

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) February 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))

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Effective February 5, 2015, the Board of Directors (“Board”) of Navidea Biopharmaceuticals, Inc. (the “Company”) elected Ricardo J. Gonzalez to the Board. The election of Mr. Gonzalez increases the number of directors on the Board to seven. Mr. Gonzalez was elected to a term ending at the Company’s Annual Stockholders’ Meeting in 2017.

Mr. Gonzalez is currently serving as the President and Chief Executive Officer of the Company. Mr. Gonzalez, 44, has more than 20 years of experience in the pharmaceutical industry, and most recently served as Vice President, Global Operations at Spectrum Pharmaceuticals, a biotechnology company focused on oncology and hematology. Mr. Gonzalez began his tenure at Spectrum in 2008 as Director, Strategic Business Services, and thereafter was appointed to positions of increasing seniority and responsibility, focusing on product development and commercialization, pharmaceutical sales, marketing and operations, as well as licensing and industry partnerships. Prior to Spectrum, Mr. Gonzalez was a Regional Accounts Manager, Product Manager and Sales Manager for Abraxis Oncology, and served in various sales and marketing positions for Genzyme Therapeutics, Corixa Corporation, Ligand Pharmaceuticals, Roche Laboratories and GlaxoSmithKline. Mr. Gonzalez graduated from Penn State University in 1992 with a B.S. in Business Logistics and served in the U.S. Army Reserve

Mr. Gonzalez will receive no additional compensation for his service on the Board, consistent with Company policy for directors who are also employees.

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.

Item 8.01 Other Events

On February 9, 2015, the Company issued a press release reporting unaudited total revenue of \$6.3 million for the year ended December 31, 2014, including total product revenue from Lymphoseek® (technetium Tc 99m tilmanocept) injection of \$4.2 million, and provided key performance indicators for 2014. The Company also described a new commercial strategy that it will pursue for Lymphoseek in 2015. A copy of the 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 8.01 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

*Exhibit
Number*

Exhibit Description

99.1 Navidea Biopharmaceuticals, Inc. press release dated February 9, 2015, entitled “Navidea Reports Preliminary 2014 Revenue; Provides Update on New Commercial Strategy”

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: February 9, 2015

By: /s/ Brent L. Larson

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



Press Release

FOR IMMEDIATE RELEASE

Navidea Reports Preliminary 2014 Revenue; Provides Update on New Commercial Strategy

DUBLIN OHIO, February 09, 2015 -- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) today reports preliminary, unaudited total revenue of \$6.3 million for the year ended December 31, 2014, including total product revenue from Lymphoseek[®] (technetium Tc 99m tilmanocept) injection of \$4.2 million. For the three months ended December 31, 2014, Navidea reports preliminary, unaudited total revenue of \$2.2 million, including total product revenue from Lymphoseek of \$1.5 million. Total revenue includes product revenue from sales of Lymphoseek to the Company's distribution partner, grant revenue and revenue generated from business development activities; however, it should be noted product revenue recognized by Navidea represents only a portion of the total brand revenue generated by the distribution partner on sales of Lymphoseek to end customers. Navidea's gross profit is expected to be \$4.7 million for the year ended December 31, 2014 and \$1.9 million for the three months ended December 31, 2014.

In 2014, Lymphoseek expanded its reach and utilization, as reflected by key performance indicators which include the following:

- Approximately 22,000 procedures using Lymphoseek were performed in 2014,
- Sustained average quarter-on-quarter growth rate of >20%.
- Realized a reorder rate in excess of 80%
- Ended 2014 with more than 500 customers

"Lymphoseek's key performance indicators, including the high reorder rate, increase in the total number of customers, and the sequential and annual procedural growth rates, provide a foundation for a strong 2015." said Rick Gonzalez, Navidea Chief Executive Officer. "We are confident about the revenue growth for the coming year enabled by the new label and driven by the new commercial strategy. Most notably, we have begun to implement a plan specifically targeting the oncology treatment team and communicating Lymphoseek's value proposition to accelerate brand utilization and adoption."

For 2015, Navidea is implementing a new commercial strategy, which includes the following initiatives:

- Launch a new branding campaign based on the new FDA label that was approved in the fourth quarter of 2014, which includes sentinel lymph node biopsy for three types of cancers
- Increase engagement with surgical oncologists as the key target within the broader treatment team
 - o Deploy a direct sales force beginning in the first quarter of 2015 with focus on regions with the greatest concentrations of cancer diagnosis
- Coordinate nuclear medicine directed activities with Navidea's US distribution partner
- Build upon the key performance indicators
 - o Accelerate growth in existing accounts
 - o Add new customers
 - o Capitalize on the greater than 80% reorder rate
- Drive patient education in partnership with advocacy groups

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“We are repurposing resources focused on our goal of driving Lymphoseek revenues while reducing all other non-related operational expenses. We expect the redeployment will show positive contribution to revenue growth by year end,” said Brent Larson, Chief Financial Officer. “Further, we continue to have access to an over \$30 million credit facility with our primary investor under which we recently completed a draw down. As a result of our mid-2014 restructuring, we achieved a meaningful reduction in cash burn in 2014, and expect gross profit from accelerating sales growth to continue to narrow our burn throughout 2015 as we move closer to achieving profitability.”

Mr. Gonzalez will further discuss the Company’s vision and activities at 10:00 a.m. EST today via a webcasted presentation from the 17th Annual BIO CEO & Investor Conference in New York City.

The live webcast can be accessed at the following URL:

<http://www.veracast.com/webcasts/bio/ceoinvestor2015/98108167461.cfm>. An archived version of the webcast will be available two hours following the presentation and can be accessed within the Investors' section of the Navidea website at www.navidea.com.

Navidea will provide a more complete discussion of its financial results for the year ended December 31, 2014, during the Company's regularly scheduled quarterly conference call currently planned for March 5, 2015. This press release contains certain preliminary, unaudited financial results for the company. These unaudited results could change as a result of further review by the Company's management and its independent auditors.

About Navidea Biopharmaceuticals Inc.

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical 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 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.

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Contact:

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Navidea Biopharmaceuticals

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or

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Associate Director, Corporate Communications

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