

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 4, 2016

NAVIDEA BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-35076</u> (Commission File Number)	<u>31-1080091</u> (IRS Employer Identification No.)
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<u>5600 Blazer Parkway, Suite 200, Dublin, Ohio</u> (Address of principal executive offices)	<u>43017</u> (Zip Code)
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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 2.02 Results of Operations and Financial Condition.

On August 4, 2016, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release regarding its consolidated financial results for the quarter ended June 30, 2016. A copy of the Company’s August 4, 2016 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 2.02 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

99.1 Press Release dated August 4, 2016.

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, ability to repay debt, the outcome of the CRG litigation, 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: August 4, 2016

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



Press Release

FOR IMMEDIATE RELEASE

Navidea Reports Second Quarter 2016 Financial Results

DUBLIN OHIO, August 4, 2016 - Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), today announced financial results for the second quarter of 2016. Navidea reported total revenue for the second quarter of 2016 of \$5.4 million, including Lymphoseek[®] (technetium Tc 99m tilmanocept) injection sales revenue of \$4.2 million. The net loss from operations was \$580,000 and the net loss attributable to common stockholders was \$6.7 million.

"Despite the significant disruption in our organization during the first half of 2016 caused by legal and financial challenges, we remain committed to advancing our Lymphoseek commercial efforts, expanding our Manocept[™] platform to other larger immunodiagnostic and immunotherapeutic indications, and controlling our operating expenses" said Jed Latkin, interim Chief Operating Officer and Chief Financial Officer at Navidea. "Despite the disruptions caused by CRG's (Capital Royalty Partners II L.P.) actions we are confident that the technology we are developing and our lead commercial product, Lymphoseek, provide Navidea and its shareholders with significant unrealized value. Given the advanced state of our technology, continued growth of Lymphoseek in the U.S. and the impending launch in Europe, we believe we will be successful in seeking a replacement financing arrangement for the CRG debt. We believe we have significant claims for damages against CRG that we intend to pursue. Finally our Macrophage Therapeutics subsidiary has made great strides towards demonstrating the breadth of the technology's potential to develop innovative immunotherapies."

Specific events and milestones achieved since the beginning of the second quarter include the following:

Commercial

- Achieved sequential quarter-on-quarter Lymphoseek revenue growth of 12% and continued improvement in key performance indicators;
- Reported investigator-initiated study results demonstrating beneficial performance characteristics of Lymphoseek and positive comparative results versus commonly-used, non-receptor-targeted imaging agents in breast cancer presented by Emory University School of Medicine and University of California San Diego (UCSD) at the 2016 Society of Nuclear Medicine and Molecular Imaging annual meeting; and
- Continued to progress our development efforts to meet the projected Q4 launch of Lymphoseek in Europe by our partner, Norgine BV.

Lymphoseek Lifecycle Management

- Continued market development clinical activities with Navidea's and investigator-initiated studies in cervical cancer, pediatric solid tumors, anal-rectal cancer, endometrial cancer, and for further confirmation of workflow efficiency compared to sulfur colloid, which are supported in large part by National Institutes of Health (NIH) grant funding; and
- Received Western Institutional Review Board (WIRB) approval of several Lymphoseek investigational protocols including anal-rectal cancer sentinel lymph node detection, imaging in Kaposi sarcoma (KS) and intravenous (IV) administration in rheumatoid arthritis (RA).

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Immunodiagnostic & Immunotherapeutic Development Pipeline

- Rheumatoid Arthritis Immunodiagnostic Indication
 - Received IRB approval at University of California, San Francisco and from WIRB for the RA subcutaneous administration clinical trial protocol;
 - Expect patient enrollment in the subcutaneous injection trial to begin shortly;
 - Awarded Part 2 grant funding of \$1.1 million from our previously announced RA grant;
- Completed cardiovascular disease imaging study with Massachusetts General Hospital, manuscripts being prepared for publication;
- Expect to begin grant-funded Phase 1/2 evaluation of Lymphoseek - IV in KS patients in the second half of 2016;
- Received \$1.8 million grant to support the development of Manocept immunotherapeutic program in KS; and
- Successfully completed a number of preclinical studies of Manocept in animal models of nonalcoholic steatohepatitis (NASH), arthritis, asthma, neuro-inflammation and tumor-associated macrophage (TAM) depletion in two cancer models. Both MT1000 class and MT2000 class molecules demonstrated their predicted activity in animal testing.

Operational & Financial

- Reduced cash used in operations by over 87% for the first half of 2016 compared to the first half of 2015; and
- Continued partnering/divestiture efforts for the Company's investigational imaging agent, NAV4694, for the detection of amyloid plaques in Alzheimer's disease.

CRG litigation update

As previously reported, on April 7, 2016, Navidea received a notice from CRG pursuant to the Term Loan Agreement, dated May 8, 2015 which claimed that certain Events of Default, unrelated to repayment terms, had occurred under the Loan Agreement. CRG commenced a state court action in Harris County, Texas District Court against the Company on that same date. By letter dated May 31, 2016, CRG declared all of the Company's obligations under the Loan Agreement and all other loan documents to be immediately due and payable in the amount of \$56,157,240.69. The Company disputes the total amount claimed to be due and owing, and contends CRG's acceleration of the maturity of the loan was improper. On July 13, 2016, a hearing was held in the District Court of Harris County, Texas with respect to CRG's application for a temporary injunction seeking to restrain Navidea from operating or using new accounts without having first entered into a blocked account control and/or pledge collateral account control agreement with CRG for any such new account. At the conclusion of the temporary injunction hearing, the Court ordered the parties to mediation and stayed any ruling on CRG's request for injunctive relief until after mediation has been completed. The parties participated in a mediation on July 20, 2016, but did not reach a settlement. The district judge in the Texas case has since recused herself from the case, and the case has been reassigned to a different Harris County District Court. The district court did not issue a ruling on the application for temporary injunction prior to the judge's recusal from the case, and no hearing or other matter is currently set in the Texas court case.

Concurrently with the Texas court case, CRG previously sent a notice to Cardinal Health demanding that all monies owing to Navidea be sent directly to CRG. In response, Cardinal filed an interpleader action in Ohio, pursuant to which the Ohio court initially ruled that 50% of the monies should be sent to Navidea, and 50% should be placed into the registry of the Court pending a determination of the parties' rights to the funds. The court has since ruled that 75% of the Cardinal payments should be sent to Navidea and 25% should be deposited into the registry of the court up until the deposit in the registry of the court equals \$1 million, which will serve as a bond pending a determination on the merits of the case, and then Navidea will receive 100% of the Cardinal payments pending further order by the Court in the Ohio case.

The Company reiterates its firmly-held position that the alleged claims by CRG do not constitute Events of Default under the Loan Agreement and will vigorously defend against such claims. The Company also contends CRG's wrongful conduct has caused harm to the Company and it will pursue its counterclaims against CRG seeking all remedies and other relief it may be entitled to under the law.

The Company is also continuing to explore alternative financing arrangements in order to refinance the CRG debt. The Company believes that the actions of CRG are a violation of the Loan Agreement and, as a result, CRG is in breach of the Loan Agreement, not the Company. The Company believes that its best course of action is to refinance the CRG debt and pursue its claims for damages.

Financials

Total revenues for the quarter ended June 30, 2016 were \$5.4 million compared to \$2.9 million in the second quarter of last year. Second quarter 2016 product revenues recognized from the sale of Lymphoseek were \$4.2 million, compared to \$3.8 million in the first quarter of 2016 and \$2.0 million in the second quarter of 2015. During the second quarter of 2016, the Company also reported \$1.2 million in grant, licensing and other revenue. For the six months ended June 30, 2016, Navidea's total revenue was \$10.1 million compared to \$5.0 million for the same period in 2015, an increase of 103%. The primary driver of this increase was revenues recognized from the sale of Lymphoseek which exceeded \$8.0 million for the six months ended June 30, 2016 compared to \$3.8 million for the same period last year.

Gross margins on Lymphoseek product sales grew to 87% for the second quarter of 2016 compared to 83% for the second quarter of 2015, primarily due to inventory written off in 2015 related to a production issue.

Research and development (R&D) expenses for the second quarter of 2016 were \$2.5 million, compared to \$2.3 million in the second quarter of last year. R&D expenses were \$5.2 million for the six months ended June 30, 2016 compared to \$6.3 million in the same period of 2015. The net decreases in year-to-date R&D expenses were primarily a result of decreased headcount costs coupled with decreased project costs related to the Company's neuro assets, offset by increased project costs related to the Company's Manocept and Lymphoseek programs. Selling, general and administrative (SG&A) expenses for the second quarter of 2016 were \$2.9 million, compared to \$4.0 million in the second quarter of last year. SG&A expenses were \$7.0 million for the six months ended June 30, 2016, compared to \$9.5 million for the same period in 2015. The net decrease in year-to-date SG&A expenses was due primarily to decreased headcount coupled with decreased costs related to contracted medical science liaisons, commercialization costs for Lymphoseek and NAV4694 and license fees, offset by increases in commercial headcount costs related to the addition of our internal sales force coupled with increased legal and professional services. Total operating expenses were \$5.4 million for the second quarter of 2016, compared to \$6.3 million in the second quarter of last year. Operating expenses were \$12.2 million for the six months ended June 30, 2016, compared to \$15.8 million for the same period in 2015.

Navidea's net loss from operations for the quarter ended June 30, 2016 was \$580,000 compared to \$3.8 million for the same period in 2015. For the six months ended June 30, 2016, Navidea's net loss from operations was \$3.1 million compared to a net loss from operations of \$11.6 million for the same period in 2015. Navidea's net loss attributable to common stockholders for the quarter ended June 30, 2016 was \$6.7 million, or \$0.04 per share, compared to \$9.7 million, or \$0.06 per share, for the same period in 2015. For the six months ended June 30, 2016, Navidea's net loss attributable to common stockholders was \$10.4 million, or \$0.07 per share, compared to a net loss attributable to common stockholders of \$17.0 million, or \$0.11 per share, for the same period in 2015. Net losses attributable to common stockholders include fees paid to CRG (which the Company is disputing in court), the interest expense on our outstanding debt, as well as significant non-cash charges. For the six-month periods ended June 30, 2016 and June 30, 2015, net loss attributable to common stockholders included \$7.2 million and \$5.4 million, respectively, in interest, debt-related fees, losses on extinguishment of debt, and changes in the fair value of financial instruments.

Navidea ended the quarter with \$1.7 million in cash, \$501,000 of which was restricted related to the CRG debt.

Conference Call Details

Investors and the public are invited to access the live audio webcast through the link below. Participants who would like to ask questions during the question and answer session must participate by telephone also. Participants are encouraged to log-in and/or dial-in fifteen minutes before the conference call begins. The webcast replay is expected to be available on our investor website, <http://ir.navidea.com>, approximately two to four hours after the live event.

Event: Navidea Biopharmaceuticals Q2 2016 Financial Results Conference Call

Date/Time: August 4, 2016; 8:30 a.m. ET

Webcast Link: <http://edge.media-server.com/m/p/2h7aqbav>

Dial-in Number – US: (855) 897-5884

Dial in Number – Int'l: (720) 634-2940

Conference ID Number: 56279154

Replay: A webcast replay will be available on the Investor Relations section of our website at <http://ir.navidea.com> for 30 days.

About Lymphoseek

Lymphoseek[®] (technetium Tc 99m tilmanocept) injection is the first and only FDA-approved receptor-targeted lymphatic mapping agent. It is a novel, receptor-targeted, small-molecule radiopharmaceutical used in the evaluation of lymphatic basins that may have cancer involvement in patients. Lymphoseek is designed for the precise identification of lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek is approved by the U.S. Food and Drug Administration (FDA) for use in solid tumor cancers where lymphatic mapping is a component of surgical management and for guiding sentinel lymph node biopsy in patients with clinically node negative breast cancer, melanoma or squamous cell carcinoma of the oral cavity. Lymphoseek has also received European approval in imaging and intraoperative detection of sentinel lymph nodes in patients with melanoma, breast cancer or localized squamous cell carcinoma of the oral cavity.

Accurate diagnostic evaluation of cancer is critical, as results guide therapy decisions and determine patient prognosis and risk of recurrence. Overall in the U.S., solid tumor cancers may represent up to 1.2 million cases per year. The sentinel node label in the U.S. and Europe may address approximately 600,000 new cases of breast cancer, 160,000 new cases of melanoma and 100,000 new cases of head and neck/oral cancer diagnosed annually.

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Lymphoseek Indication and Important Safety Information

Lymphoseek is a radioactive diagnostic agent indicated with or without scintigraphic imaging for:

- Lymphatic mapping using a handheld gamma counter to locate lymph nodes draining a primary tumor site in patients with solid tumors for which this procedure is a component of intraoperative management.
- Guiding sentinel lymph node biopsy using a handheld gamma counter in patients with clinically node negative squamous cell carcinoma of the oral cavity, breast cancer or melanoma.

Important Safety Information

In clinical trials with Lymphoseek, no serious hypersensitivity reactions were reported, however Lymphoseek may pose a risk of such reactions due to its chemical similarity to dextran. Serious hypersensitivity reactions have been associated with dextran and modified forms of dextran (such as iron dextran drugs).

Prior to the administration of Lymphoseek, patients should be asked about previous hypersensitivity reactions to drugs, in particular dextran and modified forms of dextran. Resuscitation equipment and trained personnel should be available at the time of Lymphoseek administration, and patients observed for signs or symptoms of hypersensitivity following injection.

Any radiation-emitting product may increase the risk for cancer. Adhere to dose recommendations and ensure safe handling to minimize the risk for excessive radiation exposure to patients or health care workers.

In clinical trials, no patients experienced serious adverse reactions and the most common adverse reactions were injection site irritation and/or pain (<1%).

FULL LYMPHOSEEK PRESCRIBING INFORMATION CAN BE FOUND AT:
WWW.LYMPHOSEEK.COM

About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products and platforms including Manocept™ and NAV4694 to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making, targeted treatment and, ultimately, patient care. Lymphoseek® (technetium Tc 99m tilmanocept) injection, Navidea's first commercial product from the Manocept platform, was approved by the FDA in March 2013 and in Europe in November 2014. The development activities of the Manocept immunotherapeutic platform will be conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel products and advancing the Company's pipeline through global partnering and commercialization efforts. For more information, please visit www.navidea.com.

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 in this news release, 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, our ability to repay our debt, the outcome of the CRG litigation, 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 and other Securities and Exchange Commission filings. The Company undertakes no obligation to publicly update or revise any forward-looking The Company undertakes no obligation to publicly update or revise any forward-looking statements.

Source: Navidea Biopharmaceuticals, Inc.

Contact: Navidea Biopharmaceuticals

Investors & Media

Sharon Correia, 978-655-2686

Associate Director, Corporate Communications

FINANCIAL TABLES TO FOLLOW

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NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2016 (unaudited)	December 31, 2015
Assets:		
Cash	\$ 1,155,641	\$ 7,166,260
Restricted cash	500,997	-
Other current assets	5,200,144	5,410,914
Non-current assets	1,825,367	2,387,339
Total assets	\$ 8,682,149	\$ 14,964,513
Liabilities and stockholders' deficit:		
Deferred revenue, current	\$ 681,704	\$ 1,044,281
Notes payable, current	51,652,209	333,333
Other current liabilities	10,058,459	4,806,236
Deferred revenue	26,061	192,728
Notes payable, net of discount	9,519,779	60,746,002
Other liabilities	650,931	1,677,633
Total liabilities	72,589,143	68,800,213
Navidea stockholders' deficit	(64,376,195)	(54,305,258)
Noncontrolling interest	469,201	469,558
Total stockholders' deficit	(63,906,994)	(53,835,700)
Total liabilities and stockholders' deficit	\$ 8,682,149	\$ 14,964,513

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Six Months Ended	
	June 30, 2016 (unaudited)	June 30, 2015 (unaudited)	June 30, 2016 (unaudited)	June 30, 2015 (unaudited)
Revenue:				
Lymphoseek sales revenue	\$ 4,231,719	\$ 1,963,548	\$ 8,014,399	\$ 3,798,970
Lymphoseek license revenue	245,950	250,000	500,000	333,333
Grant and other revenue	916,811	654,360	1,602,636	844,061
Total revenue	5,394,480	2,867,908	10,117,035	4,976,364
Cost of goods sold	560,740	332,730	1,095,669	781,787
Gross profit	4,833,740	2,535,178	9,021,366	4,194,577
Operating expenses:				
Research and development	2,525,581	2,297,074	5,185,101	6,278,362
Selling, general and administrative	2,888,141	4,048,799	6,984,801	9,542,967
Total operating expenses	5,413,722	6,345,873	12,169,902	15,821,329
Loss from operations	(579,982)	(3,810,695)	(3,148,536)	(11,626,752)
Interest expense, net	(7,528,475)	(1,575,741)	(9,721,998)	(2,542,317)
Equity in the loss of joint venture	(2,920)	(6,205)	(15,159)	(268,432)
Loss on disposal of joint venture	(39,732)	-	(39,732)	-
Change in fair value of financial instruments	1,469,928	(1,852,730)	2,595,287	(125,627)
Loss on extinguishment of debt	-	(2,440,714)	-	(2,440,714)
Other income (expense), net	(126)	(4,834)	(37,418)	21,698
Net loss	(6,681,307)	(9,690,919)	(10,367,556)	(16,982,144)
Net loss attributable to noncontrolling interest	(116)	(241)	(357)	(341)
Deemed dividend on beneficial conversion feature	-	-	-	(46,000)
Net loss attributable to common stockholders	\$ (6,681,191)	\$ (9,690,678)	\$ (10,367,199)	\$ (17,027,803)
Loss per common share (basic and diluted)	\$ (0.04)	\$ (0.06)	\$ (0.07)	\$ (0.11)
Weighted average shares outstanding (basic and diluted)	155,382,368	150,107,148	155,346,231	149,951,603

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