

NAVIDEA BIOPHARMACEUTICALS, INC.

Form 8-K

March 09, 2017

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 3, 2017

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.

The information set forth under Item 2.01 below is incorporated into this Item 1.01 by reference.

On March 3, 2017, Navidea Biopharmaceuticals, Inc. (the “Company”) entered into a Global Settlement Agreement with its subsidiary, Macrophage Therapeutics, Inc. (“Macrophage”), Capital Royalty Partners II L.P. and its affiliates (collectively, “CRG”), and Cardinal Health 414, LLC (“Cardinal Health 414”) to effectuate the terms of the settlement previously entered into by the parties on February 22, 2017 in the interpleader action pending in Ohio. A description of the material terms of the settlement is set forth in the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on February 23, 2017, which description is incorporated herein by reference.

In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid \$59 million (the “Deposit Amount”) of its indebtedness and other obligations outstanding under the Term Loan Agreement, dated as of May 8, 2015 (as amended, supplemented or modified, the “Loan Agreement”), by and among, the Company, Macrophage and CRG, and all other documents, instruments and agreements entered into in connection therewith (collectively with the Loan Agreement, the “CRG Loan Documents”). A description of the material terms of the CRG Loan Documents is set forth in the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on May 15, 2015, which description is incorporated herein by reference. Cardinal Health 414 paid \$3 million of the Deposit Amount as a prepayment of guaranteed earnout payments that would have otherwise been payable to the Company in the third year after closing of the Asset Sale (as defined below) pursuant to the Asset Purchase Agreement dated as of November 23, 2016 between the Company and Cardinal Health 414 (the “Purchase Agreement”). Such prepayment by Cardinal Health 414 does not affect its indemnification rights (and Cardinal Health 414 has the right to setoff its indemnification claims against all future earnout payments) under the Purchase Agreement. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the actual amount owed by the Company to CRG under the CRG Loan Documents, as more fully disclosed in the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on February 23, 2017, which description is incorporated herein by reference. As part of the settlement, the Ohio action was dismissed with prejudice, except that the Company’s rights to contest the actual amount owed to CRG within the agreed upon parameters in the Texas action were not affected. On March 3, 2017, Cardinal Health 414 posted a \$7 million letter of credit, and on March 7, 2017, CRG posted a \$12 million letter of credit, each as required by the Global Settlement Agreement.

The foregoing description of the Global Settlement Agreement does not purport to be complete, and is qualified in its entirety by reference to the Global Settlement 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.

Item 1.02 Termination of a Material Definitive Agreement.

The information set forth under Items 1.01 and 2.01 is incorporated into this Item 1.02 by reference.

Item 2.01 Completion of Acquisition or Disposition of Assets.

On March 3, 2017, pursuant to the Purchase Agreement, the Company completed its previously announced sale to Cardinal Health 414 of its 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 U.S. Food and Drug Administration (“FDA”) and similar indications approved by the FDA in the future (the “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 sold 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 Product, including the new drug application approved by the FDA for the Product and all regulatory submissions in the United States that have been made with respect to the 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 Product, as specified in the Purchase Agreement (the “Acquired Assets”).

In exchange for the Acquired Assets, Cardinal Health 414 (i) made a cash payment to the Company at closing of approximately \$80.6 million after adjustments based on inventory being transferred and an advance of \$3 million of guaranteed earnout payments as part of the CRG settlement described in Item 1.01 above, (ii) assumed certain liabilities of the Company associated with the Product as specified in the Purchase Agreement, and (iii) agreed to 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 Product subject, in each case, to Cardinal Health 414’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 \$20.1 million are guaranteed payments for the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, \$3 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG as part of the Deposit Amount paid to CRG described in Item 1.01 above.

In addition to payment of the Deposit Amount to CRG set forth in Item 1.01 above, the Company repaid to Platinum Partners Credit Opportunities Master Fund, LP (“PPCO”) an aggregate of \$7,714,109.47 in partial satisfaction of the Company’s liabilities, obligations and indebtedness under that certain Loan Agreement, dated July 25, 2012 (as amended on June 25, 2013, March 4, 2014, May 8, 2015 and otherwise) by and between the Company and Platinum-Montaur Life Sciences, LLC (“Platinum-Montaur”), which, to the extent of such payment, were transferred by Platinum Montaur to PPCO. The Company was informed by Platinum Partners Value Arbitrage Fund LP (“PPVA”) that it was the owner of the balance of the Platinum Montaur loan. Such balance was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Michael Goldberg, the Company’s Chief Executive Officer, and PPVA.

Upon closing of the Asset Sale, the Supply and Distribution Agreement, dated November 15, 2007 (as amended, the “Supply and Distribution Agreement”), between Cardinal Health 414 and the Company was terminated and, as a result, the provisions thereof are of no further force or effect (other than any indemnification, payment, notification or data sharing obligations which survive the termination). At the closing of the Asset Sale, Cardinal Health 414 paid to the Company \$1.2 million, as an estimate of the accrued revenue sharing payments owed to the Company as of the closing date, net of prior payments.

In connection with the closing of the Asset Sale, the Company entered into a License-Back Agreement (the “License-Back”) with Cardinal Health 414. Pursuant to the License-Back, Cardinal Health 414 granted to the Company a sublicensable (subject to conditions) and royalty-free license to use certain intellectual property rights included in the Acquired Assets (as defined below) and owned by Cardinal Health 414 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 Product (as defined below) throughout the world other than in the Territory. Subject to the Company’s compliance with certain restrictions in the License-Back, the License-Back also restricts Cardinal Health 414 from using the intellectual property rights included in the Acquired Assets to develop, manufacture, market, sell, or distribute any product other than the Product or other product that (a) accumulates in lymphatic tissue or tumor-draining lymph nodes for the purpose of (1) lymphatic mapping or (2) 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 Product. Pursuant to the License-Back and subject to rights under existing agreements, Cardinal Health 414 was given a right of first offer to market, sell and/or market any new products developed from the intellectual property rights licensed by Cardinal Health 414 to the Company by the License-Back.

As part of the Asset Sale, the Company and Cardinal Health 414 also entered into ancillary agreements providing for transitional services and other arrangements. The Company amended and restated 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 Health 414 entered into a license agreement with UCSD pursuant to which UCSD granted a license to Cardinal Health 414 to exploit certain intellectual property rights owned by UCSD for Cardinal Health 414 to sell the Product in the Territory.

Pursuant to the Purchase Agreement, the Company granted to each of Cardinal Health 414 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.

Prior to the Asset Sale, the Company had no material relationships with Cardinal Health 414 or its affiliates except that Cardinal Health 414 was the Company's primary distributor of the Product throughout the United States pursuant to the Supply and Distribution Agreement which, as set forth above, was terminated as of the closing of the Asset Sale.

The foregoing description of the Purchase Agreement, the License-Back, the Warrants and the UCSD License Agreement does not purport to be complete and is qualified in its entirety by reference to such documents attached hereto as Exhibits 10.2 through 10.6, and incorporated herein by reference.

Item 3.02 Unregistered Sales of Equity Securities.

Pursuant to the Purchase Agreement, the Company granted to each of Cardinal Health 414 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. The Company relied on the exemption from registration under Section 4(2) of the Securities Act of 1933, as amended, for the issuance of the warrants.

Item 9.01 Financial Statements and Exhibits.

(b)

Pro Forma Financial Information

The unaudited pro forma condensed consolidated balance sheet of the Company as of September 30, 2016 and the unaudited pro forma condensed consolidated statements of operations of the Company for the nine months ended September 30, 2016 and for the years ended December 31, 2015 and December 31, 2014 have been previously filed in the Company's Definitive Proxy Statement filed with the Securities and Exchange Commission on February 8, 2017 and are incorporated herein by reference.

(d) Exhibits.

Exhibit

Number Exhibit Description

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|------|--|
| 10.1 | Global Settlement Agreement dated March 3, 2017 by and among Navidea Biopharmaceuticals, Inc., Cardinal Health 414, LLC, Macrophage Therapeutics, Inc., Capital Royalty Partners II L.P., Capital Royalty Partners II (Cayman), L.P., Capital Royalty Partners II – Parallel Fund “A” L.P., Parallel Investment Opportunities Partners II L.P. and Capital Royalty Partners II – Parallel Fund “B” (Cayman) L.P. |
| 10.2 | Asset Purchase Agreement, dated November 23, 2016, between Navidea Biopharmaceuticals, Inc. and Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 30, 2016). |
| 10.3 | License-Back Agreement, dated March 3, 2017, between Navidea Biopharmaceuticals, Inc. and Cardinal Health 414, LLC. |
| 10.4 | Warrant, dated March 3, 2017, issued to Cardinal Health 414, LLC. |
| 10.5 | Warrant, dated March 3, 2017, issued to The Regents of the University of California (San Diego). |
| 10.6 | Amended and Restated License Agreement, dated March 3, 2017, between Navidea Biopharmaceuticals, Inc. and The Regents of the University of California (San Diego) (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission). |

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 8, 2017 By: /s/ Jed A. Latkin
Jed A. Latkin, Interim Chief Operating
Officer