NAVIDEA BIOPHARMACEUTICALS, INC.
Form 8-K
March 11, 2015

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) March 5, 2015

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.)

5600 Blazer Parkway, Suite 200, 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 March 5, 2015, the Company and SpePharm AG (an affiliate of Norgine BV), a European specialist pharmaceutical company with an extensive pan-European presence ("SpePharm"), announced that they had entered into an exclusive sublicense agreement for the commercialization and distribution of Lymphoseek® 250 microgram kit for radiopharmaceutical preparation ("Product") in the European Union ("License Agreement"). Under the terms of the License Agreement, Navidea is entitled to receive an upfront payment of $2 million and is eligible to receive additional milestone payments up to $5 million, as well as royalties on European net sales.

The territory licensed to SpePharm initially consists of countries and territories included within the Company's marketing authorization by the European Medicines Agency, with an option to expand the territory to include additional countries. SpePharm will assume development and regulatory responsibilities for the Product in the territory, including conduct of market access clinical studies.

SpePharm is responsible for developing a commercial launch plan for the Product in the licensed territory, subject to review and comment by the Company, and to use commercially reasonable efforts to market and promote the Product. SpePharm may sell the Product at prices determined in its sole discretion. In addition to the upfront payment, SpePharm is required to make additional payments to the Company of up to $5 million on the achievement of defined milestones relating to the Product and achievement of net sales targets for the Product, as well as royalties on net sales of the Product.

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

Item 8.01 Other Events.

On March 5, 2015, the Company issued a press release regarding its entry into the License Agreement. A copy of the Company's March 5, 2015 press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in Item 8.01 of this Current Report on Form 8-K, including exhibit 99.1 attached hereto, shall not be treated as "filed" for purposes of the Securities Exchange Act of 1934, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	*Exhibit Description*
10.1	Exclusive License Agreement, dated March 5, 2015 between the Company and SpePharm AG (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	Press release, dated March 5, 2015, entitled “Navidea and Norgine Enter European Commercial Partnership for Lymphoseek®; Navidea to Receive $2 Million Upfront Payment.”

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, and markets for the Company’s products, are forward-looking statements. 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, 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, and other risks detailed in the Company’s most recent Annual Report on Form 10-K 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: March 11, 2015 By: /s/ Brent L. Larson
Brent L. Larson,
Executive Vice
President and

Chief Financial
Officer