NAVIDEA BIOPHARMACEUTICALS, INC.
Form 8-K
August 22, 2013

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.

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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

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