

NAVIDEA BIOPHARMACEUTICALS, INC.

Form 8-K

November 30, 2016

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) November 23, 2016

NAVIDEA BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware 001-35076 31-1080091
(State or other jurisdiction (Commission (IRS Employer
of incorporation) File Number) 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.)

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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 November 23, 2016, Navidea Biopharmaceuticals, Inc. (the “Company”) entered into an Asset Purchase Agreement (the “Purchase Agreement”) with Cardinal Health 414, LLC, a Delaware limited liability company (“Cardinal”). Pursuant to the Purchase Agreement, Cardinal will acquire the Company’s assets used, held for use, or intended to be used in operating its business of developing, manufacturing and commercializing a product used for lymphatic mapping, lymph node biopsy, and the diagnosis of metastatic spread to lymph nodes for staging of cancer (the “Business”), including the Company’s radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the Federal Drug Administration (“FDA”) and similar indications approved by the FDA in the future (the “Business Product”), in Canada, Mexico and the United States (the “Territory”) (giving effect to the license-back described below and excluding certain assets specifically retained by the Company) (the “Asset Sale”). Such assets to be acquired in the Asset Sale consist primarily of, without limitation, (i) intellectual property used in or reasonably necessary for the conduct of the Business, (ii) inventory of, and customer, distribution, and product manufacturing agreements related to, the Business, (iii) all product registrations related to the Business Product, including the new drug application approved by the FDA for the Business Product and all regulatory submissions in the United States that have been made with respect to the Business Product and all Health Canada regulatory submissions and, in each case, all files and records related thereto, (iv) all related clinical trials and clinical trial authorizations and all files and records related thereto, and (v) all right, title and interest in and to the Business Product, as specified in the Purchase Agreement (the “Acquired Assets”). In exchange for the Acquired Assets, Cardinal agreed to (i) make a cash payment to the Company at closing of \$80 million (reduced by an aggregate of approximately \$64.5 million of indebtedness to be repaid to Capital Royalty Partners II, L.P. and Platinum-Montaur Life Sciences LLC and its affiliates on behalf of the Company, the amount by which, if any, transferred Business Product inventory is less than \$6 million, and estimated transaction costs of \$600,000), (ii) assume certain liabilities of the Company associated with the Business Product as specified in the Purchase Agreement, and (iii) make periodic earnout payments (to consist of contingent payments and milestone payments which, if paid, will be treated as additional purchase price) to the Company based on net sales derived from the purchased Business Product subject, in each case, to Cardinal’s right to off-set. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed \$230 million over a period of ten years, of which a cumulative amount of \$20.1 million are guaranteed payments for the three years immediately after closing of the Asset Sale.

The Purchase Agreement contains customary representations and warranties made by the Company and Cardinal. The Company has also agreed to comply with covenants during the interim period between the date of the execution of the Purchase Agreement and the date of consummation of the Asset Sale. In addition, the Purchase Agreement provides that the parties will indemnify each other for breaches of these representations, warranties and covenants, subject to certain limitations, and for certain other matters.

Under the Purchase Agreement, the Company agreed, subject to certain exceptions, for a period of five years after closing of the Asset Sale, to certain non-competition restrictions with respect to the Business (including marketing any products for unapproved uses that allow such products to compete with the Business Product) in the Territory.

At the closing of the Asset Sale, the parties will enter into a License-Back Agreement (“License-Back”) pursuant to which Cardinal will grant to the Company a sublicensable (subject to conditions) and royalty-free license to use certain intellectual property rights included in the Acquired Assets and owned by Cardinal as of the closing of the Asset Sale to the extent necessary for the Company to (i) on an exclusive basis, subject to certain conditions, develop, manufacture, market, sell and distribute new pharmaceutical and other products that are not Competing Products (as defined in the License-Back), and (ii) on a non-exclusive basis, develop, manufacture, market, sell and distribute the Business Product throughout the world other than in the Territory. The License-Back also restricts Cardinal from using the intellectual property rights included in the Acquired Assets and owned by Cardinal as of the closing of the Asset Sale to develop, manufacture, market, sell, or distribute any product other than the Business Product or other product that (a) accumulates in lymphatic tissue or tumor-draining lymph nodes for the purpose of lymphatic mapping or identifying the existence, location or staging of cancer in a body, or (b) provides for or facilitates any test or procedure that is reasonably substitutable for any test or procedure provided for or facilitated by the Business Product. Pursuant to the License-Back, Cardinal will be provided with a right of first offer to market, sell and/or market any new products developed from the intellectual property rights licensed by Cardinal to the Company by the License-Back.

As part of the Asset Sale, the Company and Cardinal will also enter into ancillary agreements providing for transitional services and other arrangements. The Company is required to amend and restate its license agreement with The Regents of the University of California (San Diego) (“UCSD”) pursuant to which UCSD grants a license to the Company to exploit certain intellectual property rights owned by UCSD and, separately, Cardinal will enter into a license agreement with UCSD pursuant to which UCSD will grant a license to Cardinal to exploit certain intellectual property rights owned by UCSD for Cardinal to sell the Business Product in the Territory. In addition, pursuant to the Purchase Agreement, the Company shall grant to each of Cardinal and UCSD a five (5)-year warrant to purchase up to 10 million shares and 1 million shares, respectively, of the Company’s common stock, par value \$.001 per share, at an exercise price of \$1.50 per share, each of which warrant is subject to anti-dilution and other customary terms and conditions.

Consummation of the Asset Sale is subject to customary conditions, including, among others, (i) approval by the Company's stockholders of the Asset Sale, (ii) all filings with governmental authorities, if any, shall have been made and any necessary authorizations, consents, or approvals required from such authorities shall have been obtained, (iii) if any notification is required by the Hart-Scott Rodino Act, the waiting period (and any extension thereof) under such act shall have expired or will have been terminated, and (iv) the absence of any valid order, statute, rule, regulation, executive order, stay, decree, judgment or injunction prohibiting or preventing consummation of the Asset Sale.

The Purchase Agreement also contains certain termination rights, including, without limitation, the right of either party to terminate the Purchase Agreement if the closing of the Asset Sale has not occurred on or before the date that is 180 days after the date of the Purchase Agreement, unless extended by mutual agreement of the parties, or the Company does not receive stockholder approval of the Asset Sale at its next special meeting of stockholders. The Company will also be required to pay a termination fee of \$3 million to Cardinal and reimburse Cardinal for its reasonable out-of-pocket expenses not to exceed \$2 million in the aggregate under certain circumstances, including if the Purchase Agreement is terminated by (i) the Company prior to stockholder approval and concurrently with such termination the Company shall enter into another acquisition agreement providing for implementation of transactions contemplated by a superior proposal, or (ii) Cardinal if (a) the Company's Board of Directors adversely changes its favorable recommendation that its stockholders approve the Asset Sale, (b) the Company fails to reconfirm its favorable recommendation of the Asset Sale in certain circumstances within five business days of Cardinal's request, (c) the Company or its Board of Directors makes certain public disclosures with respect to certain acquisition proposals other than the Asset Sale, or (d) the Company is in material breach of its exclusivity obligations under the Purchase Agreement.

The foregoing description of the Purchase Agreement does not purport to be complete, and is qualified in its entirety by reference to the Purchase Agreement (and exhibits), a copy of which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference. A copy of the press release announcing execution of the Purchase Agreement is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

Exhibit Description

Number

10.1 Asset Purchase Agreement, dated November 23, 2016, between Navidea Biopharmaceuticals, Inc. and Cardinal Health 414, LLC.

99.1 Press Release dated November 23, 2016.

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: November 30, 2016 By: /s/ Jed A. Latkin
Jed A. Latkin,
Interim Chief
Operating Officer