

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 4, 2015

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 November 4, 2015, the Company issued a press release regarding its consolidated financial results for the third quarter of 2015. A copy of the Company's November 4, 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 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 November 4, 2015, entitled "Navidea Reports 2015 Third Quarter Financial Results."

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: November 6, 2015

By: /s/ Brent L. Larson
Brent L. Larson, Executive Vice
President and
Chief Financial Officer



Press Release

FOR IMMEDIATE RELEASE**Navidea Reports 2015 Third Quarter Financial Results**

DUBLIN, OH, November 4, 2015 -- Navidea Biopharmaceuticals (NYSE MKT: NAVB) reports financial results for the quarter ending September 30, 2015. The Company achieved the following financial highlights:

- Third quarter 2015 total revenue of \$4 million; comprised of \$3 million in Lymphoseek[®] (technetium Tc 99m tilmanocept) injection sales, \$550,000 in Lymphoseek license revenue, and \$477,000 in grant and other revenue
- 50% sequential quarterly and 168% year-over-year third quarter Lymphoseek product sales growth
- Year-to-date gross margins on product sales of 82%
- \$6.8 million in 2015 year-to-date product sales, which puts the Company on track to achieve our product revenue guidance.

“We continue to execute on the new commercial strategy we put in place to start the year for our immuno-diagnostic product, Lymphoseek,” said Rick Gonzalez, President and Chief Executive Officer. “Sales growth is anticipated to continue in the fourth quarter and into 2016 and beyond based on further penetration of the sentinel lymph node market; expansion to lymphatic mapping with additional solid tumors; and the impact from additional hospital system and institution-wide sales activities.”

Mr. Gonzalez continued, “To position us for longer-term growth, clinical development will begin next year for new imaging applications in Kaposi’s sarcoma, rheumatoid arthritis and cardiovascular disease. These pipeline opportunities create a valuable bridge to potential immuno-therapeutics, which, similar to Lymphoseek, would take advantage of the Manocept platform’s ability to selectively target disease-associated immune cells.”

PRODUCT & PIPELINE UPDATES**Lymphoseek**

- Published results in the *Journal of Surgical Oncology* showing a statistically significant reduction in pain for Lymphoseek vs. sulfur colloid, a key differentiator for patients and physicians
- Continued market development activities with Company and investigator-initiated studies in cervical cancer, pediatric solid tumors, anal-rectal cancer, and for further confirmation of workflow efficiency compared to sulfur colloid

Technetium Tc 99m tilmanocept Pipeline

- Advanced development efforts for intravenous and subcutaneous delivery
 - o Awarded NIH grants to develop the product for early detection of rheumatoid arthritis (RA) and cardiovascular disease
 - o Academic collaborators continued development for clinical imaging of Kaposi’s sarcoma tumor lesions

Manocept[™] Therapeutic Development Pipeline

- Received Manocept-bound Accurins from BIND Therapeutics, Inc. for potential use in targeting analysis of disease-associated macrophages
- Reported data demonstrating that a Manocept-doxorubicin (MT-1001) conjugate selectively targets tumor-associated macrophages and destroys the cells through an apoptotic mechanism

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FINANCIALS

“Growth in Lymphoseek sales combined with funding from grants and our continued efforts to contain costs have contributed to an overall trend of reduction in our quarterly cash burn,” said Brent Larson, Navidea’s Chief Financial Officer. “We remain confident that we will see additional commercial momentum during the fourth quarter and into 2016 as a result of the impact from the field sales force we deployed in May. This expected increase, coupled with an estimated gross margin in excess of 80%, means that each incremental dollar of revenue our sales force generates has a significant positive impact on our cash flow. During 2015, we have continued making limited investment in the NAV4694 clinical trial process based on our expectation that we will be successful in ultimately securing a partnership that will provide us some level of return on this investment. However, in addition to a potential return, the elimination of expenses related to this asset is also expected to have positive near-term contribution to our cash burn.”

Revenue & Gross Profit

Total revenue for the quarter ended September 30, 2015 reached \$4 million, and for the nine months then ended, reached \$9 million. Of these amounts, Lymphoseek sales revenue grew to \$3 million for the quarter and \$6.8 million for the nine months ended September 30, 2015, which represents 168% and 143% in year over year growth for the respective periods. The primary driver of this increase was increased adoption of Lymphoseek by new customers. Third quarter 2015 margins also remained above 80% contributing to a total gross profit of \$3.5 million for the quarter.

	Three Months Ended		Nine Months Ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
	<u>(unaudited)</u>	<u>(unaudited)</u>	<u>(unaudited)</u>	<u>(unaudited)</u>
Revenue:				
Lymphoseek sales revenue	\$ 2,952,522	\$ 1,101,071	\$ 6,751,492	\$ 2,773,959
Lymphoseek license revenue	550,000	300,000	883,333	300,000
Grant and other revenue	<u>476,755</u>	<u>848,999</u>	<u>1,320,816</u>	<u>1,002,605</u>
Total revenue	<u>3,979,277</u>	<u>2,250,070</u>	<u>8,955,641</u>	<u>4,076,564</u>
Gross profit	\$ 3,521,687	\$ 1,442,190	\$ 7,716,264	\$ 2,804,966

Operating Expenses, Income & Balance Sheet

The Company reduced net loss for the quarter and nine months ended September 30, 2015 compared to the same periods in the prior year. Two of the key factors in these reductions were the sales growth and decreased R&D expenses on a year-to-date basis related to the Company’s non-core neuroimaging assets coupled with decreased headcount costs. This was offset by an increase to SG&A expenses due primarily to net increases in commercial headcount costs coming from the addition of the sales force and an increase in professional services costs offset by a decrease in medical science liaison costs. Net losses attributable to common stockholders include the cash interest expense on our outstanding debt, as well as significant non-cash charges related to interest, loss on debt extinguishment and changes in the fair value of financial instruments.

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	Three Months Ended		Nine Months Ended	
	September 30, 2015 (unaudited)	September 30, 2014 (unaudited)	September 30, 2015 (unaudited)	September 30, 2014 (unaudited)
Operating expenses:				
Research and development	3,902,155	4,158,085	10,180,517	14,496,977
Selling, general and administrative	3,942,609	2,646,591	13,485,576	11,465,076
Total operating expenses	7,844,764	6,804,676	23,666,093	25,962,053
Loss from operations	\$ (4,323,077)	\$ (5,362,486)	\$ (15,949,829)	\$ (23,157,087)
Net loss attributable to common stockholders	\$ (8,070,764)	\$ (6,898,896)	\$ (25,098,567)	\$ (28,861,683)

The Company ended the quarter with \$11.4 million in cash.

MILESTONES

Select milestones Navidea expects to achieve in the near-term include the following:

- Divest or partner the Company's non-core Phase 3 Alzheimer's diagnostic imaging candidate, NAV4694
- Complete preclinical studies for intravenous delivery of tilmanocept and initiate clinical trials in RA
- Achieve \$10 to \$12 million in Lymphoseek product sales for 2015

CONFERENCE CALL

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.

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Event: Navidea Biopharmaceuticals Q3 2015 Financial Results Conference Call
Date/Time: Wednesday, November 4, 2015 at 8:30 a.m. EST
Webcast Link: <http://edge.media-server.com/m/p/apewz7w6/lan/en>
Dial-in Number – US: (855) 897-5884
Dial in Number – Int'l: (720) 634-2940
Conference ID Number: 64585280
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 it guides therapy decisions and determines 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 235,000 new cases of breast cancer, 76,000 new cases of melanoma and 45,000 new cases of head and neck/oral cancer in the U.S., and approximately 367,000 new cases of breast cancer, 83,000 new cases of melanoma and 55,000 new cases of head and neck/oral cancer diagnosed in Europe 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.

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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 immuno-diagnostic agents and immuno-therapeutics. 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. Navidea’s strategy is to deliver superior growth and shareholder return by bringing to market novel immuno-diagnostic agents and immuno-therapeutics, 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, 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

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Media

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Associate Director, Corporate Communications

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Financial tables to follow

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NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2015 <u>(unaudited)</u>	December 31, 2014
Assets:		
Cash	\$ 11,370,420	\$ 5,479,006
Other current assets	3,594,242	3,120,139
Non-current assets	<u>2,518,795</u>	<u>3,321,035</u>
Total assets	<u>\$ 17,483,457</u>	<u>\$ 11,920,180</u>
Liabilities and stockholders' deficit:		
Deferred revenue, current	\$ 1,002,531	\$ -
Notes payable, net of discount, current	333,333	4,383,472
Other current liabilities	4,901,770	4,711,619
Deferred revenue	416,667	-
Notes payable, net of discount	60,946,844	29,539,135
Other liabilities	<u>1,701,939</u>	<u>3,089,420</u>
Total liabilities	<u>69,303,084</u>	<u>41,723,646</u>
Navidea stockholders' deficit	(52,289,359)	(29,803,466)
Noncontrolling interest	469,732	-
Total stockholders' deficit	<u>(51,819,627)</u>	<u>(29,803,466)</u>
Total liabilities and stockholders' deficit	<u>\$ 17,483,457</u>	<u>\$ 11,920,180</u>

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Nine Months Ended	
	September 30, 2015 (unaudited)	September 30, 2014 (unaudited)	September 30, 2015 (unaudited)	September 30, 2014 (unaudited)
Revenue:				
Lymphoseek sales revenue	\$ 2,952,522	\$ 1,101,071	\$ 6,751,492	\$ 2,773,959
Lymphoseek license revenue	550,000	300,000	883,333	300,000
Grant and other revenue	476,755	848,999	1,320,816	1,002,605
Total revenue	3,979,277	2,250,070	8,955,641	4,076,564
Cost of good sold	457,590	807,880	1,239,377	1,271,598
Gross profit	3,521,687	1,442,190	7,716,264	2,804,966
Operating expenses:				
Research and development	3,902,155	4,158,085	10,180,517	14,496,977
Selling, general and administrative	3,942,609	2,646,591	13,485,576	11,465,076
Total operating expenses	7,844,764	6,804,676	23,666,093	25,962,053
Loss from operations	(4,323,077)	(5,362,486)	(15,949,829)	(23,157,087)
Interest expense, net	(2,148,369)	(918,026)	(4,690,686)	(2,764,122)
Equity in the loss of joint venture	(26,785)	(262,198)	(295,217)	(262,198)
Change in fair value of financial instruments	(1,577,275)	(409,650)	(1,702,902)	(109,499)
Loss on extinguishment of debt	-	-	(2,440,714)	(2,610,196)
Other income (expense), net	4,402	53,464	26,100	41,419
Net loss	(8,071,104)	(6,898,896)	(25,053,248)	(28,861,683)
Net loss attributable to noncontrolling interest	(340)	-	(681)	-
Deemed dividend on beneficial conversion feature	-	-	(46,000)	-
Net loss attributable to common stockholders	\$ (8,070,764)	\$ (6,898,896)	\$ (25,098,567)	\$ (28,861,683)
Loss per common share (basic and diluted)	\$ (0.05)	\$ (0.05)	\$ (0.17)	\$ (0.19)
Weighted average shares outstanding (basic and diluted)	150,186,131	150,169,712	150,030,638	148,344,064