

**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 6, 2014

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 6, 2014, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the third quarter ended September 30, 2014. A copy of the Company’s November 6, 2014, 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 (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 7.01 Regulation FD Disclosure.**

During a conference call held by the Company on November 6, 2014, the Company discussed consolidated financial results for the quarter ended September 30, 2014. On the call, the Company provided additional information concerning components of reported operating income, including a \$539,000 charge for obsolescence of Lymphoseek® (technetium Tc 99m tilmanocept) injection inventory. The Company also announced that it will be implementing a 19% increase in the price of Lymphoseek effective December 1, 2014, and that director Michael Goldberg, M.D. will be leading a new initiative to pursue additional therapeutic opportunities for the Company’s Manocept™ platform.

The information contained in Item 7.01 of this Current Report on Form 8-K shall not be treated as “filed” for purposes of the Exchange Act or incorporated by reference in any filing under the Securities Act, except as shall be expressly set forth by specific reference in such a filing. The furnishing of the information in this Item 7.01 is not intended to, and does not, constitute a representation that such furnishing is required by Regulation FD.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

*Exhibit*

*Number*

*Exhibit Description*

99.1	Navidea Biopharmaceuticals, Inc. press release dated November 6, 2014, entitled “Navidea Announces Third Quarter 2014 Financial Results.”
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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.

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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: November 6, 2014

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

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Press Release

FOR IMMEDIATE RELEASE

**Navidea Announces Third Quarter 2014 Financial Results**

- Total Lymphoseek<sup>®</sup> Q3 revenue of \$1.4 million reported –
- Decrease of ~20% in quarterly R&D expenses –
- Conference call today at 8:30 a.m. EST –

DUBLIN, OHIO – November 6, 2014 -- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced financial results and business highlights for the third quarter of 2014. Navidea reported total revenue for third quarter 2014 of \$2.3 million including Lymphoseek<sup>®</sup> (technetium Tc 99m tilmanocept) injection sales revenue of \$1.1 million, \$300,000 of Lymphoseek milestone revenue and \$849,000 of grant and other revenue.

“As I begin my tenure at Navidea, I am excited by the potential for global growth that can be achieved as we strive to make Lymphoseek the standard of care in lymphatic mapping,” commented Rick Gonzalez, Navidea Chief Executive Officer. “While there have been initial commercial challenges since the product launch in 2013, Lymphoseek is realizing strong utilization trends including customer retention, procedural growth, and account growth. We believe the elements required for commercial success both near term and long term are coming together at an ideal time, with the strong label we received last month in the U.S., and the anticipated European approval later this year. We look forward to implementing cost-effective strategies to take advantage of these opportunities to accelerate revenue growth and ensure Lymphoseek can affect the lives of as many patients as possible.”

Brent Larson, Navidea Chief Financial Officer, commented, “We are reporting revenue growth from product sales in the third quarter of approximately 22% quarter on quarter, excluding the one-time pricing impact adjustment related to inventory re-stocking at our distributor’s pharmacies that was recorded during the second quarter of 2014. In addition, as part of our efforts to sharpen our focus on Lymphoseek and the underlying Manocept<sup>™</sup> platform, we have begun to realize the positive effects of cost containment, already attaining a nearly 20% decrease in quarterly research and development expenses from the second quarter of 2014. We believe we can continue to effectively manage our available cash with our expected growth of revenue and gross profit from Lymphoseek, our ability to continue to lower our operating costs and, when or if needed, with access to our available line of credit.”

**Financial Results**

Total revenue recognized for the third quarter of 2014 was \$2.3 million compared to \$400,000 for the same period in 2013. Product revenue derived from net sales of Lymphoseek in the third quarter of 2014 was \$1.1 million compared to \$1 million in the second quarter of 2014, an increase of 5%. However, after excluding the impact from an approximately \$145,000 positive transfer price adjustment on inventory re-stocking recognized during the second quarter of 2014, product sales of Lymphoseek increased over 22% quarter on quarter. During the third quarter of 2014, we also recorded \$300,000 related to an upfront milestone payment received by the Company related to the recent Lymphoseek distribution agreement for China and reported \$849,000 of grant and other revenue. For the nine months ended September 30, 2014, Navidea’s total revenue was \$4.1 million, compared to \$596,000 for the same period in 2013. Based on Lymphoseek revenue year-to-date and anticipated fourth quarter product sales, Navidea is revising its Lymphoseek revenue guidance for the full year 2014 to approximately \$4 million.

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Third quarter 2014 operating expenses were \$6.8 million compared to \$10.2 million for the third quarter of 2013. Operating expenses were \$26.0 million for the nine months ended September 30, 2014, compared to \$25.8 million for the same period in 2013. While total operating expenses remained flat for the nine months ended September 30, 2014 compared to the same period in 2013, the restructuring announced in May 2014 to focus resources on Lymphoseek and the Manocept pipeline began to be realized in the third quarter of 2014 resulting in a nearly 20% reduction in research and development expenses in the third quarter of 2014 as compared to the second quarter. The marked net decrease in total operating expenses the third quarter of 2014 was due primarily to a decline in R&D expenses attributable to the neurology pipeline, and a reduction in headcount, among other factors.

Third quarter 2014 net loss attributable to common stockholders was \$6.9 million, or \$0.05 per share, compared to net loss attributable to common stockholders of \$11.3 million, or \$0.09 per share, in the third quarter of 2013. For the nine months ended September 30, 2014, Navidea's net loss attributable to common stockholders was \$28.9 million, or \$0.19 per share, compared to a net loss attributable to common stockholders of \$28.9 million, or \$0.25 per share, for the same period in 2013.

### **Milestones & Highlights**

Select milestones and highlights that the Company has achieved to date in 2014 include the following:

- Received expanded Lymphoseek approval on October 15<sup>th</sup> from the U.S. Food and Drug Administration (FDA), making Lymphoseek the only agent approved for lymphatic mapping across all solid tumors when used as a component of surgical management and the first and only FDA-approved radiopharmaceutical for sentinel lymph node (SLN) detection for guiding sentinel lymph node biopsy in breast cancer and melanoma in addition to the previous approval for certain head and neck cancer patients.
  - In September, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending marketing authorization for Lymphoseek for detection of sentinel lymph nodes in breast cancer, melanoma, or certain head and neck cancer patients. Final approval by the European Commission is expected by year end.
  - Fast Track NIH Small Business Innovation Research Grant of up to \$1.67M was awarded for a multicenter study evaluating Lymphoseek in cervical cancer.
  - Lymphoseek was granted Orphan Drug Designation by the FDA for use in sentinel lymph node detection in patients with cancer of the head and neck, strengthening Navidea's competitive position by providing seven years of market exclusivity in this indication. The FDA recently notified Navidea the previously paid filing fees of \$1.1 million would be refunded before the end of the year.
  - A development and commercialization agreement was signed with Hainan Sinotau Pharmaceutical Co., Ltd (Sinotau) for Lymphoseek in China including expected revenue based on unit sales to Sinotau, a royalty based on Sinotau's sales of Lymphoseek and up to \$2.5 million in milestones from Sinotau, including a \$300,000 upfront payment.
  - Encouraging positive data and results were presented from Lymphoseek studies in breast cancer, melanoma or head and neck cancer at two major European medical meetings, European Association of Nuclear Medicine and European Society of Surgical Oncology.
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- Rick Gonzalez was appointed Navidea CEO, bringing more than 20 years of experience in the pharmaceutical industry with notable global commercial expertise with oncology and radiotherapy products.
- NIH agreed to repurpose the grant previously awarded for our RIGS initiative towards the study of tumor activated macrophages in colorectal cancer using a Manocept compound.

**Conference Call Details**

Navidea will provide a business update and discuss the third quarter 2014 financial results during a conference call with the investment community scheduled for Thursday, November 6, 2014 at 8:30 a.m. EST. Investors and the public are invited to access the live webcast through the link below. Participants who would like to ask questions during the question and answer session following the presentation 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 Q3 2014 Financial Results Conference Call
Date/Time:	Thursday, November 6, 2014 at 8:30 a.m. EST
Webcast Link:	<a href="http://edge.media-server.com/m/p/24azfty4/lan/en">http://edge.media-server.com/m/p/24azfty4/lan/en</a>
Dial-in Number – US:	1 (800) 446-2782
Dial in Number – Int'l:	1 (847) 413-3235
Participant Passcode:	38384306
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 Navidea Biopharmaceuticals Inc.**

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is developing multiple precision diagnostic products and platforms including Manocept™, NAV4694, NAV5001, and NAV1800, to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making 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. Navidea’s strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and advancing the Company’s pipeline through selective acquisitions, global partnering and commercialization efforts. For more information, please visit [www.navidea.com](http://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.*

**NAVIDEA BIOPHARMACEUTICALS**

Page | 4

Source: Navidea Biopharmaceuticals, Inc.  
Navidea Biopharmaceuticals

Brent Larson, 614-822-2330  
Executive VP & CFO

Or

Sharon Correia, 978-655-2686  
Associate Director, Corporate Communications

**Financial tables to follow**

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**NAVIDEA BIOPHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

	September 30, 2014 (unaudited)	December 31, 2013
<b>Assets:</b>		
Cash	\$ 10,388,618	\$ 32,939,026
Other current assets	3,589,110	4,392,156
Non-current assets	<u>3,664,190</u>	<u>2,985,335</u>
<b>Total assets</b>	<b><u>\$ 17,641,918</u></b>	<b><u>\$ 40,316,517</u></b>
<b>Liabilities and stockholders' deficit:</b>		
Notes payable, net of discount, current	\$ 2,725,107	\$ 4,095,650
Other current liabilities	5,608,635	7,195,312
Notes payable, net of discount	29,756,627	23,572,603
Derivative liabilities	7,697,130	7,692,087
Other liabilities	3,116,188	1,770,452
Stockholders' deficit	<u>(31,261,769)</u>	<u>(4,009,587)</u>
<b>Total liabilities and stockholders' deficit</b>	<b><u>\$ 17,641,918</u></b>	<b><u>\$ 40,316,517</u></b>

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended		Nine Months Ended	
	September 30, 2014 (unaudited)	September 30, 2013 (unaudited)	September 30, 2014 (unaudited)	September 30, 2013 (unaudited)
<b>Revenue:</b>				
Lymphoseek sales revenue	\$ 1,101,071	\$ 143,799	\$ 2,773,959	\$ 271,620
Lymphoseek milestone revenue	300,000	-	300,000	-
Grant and other revenue	848,999	256,575	1,002,605	324,031
<b>Total revenue</b>	<b><u>2,250,070</u></b>	<b><u>400,374</u></b>	<b><u>4,076,564</u></b>	<b><u>595,651</u></b>
<b>Cost of good sold</b>	<b><u>807,880</u></b>	<b><u>75,422</u></b>	<b><u>1,271,598</u></b>	<b><u>180,860</u></b>
<b>Gross profit</b>	<b><u>1,442,190</u></b>	<b><u>324,952</u></b>	<b><u>2,804,966</u></b>	<b><u>414,791</u></b>
<b>Operating expenses:</b>				
Research and development	4,158,085	6,278,459	14,496,977	14,295,049
Selling, general and administrative	2,646,591	3,971,172	11,465,076	11,505,099
<b>Total operating expenses</b>	<b><u>6,804,676</u></b>	<b><u>10,249,631</u></b>	<b><u>25,962,053</u></b>	<b><u>25,800,148</u></b>
<b>Loss from operations</b>	<b><u>(5,362,486)</u></b>	<b><u>(9,924,679)</u></b>	<b><u>(23,157,087)</u></b>	<b><u>(25,385,357)</u></b>
Interest expense	(920,905)	(976,226)	(2,778,813)	(1,804,576)
Equity in the loss of R-NAV, LLC	(262,198)	-	(262,198)	-
Change in fair value of financial instruments	(409,650)	(377,474)	(109,499)	(377,474)
Loss on extinguishment of debt	-	-	(2,610,196)	(1,372,266)
Other income (expense), net	<u>56,343</u>	<u>(27,828)</u>	<u>56,110</u>	<u>(7,904)</u>
<b>Net loss attributable to common stockholders</b>	<b><u>\$ (6,898,896)</u></b>	<b><u>\$ (11,306,207)</u></b>	<b><u>\$ (28,861,683)</u></b>	<b><u>\$ (28,947,577)</u></b>
<b>Loss per common share (basic and diluted)</b>	<b>\$ (0.05)</b>	<b>\$ (0.09)</b>	<b>\$ (0.19)</b>	<b>\$ (0.25)</b>
<b>Weighted average shares outstanding (basic and diluted)</b>	<b>150,169,712</b>	<b>121,117,562</b>	<b>148,344,064</b>	<b>117,740,754</b>

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