

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 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 August 6, 2014, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the second quarter ended June 30, 2014. A copy of the Company’s August 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

Number

Exhibit Description

99.1	Navidea Biopharmaceuticals, Inc. press release dated August 6, 2014, entitled “Navidea Biopharmaceuticals Announces Second Quarter 2014 Financial Results; Total Revenues Grow to \$1.1 Million.”
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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.

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 11, 2014

By: /s/ Brent L. Larson

Brent L. Larson, Executive Vice President and
Chief Financial Officer



Press Release

FOR IMMEDIATE RELEASE

Navidea Announces Second Quarter 2014 Financial Results; Total Revenues Grow to \$1.1 Million

DUBLIN, OHIO – August 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 second quarter and first half of 2014. Revenue to Navidea from sales of Lymphoseek[®] (technetium Tc 99m tilmanocept) Injection grew to more than \$1 million in the second quarter of 2014, an increase of 67% compared to the first quarter 2014 and an increase of over 700% compared to the second quarter of 2013 when the product was first launched. Based on the sales trends observed, Navidea reiterates its full-year 2014 Lymphoseek revenue expectation of \$5 to \$6 million.

"Lymphoseek sales growth is being driven by favorable product characteristics, recent CMS reimbursement, as well as commercial and medical education activities directed at major cancer centers," said Michael Goldberg, M.D., Navidea Interim Chief Executive Officer. "This is resulting in strong customer retention with positive trends in utilization and account growth. We believe additional near-term and medium-term revenue growth will be enhanced in part by our recent label expansion for guiding sentinel lymph node biopsy in certain head and neck cancers, anticipated U.S. label expansion stemming from our second sNDA later this year, as well as increased commercial activities targeting surgical oncologists, and our international activities."

Dr. Goldberg continued, "We have significantly advanced our pipeline by adding a therapeutic application to our Manocept[™] platform by having recently entered a partnership with a company funded by the leading venture capital firm, Essex Woodlands, to co-develop Manocept to detect and treat Rheumatoid Arthritis and other arthritic conditions. We continue to aggressively pursue partnerships for our neurodegenerative disease detection agents to complete Phase 3 development and registration. Late in the second quarter, we announced a restructuring to reduce expenses primarily related to the reprioritization of our product development pipeline which, coupled with strong gross profit from Lymphoseek, we anticipate will begin to meaningfully offset our cash burn by Q4 2014."

Milestones & Highlights

Select milestones and highlights that the Company has achieved during the first half of 2014 include the following:

- With our partner, Lymphoseek generated approximately \$2 million in sales, of which just over \$1 million in revenue was recognized by Navidea in the second quarter of 2014, a 67% increase from the prior quarter.
- Realized attractive gross margins on Lymphoseek revenue of nearly 75% for the second quarter and the first half of 2014.
- Grew Lymphoseek customer base since launch to more than 350 hospitals with 123 new accounts added in Q2 2014 alone.
- Received U.S. Food and Drug Administration (FDA) approval of Lymphoseek for guiding sentinel lymph node (SLN) biopsy in head and neck cancer patients with clinically node negative squamous cell carcinoma of the oral cavity, making Lymphoseek the first and only FDA-approved radiopharmaceutical for sentinel lymph node detection.

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- Presented encouraging positive data and results from Lymphoseek studies in breast cancer, melanoma, head and neck or colorectal cancer and Manocept studies in Rheumatoid Arthritis and Kaposi's Sarcoma at the Society of Nuclear Medicine and Molecular Imaging Annual Meeting. Eleven presentations were made by Navidea and its collaborators which reinforce the sensitivity, specificity and accuracy of Lymphoseek and the potential for our macrophage-targeting Manocept platform.
- Formed a joint enterprise, R-NAV, LLC, with Essex Woodlands-backed Rheumco, LLC to develop and commercialize radiolabeled diagnostics and therapeutics for rheumatologic and arthritic diseases using Navidea's Manocept macrophage targeting platform and Rheumco's Tin-117m technology.

Financial Results

Total recognized revenue for the second quarter of 2014 was \$1.1 million compared to \$195,000 for the same period in 2013. Product revenue from sales of Lymphoseek in the second quarter of 2014 was \$1,046,000 compared to \$627,000 in the first quarter of 2014. For the six months ended June 30, 2014, Navidea's total revenue was \$1,826,000 compared to \$195,000 for the same period in 2013.

Second quarter 2014 operating expenses were \$10.0 million compared to \$8.5 million for the second quarter of 2013. Operating expenses were \$19.2 million for the six months ended June 30, 2014, compared to \$15.6 million for the same period in 2013. Research and development (R&D) expenses were \$5.1 million in the second quarter of 2014 compared to \$4.4 million in the same period of 2013. R&D expenses were \$10.3 million for the six months ended June 30, 2014, compared to \$8.0 million for the same period in 2013. The net increases in R&D expenses were primarily a result of NAV4694, NAV5001 and Manocept product development and clinical trial-related costs incurred prior to our decision late in the second quarter to reprioritize our development plans to reduce our cash burn. Selling, general and administrative (SG&A) expenses for the second quarter of 2014 were \$4.9 million compared to \$4.2 million in the same period of 2013. SG&A expenses were \$8.8 million for the six months ended June 30, 2014, compared to \$7.5 million for the same period in 2013. The net increases in SG&A expenses were due primarily to the one-time separation costs associated with the Company's former CEO coupled with costs to support Lymphoseek medical education efforts.

Second quarter 2014 net loss attributable to common stockholders was \$10.2 million, or \$0.07 per share, compared to net loss attributable to common stockholders of \$10.3 million, or \$0.09 per share, in the second quarter of 2013. For the six months ended June 30, 2014, Navidea's net loss attributable to common stockholders was \$22.0 million, or \$0.15 per share, compared to a net loss attributable to common stockholders of \$17.6 million, or \$0.15 per share, for the same period in 2013.

Conference Call Details

Navidea will provide a business update and discuss the second quarter 2014 financial results during a conference call with the investment community scheduled for Wednesday, August 6, 2014 at 8:30 a.m. EDT. 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 Q2 2014 Financial Results Conference Call
Date/Time: Wednesday, August 6, 2014 at 8:30 a.m. EDT
Webcast Link: <http://edge.media-server.com/m/p/bz3vnygi/lan/en>
Dial-in Number – US: 1 (866) 638-3013
Dial in Number – Int'l: 1 (630) 691-2761
Participant Passcode: 37774632
Replay: A webcast replay will be available on the Investor Relations section of our website at <http://ir.navidea.com> 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 (RIGScan™), 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.

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.
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

	June 30, 2014 <u>(unaudited)</u>	December 31, 2013 <u></u>
Assets:		
Cash	\$ 17,471,780	\$ 32,939,026
Other current assets	3,093,473	4,392,156
Non-current assets	<u>3,023,072</u>	<u>2,985,335</u>
Total assets	<u>\$ 23,588,325</u>	<u>\$ 40,316,517</u>
Liabilities and stockholders' deficit:		
Notes payable, net of discount, current	\$ 782,512	\$ 4,095,650
Other current liabilities	5,369,866	7,195,312
Notes payable, net of discount	30,438,739	23,572,603
Derivative liabilities	7,689,550	7,692,087
Other liabilities	3,142,933	1,770,452
Stockholders' deficit	<u>(23,835,275)</u>	<u>(4,009,587)</u>
Total liabilities and stockholders' deficit	<u>\$ 23,588,325</u>	<u>\$ 40,316,517</u>

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Six Months Ended	
	June 30, 2014 (unaudited)	June 30, 2013 (unaudited)	June 30, 2014 (unaudited)	June 30, 2013 (unaudited)
Revenue:				
Net sales	\$ 1,046,257	\$ 127,821	\$ 1,672,888	\$ 127,821
Grant revenue	28,433	67,456	153,606	67,456
Total revenue	<u>1,074,690</u>	<u>195,277</u>	<u>1,826,494</u>	<u>195,277</u>
Cost of goods sold	<u>270,498</u>	<u>105,438</u>	<u>463,718</u>	<u>105,438</u>
Gross profit	<u>804,192</u>	<u>89,839</u>	<u>1,362,776</u>	<u>89,839</u>
Operating expenses:				
Research and development	5,112,098	4,376,833	10,338,892	8,016,590
Selling, general and administrative	4,907,652	4,169,437	8,818,485	7,533,927
Total operating expenses	<u>10,019,750</u>	<u>8,546,270</u>	<u>19,157,377</u>	<u>15,550,517</u>
Loss from operations	<u>(9,215,558)</u>	<u>(8,456,431)</u>	<u>(17,794,601)</u>	<u>(15,460,678)</u>
Interest expense	(914,070)	(465,268)	(1,857,908)	(828,350)
Change in fair value of financial instruments	(92,332)	-	300,151	-
Loss on extinguishment of debt	-	(1,372,266)	(2,610,196)	(1,372,266)
Other income (expense), net	(274)	(6,386)	(233)	19,924
Net loss attributable to common stockholders	<u>\$ (10,222,234)</u>	<u>\$ (10,300,351)</u>	<u>\$ (21,962,787)</u>	<u>\$ (17,641,370)</u>
Loss per common share (basic and diluted)	\$ (0.07)	\$ (0.09)	\$ (0.15)	\$ (0.15)
Weighted average shares outstanding (basic and diluted)	150,019,939	118,260,288	147,416,111	116,024,366

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