

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 17, 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 May 17, 2016, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release regarding its consolidated financial results for the quarter ended March 31, 2016. A copy of the Company’s May 17, 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 May 17, 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.

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**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 17, 2016

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

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Press Release

FOR IMMEDIATE RELEASE

### Navidea Reports First Quarter 2016 Financial Results

DUBLIN OHIO, May 17, 2016 - Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), today announced financial results for the first quarter of 2016. Navidea reported total revenue for the first quarter of 2016 of \$4.7 million, including Lymphoseek<sup>®</sup> (technetium Tc 99m tilmanocept) injection sales revenue to Navidea of \$3.8 million. The net loss attributable to common stockholders was \$3.7 million.

“Since the start of the year there have been numerous changes at Navidea as we position the company for the best return on the commercialization of our Lymphoseek immunodiagnostic product and our exciting Manocept<sup>™</sup> therapeutic platform,” said Jed Latkin, interim Chief Operating Officer. “Lymphoseek Q1 2016 revenue grew 8% quarter-on-quarter and 106% versus the same quarter last year and we expect much stronger revenue growth in future quarters reflective of the addition of four key regional sales reps and positive utilization trends observed in some major medical accounts. Of note, our operating expenses continue to decline and are significantly reduced from 2015 as we seek to gain operational cash flow breakeven in 2016.”

Mr. Latkin continued, “Additionally we are making progress in expanding the clinical application of Lymphoseek into new solid tumors in the U.S. and an expected Q4 2016 launch in Europe, as well as immunodiagnostic indications such as Rheumatoid Arthritis and cardiovascular diseases. We are also obtaining baseline proof of concept data for technology in therapeutic applications. These therapeutic pre-clinical studies will allow us to seek a foundational partnership in each key therapeutic area to help fund development while maximizing return and minimizing the dilution to our shareholders. We look forward to a strong, eventful 2016.”

### PRODUCT, PIPELINE & BUSINESS UPDATES

#### **Lymphoseek**

- Grew Lymphoseek revenue 106% in Q1 2016 versus same quarter last year, maintained gross margins on sales of Lymphoseek in excess of 85%, maintained high reorder rates in excess of 80% and continued to accelerate trial and adoption in major cancer centers;
- Added and trained four new regional sales reps, expanding our sales team from 12 to 16 sales professionals supported by four Medical Science Liaisons (MSLs);
- Broadened access to Lymphoseek through the voucher program and vial consignment program within major multi-hospital chains who have high potential to adopt Lymphoseek and who are influential in the practices of other institutions. These large multi-hospital accounts have the potential to rapidly increase volume growth; and
- Continued market development clinical activities with Navidea 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 part by National Institutes of Health (NIH) grant funding.

#### **Manocept Immunodiagnostic Pipeline**

- Advanced development efforts for intravenous (IV) and subcutaneous delivery supported by NIH grant funds in order to expand the label of tilmanocept;
- Submitted non-clinical data package and held successful Food and Drug Administration (FDA) meeting in March with agreed submission of an Investigational New Drug (IND) amendment to the FDA that will allow initiation of IV clinical studies of Lymphoseek;
- Awaiting Institutional Review Board (IRB) approval to begin sub-cutaneous Phase 1 study in Rheumatoid Arthritis (RA). Expect to begin Phase 1/2 IV study in RA later in the year;
- Completed enrollment in a pilot cardiovascular imaging study evaluating detection of vulnerable plaque at Massachusetts General Hospital. Preliminary results are very promising and are being prepared for publication in medical journals; and
- Expect to begin grant-funded Phase 1/2 evaluation of Lymphoseek - IV in Kaposi’s Sarcoma patients in the second half of 2016.

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**Manocept Immunotherapeutic Development Pipeline (Macrophage Therapeutics)**

- Completed an 8-week, preclinical mouse study in an arthritis mouse model with a Manocept anti-inflammatory targeted therapeutic product, MT2002, with initial results reporting clear anti-inflammatory activity with no apparent significant side effects;
- Completed an animal study in an asthma model that measured the ability of MT2002 to decrease all three markers of pro-inflammatory markers secreted by disease-causing macrophages that successfully demonstrates an anti-inflammatory effect;
- Completed dosing in two studies using a neuro-inflammation model and an animal model for NASH, nonalcoholic steatohepatitis, with results expected in coming weeks; and
- Initiated a number of studies evaluating the performance of compounds from the MT1000 class of compounds designed to deplete tumor associated macrophages (TAMs) in a number of different cancer models.

**Business**

- Named Jed Latkin as interim Chief Operating Officer to direct the Company's day-to-day operations and act as principal executive officer and principal financial and accounting officer until replacements are hired following the departure of Rick Gonzalez as President and CEO and a medical leave by Brent Larson, EVP and CFO;
- Named Marcum LLP as corporate independent registered public accounting firm following resignation of BDO USA, L.L.P.;
- Announced appointment of Mark I. Greene, M.D., Ph.D. FRCP, Tony Fiorino, M.D., Ph.D. and Michael Rice to the Board of Directors and the departure of Brendan Ford, Anton Gueth, Rick Gonzalez and Gordon Troup; and
- Capital Royalty Partners II L.P. (CRG) commenced a lawsuit alleging that events of default have occurred under the Company's loan agreement with CRG. The Company intends to vigorously defend against these claims. The Company is evaluating its options, including the possible assertion of counterclaims.

**FINANCIALS**

Total revenues for the quarter ended March 31, 2016 were \$4.7 million compared to \$2.1 million in the first quarter of last year. First quarter 2016 product revenues recognized from the sale of Lymphoseek were \$3.8 million, compared to \$3.5 million in the fourth quarter of last year and \$1.8 million in the first quarter of last year. This represents a sequential quarter-on-quarter growth of 8% and year-over-year growth of approximately 106%. Q1 2016 revenue for licensing milestones, various federal grants and other revenue were \$940,000 compared to \$791,000 in the fourth quarter of last year and \$273,000 in the first quarter of last year.

Gross margins on Lymphoseek product sales remain strong at 86% for the first quarter of 2016 compared to 76% for the first quarter of 2015.

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Total operating expenses were \$6.8 million, compared to \$9.5 million in the first quarter of last year. Research and development expenses for the first quarter of 2016 were \$2.7 million, compared to \$4.0 million in the first quarter of last year. The net decrease from 2015 to 2016 was primarily a result of reductions in NAV4694, NAV5001 and Lymphoseek product development costs coupled with reduced headcount and related support costs, offset by increased therapeutics product development costs. Selling, general and administrative expenses for the first quarter of 2016 were \$4.1 million, compared to \$5.5 million in the first quarter of last year. The net decrease was primarily due to decreased general and administrative headcount following the first quarter 2015 reduction in force coupled with decreased costs for contracted medical science liaisons, business development consulting services, market development expenses related to Lymphoseek, and license fees, offset by increased commercial and medical headcount coupled with increased legal and professional services.

Navidea's net loss attributable to common stockholders for the quarter ended March 31, 2016 was \$3.7 million, or \$0.02 per share, compared to \$7.3 million, or \$0.05 per share, for the same period in 2015.

Based on CRG's claims that the Company is in default under the terms of the CRG Loan Agreement, and in accordance with current accounting guidance, the Company has classified the net balance of the CRG Term Loan as a current liability on the consolidated balance sheet as of March 31, 2016.

Navidea ended the quarter with \$5.5 million in cash.

The Company reiterates its 2016 total revenue estimate of \$23 million to \$25 million. Margins on Lymphoseek product sales are expected to continue to exceed 80% in the coming quarters. The Company also expects, following completion of the partnering activities for NAV4694, that cash operating expenses on a quarterly basis will continue to decrease to the point necessary for the Company to achieve its goals of cash flow breakeven from operations. This guidance excludes therapeutic-related research and development costs for the Manocept platform which are expected to be funded separately by Macrophage Therapeutics, Inc.

#### **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 Q1 2016 Financial Results Conference Call
Date/Time:	Tuesday, May 17, 2016 at 8:00 a.m. ET
Webcast Link:	<a href="http://edge.media-server.com/m/p/b5ki35y5/lan/en">http://edge.media-server.com/m/p/b5ki35y5/lan/en</a>
Dial-in Number – US:	1 (855) 897-5884
Dial in Number – Int'l:	1 (720) 634-2940
Participant Passcode:	11165733
Replay	A webcast replay will be available on the Investor Relations section of our website at <a href="http://ir.navidea.com">http://ir.navidea.com</a> 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.

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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.

**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](http://www.navidea.com).

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*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 statements.*

**Source:** Navidea Biopharmaceuticals, Inc.

**Contact:** Navidea Biopharmaceuticals

Investors & Media

Sharon Correia, 978-655-2686

Senior Director, Corporate Communications

FINANCIAL TABLES TO FOLLOW

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NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2016 <u>(unaudited)</u>	December 31, 2015 <u></u>
Assets:		
Cash	\$ 5,484,083	\$ 7,166,260
Other current assets	4,552,041	5,410,914
Non-current assets	2,247,557	2,387,339
Total assets	<u>\$ 12,283,681</u>	<u>\$ 14,964,513</u>
Liabilities and stockholders' deficit:		
Deferred revenue, current	\$ 945,190	\$ 1,044,281
Notes payable, current, net of discount	50,179,537	333,333
Other current liabilities	5,968,108	4,806,236
Deferred revenue	26,061	192,728
Notes payable, net of discount	10,672,265	60,746,002
Other liabilities	1,653,328	1,677,633
Total liabilities	<u>69,444,489</u>	<u>68,800,213</u>
Navidea stockholders' deficit	(57,630,124)	(54,305,258)
Noncontrolling interest	469,316	469,558
Total stockholders' deficit	<u>(57,160,808)</u>	<u>(53,835,700)</u>
Total liabilities and stockholders' deficit	<u>\$ 12,283,681</u>	<u>\$ 14,964,513</u>

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**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended	
	March 31, 2016 (unaudited)	March 31, 2015 (unaudited)
Revenue:		
Lymphoseek sales revenue	\$ 3,782,680	\$ 1,835,422
Lymphoseek license revenue	254,050	83,333
Grant and other revenue	685,825	189,701
Total revenue	<u>4,722,555</u>	<u>2,108,456</u>
Cost of goods sold	<u>534,929</u>	<u>449,057</u>
Gross profit	<u>4,187,626</u>	<u>1,659,399</u>
Operating expenses:		
Research and development	2,659,520	3,981,288
Selling, general and administrative	4,096,660	5,494,168
Total operating expenses	<u>6,756,180</u>	<u>9,475,456</u>
Loss from operations	<u>(2,568,554)</u>	<u>(7,816,057)</u>
Other income (expense):		
Interest expense, net	(2,193,523)	(966,576)
Equity in the loss of joint venture	(12,239)	(262,227)
Change in fair value of financial instruments	1,125,359	1,727,103
Loss on extinguishment of debt	-	-
Other income (expense), net	<u>(37,292)</u>	<u>26,532</u>
Net loss	<u>(3,686,249)</u>	<u>(7,291,225)</u>
Less loss attributable to noncontrolling interest	(241)	(100)
Deemed dividend on beneficial conversion feature	-	(46,000)
Net loss attributable to common stockholders	<u>\$ (3,686,008)</u>	<u>\$ (7,337,125)</u>
Loss per common share (basic and diluted)	\$ (0.02)	\$ (0.05)
Weighted average shares outstanding (basic and diluted)	155,308,094	149,794,331

- end-