NAVIDEA BIOPHARMACEUTICALS, INC.
Form 8-K
May 16, 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) May 10, 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 May 10, 2013, Navidea Biopharmaceuticals, Inc. (the "Company") entered into a clinical supply agreement (the "Supply Agreement") with Nordion (Canada,) Inc. ("Nordion"). The Supply Agreement focuses on Nordion's cGMP manufacturing and supply of NAV5001 clinical trial material to be produced at Nordion's Vancouver, British Columbia, facility. Accordingly, Nordion will radiolabel the Company's precursor drug product with Iodine-123 to form [^{123}I]NAV5001, manage the logistics and make arrangements for shipment of [^{123}I]NAV5001 to third-party clinical trial sites on behalf of the Company. [^{123}I]NAV5001 is a single photon emission computed tomography (SPECT) imaging agent being developed as an aid in the diagnosis of Parkinson's disease and other movement disorders. The Supply Agreement has a term which commenced on May 10, 2013 (the "Effective Date"), and, unless earlier terminated as provided pursuant to its terms, which will expire three years after the Effective Date.

In consideration for the services provided by Nordion, the Company paid Nordion an initial amount upon the execution of the Supply Agreement, and will pay Nordion: (1) additional amounts upon Nordion's achievement of milestones associated with the return to operation of the Nordion facility for purposes of manufacturing a supply of [^{123}I]NAV5001 for the Company's use in clinical trials; and (2) a price per batch of [^{123}I]NAV5001 manufactured pursuant to the Supply Agreement. Commencing in the full first month following the completion of the Nordion facility and its readiness to manufacture [^{123}I]NAV5001, the Company will have an obligation to purchase a minimum amount of [^{123}I]NAV5001 from Nordion. If the Company fails to meet its minimum purchase obligations, Nordion may suspend its manufacturing operations at the facility and terminate the Supply Agreement. During the effective term of the Supply Agreement Nordion will not produce [^{123}I]NAV5001 for, or sell or provide [^{123}I]NAV5001 to, any third-party, except as instructed by the Company.

The foregoing description of the terms of the Supply Agreement is qualified in its entirety by reference to the text of the Supply 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 May 15, 2013, the Company issued a press release announcing that it had entered into the Supply Agreement with Nordion to produce and supply ^{123}I-labeled NAV5001 for the Company's late-phase clinical trials. A copy of the complete text of the Company's May 15, 2013, press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	*Exhibit Description*
10.1	[^{123}I]NAV5001 Clinical Supply Agreement, dated May 10, 2013, by and between Nordion (Canada) Inc. and Navidea Biopharmaceuticals, 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 May 15, 2013, entitled “Navidea Biopharmaceuticals Signs Manufacturing and Supply Agreement with Nordion.”

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: May 16, 2013 By: /s/ Brent L. Larson
Brent L. Larson, Executive Vice President and

Chief Financial Officer