**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) May 7, 2014

NAVIDEA BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

| Delaware | 001-35076 | 31-1080091 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| 5600 Blazer Parkway, Suite 200, Dublin, Ohio | 43017 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

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 May 7, 2014, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release announcing its consolidated financial results for the first quarter ended March 31, 2014. A copy of the Company's May 7, 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 May 7, 2014, the Company discussed consolidated financial results for the quarter ended March 31, 2014. On the call, the Company reiterated its guidance for 2014 Lymphoseek® revenues between $5 and $6 million, and for research and development expense for the year between $25 and $30 million. The Company also announced that April was another record month for Lymphoseek revenues, consistent with recent trends.

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 May 7, 2014, entitled "Navidea Biopharmaceuticals Announces First Quarter 2014 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: May 7, 2014

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

Press Release

**Exhibit 99.1**

**FOR IMMEDIATE RELEASE**

# Navidea Biopharmaceuticals Announces First Quarter 2014 Financial Results

DUBLIN, OHIO -- May 7, 2014 -- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced its financial results and business highlights for the first quarter of 2014.

"As we begin 2014, we are encouraged by the continued advances in utilization, market penetration and account growth for Lymphoseek®. We are realizing increasing traction in our commercial and medical education activities directed toward surgical oncologists and major lymphatic mapping centers," said Dr. Mark Pykett, Navidea Chief Executive Officer. "We continue to focus our efforts on expanding market opportunities in the U.S. and abroad by obtaining additional regulatory clearances, expanding the Lymphoseek label, and building strong commercial relationships to enhance the full potential of the product. The results we are seeing and building on enhance our confidence that our sustained efforts will culminate in market leadership for Lymphoseek. Throughout 2014, we also expect continued advances in our pipeline programs, including the Phase 2 and Phase 3 studies for our neuro-tracers in the neurodegenerative areas of dementia, mild cognitive impairment and movement disorders, and in other pipeline programs."

**Highlights:**

- Realized revenue to Navidea of $627,000 in Lymphoseek® (technetium Tc 99m tilmanocept) Injection sales in the first quarter of 2014 under the revenue sharing agreement with our U.S. distribution partner. This represents an 83% increase from the prior quarter, based in part on strong month-on-month growth in units, expansion of accounts and high customer retention, among other positive sales trends.

- Obtained Priority Review by the U.S. Food and Drug Administration (FDA) for the Supplemental New Drug Application (sNDA) to expand Lymphoseek labeling for sentinel lymph node detection in patients with head and neck cancer, with a Prescription Drug User Fee Act (PDUFA) date set for June 16, 2014.

- Received FDA acceptance of an additional sNDA for review to further expand the Lymphoseek label, focusing on more flexible and extended utilization practices with a PDUFA date set for October 16, 2014.

- Continued market expansion activities to drive product commercialization worldwide, highlighted by the signing of a sales and distribution agreement in Taiwan, continuing market preparation activities in Canada and continuing shipment of Lymphoseek to select medical centers in the Middle East.

- Advanced the Lymphoseek Marketing Authorization Application (MAA) in Europe, and subsequently received notice that the Committee for Medicinal Products for Human Use (CHMP) in Europe will convene a Scientific Advisory Group on Oncology meeting to discuss elements of the Lymphoseek clinical study in patients with head and neck cancer.

*- more -*

- Reported positive, single-center results from the Phase 2b Trial of NAV4694 in subjects with Mild Cognitive Impairment (MCI) demonstrating the agent's ability to identify beta-amyloid in early stage patients.

- Presented encouraging results at several major scientific forums from Manocept™ platform studies in Kaposi Sarcoma and rheumatoid arthritis (RA) where, in an animal model of RA, Manocept constructs were shown to identify and localize to disease-state macrophages when administered intravenously, enabling detection of immune-mediated arthritis with preferential localization in affected joints with little to no localization in unaffected joints, opening potential avenues to new applications and product opportunities..

- Appointed Perry A. Karsen to the Navidea Board of Directors. Mr. Karsen is currently Executive Vice President and Chief Operations Officer at Celgene Corporation and Chief Executive Officer of Celgene Cellular Therapeutics.

- Closed a $30 million loan transaction with Oxford Finance LLC providing the Company with an enhanced working capital position.

**First Quarter Ended March 31, 2014 Financial Results:** Total revenues for the first quarter of 2014 were $752,000 compared to no revenue for the same period in 2013. Product revenues from sales of Lymphoseek in first quarter of 2014 were $627,000 compared to $343,000 in the fourth quarter of 2013. The fourth quarter of 2013 represented the first quarter of Lymphoseek sales under Centers for Medicare and Medicaid Services (CMS) reimbursement.

First quarter 2014 operating expenses were $9.1 million compared to $7.0 million for the first quarter of 2013. Research and development expenses were $5.2 million in the first quarter of 2014 compared to $3.6 million in the same period of 2013. The net increase was primarily a result of net increases in NAV4694, NAV5001 and Manocept platform product development costs, compensation and other support costs related to increased headcount. Selling, general and administrative expenses for the first quarter of 2014 were $3.9 million compared to $3.4 million in the same period of 2013.

First quarter 2014 net loss attributable to common stockholders was $11.7 million, or $0.08 per share, compared to a net loss attributable to common stockholders of $7.3 million, or $0.06 per share, in the first quarter of 2013. In addition to the changes in operating expenses reported above, the Company recorded a $2.6 million loss on the extinguishment of debt related to the refinancing of its debt facilities during the first quarter of 2014.

**Financial Guidance:** Based on sales trends observed by the Company from launch through April 2014, Navidea is reiterating its full-year 2014 revenue expectation of between $5 and $6 million from Lymphoseek sales based on its revenue sharing agreement with its U.S. distribution partner.

**Conference Call Details:** Navidea will provide a business update and discuss the first quarter 2014 financial results during a conference call with the investment community scheduled for Wednesday, May 7, 2014 at 8:30 a.m. ET. 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 Q1 2014 Financial Results Conference Call |
| Date/Time: | Wednesday, May 7, 2014 at 8:30 a.m. ET |
| Webcast Link: | http://www.media-server.com/m/p/2se8k7yt |
| Dial-in Number – US: | 1 (800) 708-4539 |
| Dial in Number – Int'l: | 1 (847) 619-6396 |
| Participant Passcode: | 37204450 |
| Replay | A webcast replay will be available on the Investor Relations section of our website at http://ir.navidea.com. |

**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 NAV4694, NAV5001, Manocept™ 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**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

| | March 31, 2014 (unaudited) | December 31, 2013 |
|---|---|---|
| Assets: | | |
| Cash | $ 26,006,463 | $ 32,939,026 |
| Other current assets | 3,516,469 | 4,392,156 |
| Non-current assets | 3,116,544 | 2,985,335 |
| Total assets | $ 32,639,476 | $ 40,316,517 |
| | | |
| Liabilities and stockholders' deficit: | | |
| Notes payable, net of discount, current | $ - | $ 4,095,650 |
| Other current liabilities | 5,445,579 | 7,195,312 |
| Notes payable, net of discount | 30,939,076 | 23,572,603 |
| Derivative liabilities | 7,693,351 | 7,692,087 |
| Other liabilities | 3,169,656 | 1,770,452 |
| Stockholders' deficit | (14,608,186) | (4,009,587) |
| Total liabilities and stockholders' deficit | $ 32,639,476 | $ 40,316,517 |

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

| | Three Months Ended | |
|---|---|---|
| | March 31, 2014 (unaudited) | March 31, 2013 (unaudited) |
| Revenue: | | |
| Net sales | $ 626,631 | $ - |
| Grant and other revenue | 125,173 | - |
| Total revenue | 751,804 | - |
| | | |
| Cost of goods sold | 193,220 | - |
| | | |
| Gross profit | 558,584 | - |
| | | |
| Operating expenses: | | |
| Research and development | 5,226,794 | 3,639,757 |
| Selling, general and administrative | 3,910,833 | 3,364,490 |
| Total operating expenses | 9,137,627 | 7,004,247 |
| | | |
| Loss from operations | (8,579,043) | (7,004,247) |
| | | |
| Interest expense | (943,838) | (363,082) |
| Change in fair value of financial instruments | 392,483 | - |
| Loss on extinguishment of debt | (2,610,196) | - |
| Other income, net | 41 | 26,310 |
| | | |
| Net loss attributable to common stockholders | $ (11,740,553) | $ (7,341,019) |
| | | |
| Loss per common share (basic and diluted) | $ (0.08) | $ (0.06) |
| | | |
| Weighted average shares outstanding (basic and diluted) | 144,783,351 | 113,763,600 |

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