Implementation Fees

-[*]

(Initiation to begin immediately after contract execution and start of Technology Transfer)

- [*]

Infrastructure and Equipment Fees

[*]

[*]

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EXHIBIT D

NAVIDEA Materials

NAV4694RS 2-[2- (fluoro) -6- (methylamino) -3-pyridinyl]-5-benzofuranol

NAV4614 *t*-Butyl 5-(5-(ethoxymethoxy)benzofuran-2-yl)-6-nitropyridine-2-yl(methyl)carbamate

[*]

- [*]
- [*]
- [*]
- [*]

Exhibit 99.1

Press Release

FOR IMMEDIATE RELEASE

Navidea Biopharmaceuticals Announces Centers for Medicare & Medicaid Services (CMS) Issuance of Lymphoseek® Reimbursement Pass-Through C Code, Effective as of October 1, 2013

- HCPCS Code Establishes Reimbursement Mechanism for Healthcare Providers -

DUBLIN OHIO, August 20, 2013 -- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that the Centers for Medicare & Medicaid Services (CMS) has issued a Healthcare Common Procedure Coding System (HCPCS) Pass-Through "C Code", for Lymphoseek (technetium Tc 99m tilmanocept) Injection. Navidea anticipates that the billing code, which will become effective on October 1, 2013, will streamline the billing and reimbursement process for hospital providers who use Lymphoseek and support its fair and equitable reimbursement. Lymphoseek was approved by the U.S. Food and Drug Administration in March, 2013 for use in lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma.

About Lymphoseek®

Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule radiopharmaceutical used in lymphatic mapping procedures that are performed to help in the diagnostic evaluation of potential cancer spread for patients with breast cancer and melanoma. Lymphoseek is designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek was approved by the U.S. Food and Drug Administration in March, 2013 for use in lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma. The Company anticipates continuing development of Lymphoseek into other solid tumor areas that may include head and neck cancers, prostate cancer, thyroid cancer, lung/bronchus cancers, colorectal cancer and others.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to the American Cancer Society, approximately 232,000 new cases of breast cancer, 77,000 new cases of melanoma and 67,000 new cases of head and neck/oral cancer are expected to be diagnosed in the United States in 2013.

U.S. Indication and Important Safety Information About Lymphoseek
Indication

Lymphoseek (technetium Tc 99m tilmanocept) Injection is a lymphatic mapping agent indicated for use with a hand-held gamma counter to assist in the localization of lymph nodes draining a primary tumor site in patients with breast cancer or melanoma.

- more -

NAVIDEA BIOPHARMACEUTICALS
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Important Safety Information
In clinical trials with Lymphoseek, no serious hypersensitivity reactions were reported, however Lymphoseek may pose a risk of such reactions due to its chemical similarity to dextran. Serious hypersensitivity reactions have been associated with dextran and modified forms of dextran (such as iron dextran drugs).

Prior to the administration of Lymphoseek, patients should be asked about previous hypersensitivity reactions to drugs, in particular dextran and modified forms of dextran. Resuscitation equipment and trained personnel should be available at the time of Lymphoseek administration, and patients observed for signs or symptoms of hypersensitivity following injection.

The most common adverse reactions are injection site irritation and/or pain (<1%).

FULL LYMPHOSEEK PRESCRIBING INFORMATION CAN BE FOUND AT:
WWW.LYMPHOSEEK.COM

About Navidea Biopharmaceuticals Inc.
Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is actively developing four radiopharmaceutical agent platforms – Lymphoseek® (technetium 99m tilmanocept) Injection, NAV4694, NAV5001 and RIGScan ^{TM} – to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. Navidea's first commercial agent, Lymphoseek, was approved by the FDA in March 2013. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and advancing the Company's pipeline through selective acquisitions, global partnering and commercialization efforts. For more information, please visit www.navidea.com.

The Private Securities Litigation Reform Act of 1995 (the Act) provides a safe harbor for forward-looking statements made by or on behalf of the Company. Statements in this news release, which relate to other than strictly historical facts, such as statements about the Company's plans and strategies, expectations for future financial performance, new and existing products and technologies, anticipated clinical and regulatory pathways, and markets for the Company's products are forward-looking statements within the meaning of the Act. The words "believe," "expect," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date hereof. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, the Company's continuing operating losses, uncertainty of market acceptance of its products, reliance on third party manufacturers, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on limited product line and distribution channels, competition, limited marketing and manufacturing experience, risks of development of new products, regulatory risks and other risks detailed in the Company's most recent Annual Report on Form 10-K and other Securities and Exchange Commission filings. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

Contact:
Source: Navidea Biopharmaceuticals, Inc.
Navidea Biopharmaceuticals
Brent Larson, 614-822-2330
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Beth DelGiacco, 212-362-1200

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Exhibit 99.2

Navidea BIOPHARMACEUTICALS

Press Release

FOR IMMEDIATE RELEASE

Navidea Biopharmaceuticals Signs Manufacturing Agreement with Siemens' PETNET Solutions for NAV4694 Beta-amyloid Imaging Agent

- NAV4694 clinical trial doses to be manufactured and supplied by PETNET Solutions' locations in the United States -

DUBLIN, OHIO – August 21, 2013 – Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced it has signed an agreement with Siemens' PETNET Solutions that grants PETNET Solutions the right to manufacture Navidea's Fluorine-18 labeled NAV4694, an investigational beta-amyloid PET imaging agent, which is currently being evaluated in Phase 2 and 3 clinical trials evaluating subjects with signs or symptoms of cognitive impairment such as Mild Cognitive Impairment and Alzheimer's disease. Under the terms of its agreement with Navidea, Siemens' PETNET Solutions will initially manufacture NAV4694 clinical trial material at select U.S. radiopharmacies, with the possibility of expanding into additional Siemens' PETNET Solutions locations next year.

"We are delighted that the NAV4694 clinical program will be supported by Siemens' PETNET Solutions' extensive PET manufacturing and dispensing expertise." said Mark Pykett, CEO of Navidea. "Navidea is committed to providing the medical community and patients afflicted by Alzheimer's disease, Parkinson's disease and other neurodegenerative disorders with valuable precision diagnostics that ensure the best patient outcome including improved diagnostic accuracy, clinical decision-making and patient care."

"Siemens' PETNET Solutions is proud to collaborate with Navidea, a leading biopharmaceutical company, to support the availability of new PET imaging agents with our manufacturing expertise as the largest PET radiopharmaceutical manufacturer in the world," said Dr. Christoph Zindel, CEO of Siemens' PETNET Solutions. "Our collaboration with Navidea reaffirms our commitment to help fight the world's most challenging diseases, including Alzheimer's disease."

Siemens' PETNET Solutions operates the world's largest network of PET radiopharmaceutical drug manufacturing facilities and dispensing nuclear pharmacies, with over 50 locations worldwide. They manufacture and dispense PET radiopharmaceuticals for hospitals, clinics and research facilities worldwide.

About NAV4694
NAV4694 is a Fluorine-18 labeled precision radiopharmaceutical candidate intended for use in Positron Emission Tomography (PET) imaging and evaluation of patients with signs or symptoms of cognitive impairment such as Alzheimer's disease (AD). NAV4694 binds to beta-amyloid deposits in the brain that can then be imaged in scans. Beta-amyloid plaque pathology is widely used in the diagnosis of AD. The ability of NAV4694 imaging to display amyloid plaque pathology may enable earlier identification of AD and improve monitoring of disease progression and interpretation of brain scan images. Navidea has an ongoing NAV4694 Phase 2b trial in Mild Cognitive Impairment and a Phase 3 program for NAV4694 in AD.

- more -

About Navidea Biopharmaceuticals Inc.
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Exhibit 99.3

Navidea BIOPHARMACEUTICALS

Press Release

FOR IMMEDIATE RELEASE

Navidea Awarded NIH SBIR Grant for NAV4694 Beta-Amyloid Imaging Agent Phase 3 Clinical Program Aimed at Alzheimer's Disease

DUBLIN OHIO, August 21, 2012 — Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced the award of a Small Business Innovation Research (SBIR) grant from the National Institute On Aging (NIA) of the National Institutes of Health (NIH) in connection with the Company's Phase 3 clinical program for its NAV4694 beta-amyloid imaging agent as an aid in the differential diagnosis of Alzheimer's disease. The SBIR grant has the potential to provide up to $1.8 million in support, if fully funded, through the conclusion of the Phase 3 clinical study. Funding for the approved first stage of the grant ($259,000) is intended to provide support for initiation activities of the Phase 3 clinical program. Funding of the second stage of the grant is contingent upon meeting specific aims related to the first stage of the grant such as institutional review board approval of the Phase 3 protocol, clinical site contracting and investigator training. Navidea announced the initiation of the Phase 3 program in June 2013.

"We are pleased that the NIH has recognized the potential value for NAV4694 which we believe can play an important role in clinical practice allowing for earlier diagnosis and therapeutic intervention in cases of dementia," said Frederick Cope, PhD, FACN, Navidea Senior Vice President and Chief Scientific Officer. "We expect this trial will further highlight several of the key features of NAV4694 such as high amyloid binding/sensitivity, low white matter uptake, strong signal-to-noise ratios and clear, unambiguous images. We believe that earlier and more effective diagnosis is directly in line with the federal government's aim to address the impact of this devastating disease. We very much appreciate the support of the NIH as we conduct this pivotal Phase 3 clinical trial."

"The pivotal Phase 3 study is designed to provide a direct comparison of NAV4694 patient images collected during life with postmortem histopathology findings. The results from this study may lead to improved differential diagnosis and patient management," said Cornelia Reininger, MD, PhD, Navidea Senior Vice President and Chief Medical Officer. "NAV4694 is a great example of a precision diagnostic agent with the potential to help physicians overcome the frequent challenges of diagnostic uncertainty and provide millions of patients with more accurate diagnoses."

About NAV4694

NAV4694 is a Fluorine-18 labeled precision radiopharmaceutical candidate intended for use in Positron Emission Tomography (PET) imaging and evaluation of patients with signs or symptoms of cognitive impairment such as Alzheimer's disease (AD). NAV4694 binds to beta-amyloid deposits in the brain that can then be imaged in scans. Beta-amyloid plaque pathology is widely used in the diagnosis of AD. The ability of NAV4694 imaging to display amyloid plaque pathology may enable earlier identification of AD and improve monitoring of disease progression and interpretation of brain scan images. Navidea has an ongoing NAV4694 Phase 2b trial in Mild Cognitive Impairment and a Phase 3 program for NAV4694 in AD.

- more -

About Alzheimer's
Alzheimer's disease (AD) is a progressive and fatal neurodegenerative disease which affects a person's memory and ability to learn, reason, communicate and carry out daily activities. Increasing age is the greatest risk factor for AD and there is no prevention or cure. The World Health Organization estimates that Alzheimer's disease affects over 24 million people worldwide. Currently in the U.S. alone, there are over 5 million Alzheimer's patients with estimates that by 2050, as many as 14 million Americans could have the disease according to the Alzheimer's Association**.** Among the brain changes believed to contribute to the development of Alzheimer's are the accumulation of the protein beta-amyloid *outside* nerve cells (neurons) in the brain and the accumulation of the protein tau *inside* neurons. Approximately 75 to 100 experimental technologies aimed at diagnosing, slowing or stopping the progression of Alzheimer's are now in human clinical trials.

About Navidea Biopharmaceuticals Inc.
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Exhibit 99.4

Navidea BIOPHARMACEUTICALS

Press Release

FOR IMMEDIATE RELEASE

Navidea Biopharmaceuticals Announces Agreement with FDA on Special Protocol Assessments for NAV5001 Phase 3 Program

- SPA provides clear pathway to NDA — preparations underway to commence enrollment -

DUBLIN, OHIO – August 22, 2013 – Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) for two special protocol assessments (SPA) for the Company's pivotal Phase 3 program with NAV5001 as an aid in the differential diagnosis of Parkinsonian Syndromes from non-Parkinsonian tremor. NAV5001 is an investigational imaging agent used to visualize dopamine transporters (DAT) in the brain using single photon emission tomography (SPECT) imaging. The SPAs are written agreements between the Company, as the program's sponsor, and FDA regarding the design, endpoints and statistical analysis for the two, pivotal Phase 3 clinical trials to be used in support of a potential NAV5001 New Drug Application (NDA). The Company is actively preparing for the initiation of the pivotal Phase 3 trials later this year.

"Reaching an agreement on the SPAs indicates that FDA considers the design of the program and positive results from the Phase 3 trials will be appropriate for FDA consideration for regulatory approval of NAV5001 as an aid in the diagnosis of Parkinonsian syndromes," said William J. Regan, Navidea Senior Vice President, Global Regulatory Strategy. "In achieving the SPA agreements on a first-cycle review, we are extremely pleased to have more certainty around FDA registration requirements."

The international, open-label, pivotal NAV5001 Phase 3 program consists of two similar clinical trials that will run in parallel and enroll approximately 550 total subjects who exhibit early stage tremor. Each Phase 3 trial was the subject of a SPA with FDA. The primary endpoint of both studies is to evaluate the relative diagnostic efficacy of the NAV5001 SPECT images compared with the diagnosis made by neurologists and that established by a consensus panel of three movement disorder specialists as the 'Standard of Truth'. In one study, each subject will undergo SPECT imaging with NAV5001 only. In the second study, subjects will undergo SPECT imaging with both NAV5001 and an alternative SPECT agent, ioflupane, in a cross-over comparison design.

"Clinicians often struggle with diagnosing neurodegenerative diseases such as Parkinsonian syndromes," said Cornelia Reininger, MD, PhD, Navidea Senior Vice President and Chief Medical Officer. "The differential diagnoses of movement disorders and tremor are extensive, and the disorders often exhibit similarities, especially early in the initial clinical presentation. The data accumulated to date from NAV5001 clinical trials suggests that it may be an effective, well-tolerated imaging agent with high affinity for DAT and rapid kinetics which enable faster generation of clear images, and may assist physicians in reaching an accurate diagnosis. We are excited to begin this registration program focused on patients with emerging symptoms where diagnostic uncertainty and unmet need are highest. We believe that NAV5001 has the promise to address the needs of a rapidly growing market and will provide another option to the currently marketed diagnostic products and methods."

- more -

About NAV5001
Iodine-123 labeled NAV5001 is a patented, novel, small molecule radiopharmaceutical used with single photon emission computed tomography (SPECT) imaging to identify the status of specific regions in the brains of patients suspected of having Parkinson's disease. The agent binds to the dopamine transporter (DAT) on the cell surface of dopaminergic neurons in the striatum and substantia nigra regions of the brain. Loss of these neurons is a widely recognized hallmark of Parkinson's disease and other forms of Parkinsonism.

NAV5001 has been administered to more than 600 subjects in multi-phase clinical trials to date. Results from these clinical trials have demonstrated that NAV5001 has high affinity for DAT and rapid kinetics which enable the generation of clean diagnostic images quickly, beginning within approximately 20 minutes after injection. In addition to its potential use as an aid in the differential diagnosis of Parkinsonian syndromes and movement disorders, NAV5001 may also be useful in the diagnosis of Dementia with Lewy Bodies (DLB), which is the second most common cause of progressive dementia after Alzheimer's disease.

About Parkinsonian Syndromes, Parkinson's Disease and other movement disorders
Parkinsonian syndromes and movement disorders such as Essential Tremor represent a class of neurodegenerative diseases with important diagnostic needs. Parkinsonian syndromes (PS) are neurodegenerative disorders that affect a person's ability to control movement and other muscle functions. Parkinson's Disease is the most common form of Parkinsonian Syndromes believed to be caused by loss of dopamine producing neurons in the brain and with first symptoms such as tremor, rigidity, or slow movement. Other less common Parkinsonian Syndromes include multiple system atrophy (MSA), Progressive Supranuclear Palsy (PSP), and drug-induced Parkinsonism. The Parkinson's Disease Foundation (PDF) estimates that up to 10 million people worldwide are living with PD, including 1 million people in the U.S. Approximately 60,000 new cases of PD are diagnosed in the U.S. each year.[i] The International Essential Tremor Foundation estimates that as many as 10 million people in the United States are afflicted by essential tremor.

PD is commonly misdiagnosed or completely missed in clinical evaluations as symptoms are often attributed to the normal aging process. Essential tremor and the other similar conditions are also common sources of confusion in PD diagnosis. Collectively, there are over 25 million people in the U.S. and Europe with some type of movement disorder, comprising a large differential diagnosis population.

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NAVIDEA BIOPHARMACEUTICALS
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[i] Parkinson's Disease Foundation. Statistics on Parkinson's: http://www.pdf.org/en/parkinson_statistics. Accessed on August 21, 2013.

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