

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) March 5, 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))

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**Item 2.02. Results of Operations and Financial Condition.**

On March 5, 2015, the Company issued a press release regarding its consolidated financial results for the fourth quarter of 2014, and for the year ended December 31, 2014. A copy of the Company's March 5, 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 March 5, 2015, entitled "Navidea Announces Fourth Quarter and Full Year 2014 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.

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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: March 6, 2015

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 Fourth Quarter and Full Year 2014 Results**

– Management hosting webcast and conference call on March 5, 2015 at 8:30 a.m. EST –

DUBLIN, OHIO – March 5, 2015 – Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), today announced results for the fourth quarter and year ended December 31, 2014. Navidea reported total revenue for 2014 of \$6.3 million including Lymphoseek<sup>®</sup> (technetium Tc 99m tilmanocept) injection sales revenue of \$4.2 million. Projected guidance for Navidea's share of Lymphoseek revenue in 2015 is \$10 million to \$12 million. Based on expected revenue run rates and consistent with revenue guidance, Navidea expects to achieve break-even cash flow in first quarter 2016 based on our current strategic plans.

“Lymphoseek's recently expanded U.S. label, our sharpened focus on commercial execution and our new commercial and medical affairs teams strongly position Navidea to accelerate near-term revenue growth. We continue to practice fiscal discipline as evidenced by the nearly 50% reduction in cash used in operations from the first quarter to the fourth quarter of 2014. We believe these actions put us on a solid path toward profitability,” said Rick Gonzalez, Navidea President and Chief Executive Officer. “Lymphoseek's lymphatic mapping indication in solid tumors beyond breast, melanoma and head & neck cancers, combined with the recent European approval, will be drivers to the medium term revenue growth while, in parallel, Macrophage Therapeutics advances therapeutic applications of our Manocept<sup>™</sup> platform.”

**Financial Results**

**Full Year Financial Results:** Revenues for the year ended December 31, 2014 were \$6.3 million compared to \$1.1 million for 2013. Navidea's revenues for 2014 consisted of \$4.2 million in sales of Lymphoseek, \$300,000 from business development milestones and \$1.7 million from various federal grants and other revenue, compared to \$614,000, \$0 and \$516,000, respectively, for 2013.

Operating expenses for the year ended December 31, 2014 were \$32.3 million compared to \$39.2 million for 2013. Research and development expenses were \$16.8 million during 2014 compared to \$23.7 million during 2013. The net decrease from 2013 to 2014 was primarily a result of reductions in Lymphoseek, NAV5001 and NAV4694 product development costs coupled with reduced headcount. Selling, general and administrative expenses were \$15.5 million for 2014 and 2013. Increased medical education costs, legal and professional services and other support costs were offset by decreased investor relations costs, compensation, and out-of-pocket marketing costs to support the commercial launch of Lymphoseek.

Navidea's loss from operations for the year ended December 31, 2014 was \$27.6 million compared to \$38.4 million for the same period in 2013. For the year ended December 31, 2014, Navidea reported a loss attributable to common stockholders of \$35.7 million, or \$0.24 per share, compared to a loss attributable to common stockholders of \$42.7 million, or \$0.35 per share, for the same period in 2013.

**Fourth Quarter Financial Results:** Revenues for the fourth quarter of 2014 were \$2.2 million compared to \$535,000 for the same period in 2013. Navidea's revenues for the fourth quarter of 2014 consisted of \$1.5 million in sales of Lymphoseek and \$738,000 from various federal grants and other revenue, compared to \$343,000 and \$192,000, respectively, for the same period in 2013.

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Fourth quarter 2014 operating expenses were \$6.4 million compared to \$13.4 million for the fourth quarter of 2013. Research and development expenses were \$2.3 million during the fourth quarter of 2014 compared to \$9.4 million during fourth quarter of 2013. The net decrease from 2013 to 2014 was primarily a result of reductions in Lymphoseek, NAV5001 and NAV4694 product development costs coupled with reduced headcount and related support costs. Selling, general and administrative expenses were \$4.1 million for the fourth quarter of 2014 compared \$4.0 million for the same period in 2013. Increased out-of-pocket Lymphoseek marketing costs and medical education costs were offset by decreased compensation and related support costs.

Navidea loss from operations for the fourth quarter of 2014 was \$4.5 million compared to \$13.1 million for the fourth quarter of 2013. For the fourth quarter of 2014, Navidea reported a loss attributable to common stockholders of \$6.9 million, or \$0.05 per share, compared to a loss attributable to common stockholders of \$13.8 million, or \$0.10 per share, for the fourth quarter of 2013.

### Milestones & Highlights

Select milestones and highlights that the Company achieved in 2014 and year to date in 2015 include:

- A sharpened corporate focus with new management team additions
  - Appointed Rick Gonzalez as CEO, bringing more than 20 years of experience in the pharmaceutical industry with notable global commercial expertise with oncology and radiotherapy products
  - Added Tom Klima as Chief Commercial Officer to lead commercial strategy design and execution and Michael Tomblyn, M.D. as Executive Medical Director to develop, in collaboration with the medical community and potentially other corporate partners, the application of Lymphoseek across multiple tumor types
- Lymphoseek<sup>®</sup> (technetium Tc 99m tilmanocept) Injection
  - Experienced encouraging sales metrics as measured by increasing number of procedures, account growth and re-order rates
  - Expanded indications in the U.S. for sentinel lymph node biopsy (SLNB) in melanoma, head & neck and breast cancers as well as for lymphatic mapping in all solid tumors
  - Attained European approval of Lymphoseek Marketing Authorization Application for SLNB in melanoma, breast and certain head & neck cancers
  - Executed a sublicense agreement with SpePharm AG, an affiliate of Norgine BV, covering distribution of Lymphoseek in the European Union. In connection with the agreement, the Company received an upfront payment of \$2 million and is eligible to receive additional commercial milestone payments up to \$5 million, as well as royalties on European net sales.
  - Received Orphan Drug designation for head & neck cancers and triggered a \$1 million refund of PDUFA fees associated with the head & neck cancer sNDA
  - Signed development and commercialization agreements in China, Taiwan and Hong Kong
  - Published the Lymphoseek Phase 3 head & neck cancer clinical trial results and results of a Lymphoseek comparative study in breast cancer in peer-reviewed journals
  - Supported Lymphoseek lifecycle management efforts with Fast Track NIH Small Business Innovation Research grants and investigator-initiated studies in several cancer types
- Manocept<sup>™</sup> Platform
  - Formed Macrophage Therapeutics, Inc. as a subsidiary to explore therapeutic applications of Manocept platform compounds
  - Assembled an expert Scientific Advisory Board to serve as a strategic resource to develop therapeutic applications for the Manocept platform

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- Completed the initial cohort of a physician-initiated study in Kaposi's Sarcoma patients at the University of California at San Francisco
- Formed R-NAV joint venture with Essex Woodlands' Rheumco to explore diagnostic and therapeutic applications in rheumatoid arthritis and canine osteoarthritis
- Neurodegenerative Products
  - Evaluating out-licensing/divestiture proposals for the Phase 3 NAV4694 and NAV5001 assets

**Conference Call**

Navidea will provide a business update and discuss the fourth quarter and full year 2014 financial results during a conference call with the investment community scheduled for Thursday, March 5, 2015 at 8:30 a.m. ET. 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 Q4 and Year-End 2014 Financial Results Conference Call
Date/Time:	Thursday, March 5, 2015 at 8:30 a.m. EST
Webcast Link:	<a href="http://edge.media-server.com/m/p/wnxb6jnn/lan/en">http://edge.media-server.com/m/p/wnxb6jnn/lan/en</a>
Dial-in Number – US:	1-(800) 708-4540
Dial in Number – Int'l:	1 (847) 619-6397
Participant Passcode:	39040655
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 commercial stage precision medicine company focused on the development and commercialization of precision diagnostics, therapeutics and radiopharmaceutical agents. Navidea is developing multiple precision-targeted products and platforms including Manocept™, NAV4694, and NAV5001, 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 by the EMA in November 2014. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and therapeutics, 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, 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

	December 31, 2014 (unaudited)	December 31, 2013
<b>Assets:</b>		
Cash	\$ 5,479,006	\$ 32,939,026
Other current assets	3,120,139	4,392,156
Non-current assets	<u>3,321,035</u>	<u>2,985,335</u>
<b>Total assets</b>	<b><u>\$ 11,920,180</u></b>	<b><u>\$ 40,316,517</u></b>
<b>Liabilities and stockholders' deficit:</b>		
Notes payable, net of discount, current	\$ 4,383,472	\$ 4,095,650
Other current liabilities	4,711,619	7,195,312
Notes payable, net of discount	29,539,135	23,572,603
Derivative liabilities	-	7,692,087
Other liabilities	3,089,420	1,770,452
Stockholders' deficit	<u>(29,803,466)</u>	<u>(4,009,587)</u>
<b>Total liabilities and stockholders' deficit</b>	<b><u>\$ 11,920,180</u></b>	<b><u>\$ 40,316,517</u></b>

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Twelve Months Ended	
	December 31, 2014 (unaudited)	December 31, 2013 (unaudited)	December 31, 2014 (unaudited)	December 31, 2013
<b>Revenue:</b>				
Lymphoseek sales revenue	\$ 1,459,994	\$ 342,803	\$ 4,233,953	\$ 614,423
Lymphoseek milestone revenue	-	-	300,000	-
Grant and other revenue	738,291	192,176	1,740,896	516,207
<b>Total revenue</b>	<b><u>2,198,285</u></b>	<b><u>534,979</u></b>	<b><u>6,274,849</u></b>	<b><u>1,130,630</u></b>
<b>Cost of good sold</b>	<b><u>314,547</u></b>	<b><u>151,955</u></b>	<b><u>1,586,145</u></b>	<b><u>332,815</u></b>
<b>Gross profit</b>	<b><u>1,883,738</u></b>	<b><u>383,024</u></b>	<b><u>4,688,704</u></b>	<b><u>797,815</u></b>
<b>Operating expenses:</b>				
Research and development	2,282,612	9,415,134	16,779,589	23,710,183
Selling, general and administrative	4,076,995	4,020,847	15,542,071	15,525,946
<b>Total operating expenses</b>	<b><u>6,359,607</u></b>	<b><u>13,435,981</u></b>	<b><u>32,321,660</u></b>	<b><u>39,236,129</u></b>
<b>Loss from operations</b>	<b><u>(4,475,869)</u></b>	<b><u>(13,052,957)</u></b>	<b><u>(27,632,956)</u></b>	<b><u>(38,438,314)</u></b>
Interest expense	(927,357)	(974,204)	(3,706,170)	(2,778,780)
Equity in the loss of R-NAV, LLC	(261,611)	-	(523,809)	-
Change in fair value of financial instruments	(1,232,890)	265,401	(1,342,389)	(112,073)
Loss on extinguishment of debt	-	-	(2,610,196)	(1,372,266)
Other income (expense), net	32,741	9,879	88,851	1,975
<b>Net loss attributable to common stockholders</b>	<b><u>\$ (6,864,986)</u></b>	<b><u>\$ (13,751,881)</u></b>	<b><u>\$ (35,726,669)</u></b>	<b><u>\$ (42,699,458)</u></b>
<b>Loss per common share (basic and diluted)</b>	<b>\$ (0.05)</b>	<b>\$ (0.10)</b>	<b>\$ (0.24)</b>	<b>\$ (0.35)</b>
<b>Weighted average shares outstanding (basic and diluted)</b>	<b>149,888,696</b>	<b>133,881,021</b>	<b>148,748,396</b>	<b>121,808,986</b>