**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 3, 2016

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 November 3, 2016, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release regarding its consolidated financial results for the quarter ended September 30, 2016. A copy of the Company's November 3, 2016 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 November 3, 2016. |

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: November 3, 2016

By: /s/ Jed A. Latkin
Jed A. Latkin, Interim Chief Operating Officer

**Exhibit 99.1**

Navidea BIOPHARMACEUTICALS

Press Release

**FOR IMMEDIATE RELEASE**

**Navidea Reports 2016 Third Quarter Financial Results**

DUBLIN, OHIO November 3, 2016 -- Navidea Biopharmaceuticals (NYSE MKT: NAVB) reports financial results for the quarter ending September 30, 2016. Navidea reported total revenue for the third quarter of 2016 of $8.5 million, including Lymphoseek® (technetium Tc 99m tilmanocept) injection sales revenue of $6.7 million. The income from operations was $3.4 million and the net loss attributable to common stockholders was $59,000.

"We ended the third quarter with a clear plan for Navidea's future. With our previously announced Letter of Intent with Cardinal Health, Inc., we believe that we have successfully identified an arrangement to extinguish the CRG (Capital Royalty Partners II L.P) debt and to focus Navidea on several attractive development efforts outside of lymphatic mapping, lymph node biopsy and the diagnosis of metastatic spread to lymph nodes for the staging of cancer in North America. The contemplated transaction with Cardinal Health, as well as the impending launch of Lymphoseek in Europe by our partner SpePharm AG (Norgine BV), should provide additional income for many years to come," said Dr. Michael Goldberg, Navidea President and CEO. "Our focus moving forward will be on expansion and development of Manocept-based diagnostic markets initially in rheumatoid arthritis and cardiovascular disease, as well as developing our immunotherapeutic platform with a strong preclinical pipeline for cancer, autoimmune, inflammatory and infectious diseases."

Specific events and milestones achieved since the beginning of the third quarter include the following:

*Operational & Financial*

- Entered into Letter of Intent with Cardinal Health, Inc. for the sale of Lymphoseek in North America;
- Operating activities provided cash of $1.3 million during the first nine months of 2016, compared to $14.9 million cash used in operations during the same period in 2015;
- Reduced cash used in operations by over 100% for the first nine months of 2016 compared to the same period of 2015; and
- Appointed Michael M. Goldberg, M.D. President and Chief Executive Officer, and Eric K. Rowinsky, M.D. Chairman of the Board.

*Commercial*

- Achieved sequential quarter-on-quarter Lymphoseek sales revenue growth;
- Earned a $500,000 milestone payment from Cardinal Health with the sale of the 100,000$^{th}$ Lymphoseek dose;
- Received positive opinion in Europe for new Lymphoseek reduced-mass vial enabling a single injection per vial and triggering a $500,000 milestone payment by our partner, Norgine BV; and
- Continued to support the projected Q4 launch of Lymphoseek in Europe by Norgine BV.

*Immunodiagnostic & Immunotherapeutic Development Pipeline*

- Received both Institutional Review Board at University of California, San Francisco and Western Institutional Review Board approvals for a tilmanocept subcutaneous administration clinical trial protocol in rheumatoid arthritis, allowing subject enrollment to begin. To date, 17 of 18 patients have been dosed and imaged;
- Received Institutional Review Board approval for a tilmanocept clinical trial protocol in Kaposi Sarcoma which is supported by an NIH grant;
- Clinical trial results of tilmanocept in cardiovascular disease from Massachusetts General Hospital have been submitted for publication; and
- Completed a number of additional preclinical animal studies and initiated additional studies with the MT 1000 and MT 2000 class of compounds.

**Financials**

"We are pleased with our financial performance despite the significant disruption in our organization caused by the ongoing litigation with CRG. Our results demonstrate our commitment to our commercial efforts and controlling our operating expenses," said Jed Latkin, interim Chief Operating Officer and Chief Financial Officer at Navidea.

Total revenues for the quarter ended September 30, 2016 were $8.5 million compared to $4.0 million in the third quarter of last year. Third quarter 2016 product revenues recognized from the sale of Lymphoseek were $6.7 million, compared to $4.2 million in the second quarter of 2016 and $3.0 million in the third quarter of 2015. During the third quarter of 2016, the Company also reported $1.8 million in licensing, grant and other revenue. For the nine months ended September 30, 2016, Navidea's total revenue was $18.6 million compared to $9.0 million for the same period in 2015, an increase of 108%. The primary driver of this increase was revenues recognized by Navidea from the sale of Lymphoseek which exceeded $14.7 million for the nine months ended September 30, 2016 compared to $6.8 million for the same period last year. Third quarter 2016 revenue from the sale of Lymphoseek included $2.0 million of inventory purchases by Cardinal Health and $500,000 of additional revenue from a milestone related to the sale of the 100,000$^{th}$ Lymphoseek dose by Cardinal Health.

Third quarter 2016 margins also remained above 80%, contributing to a total gross profit of $7.6 million for the quarter, compared to $3.5 million for the same period last year. For the nine months ended September 30, 2016, total gross profit rose to $16.6 million versus $7.7 million for the same period last year, an increase of 115%. The increases in total gross profit in the third quarter and first nine months of 2016 was primarily due to $2.0 million of inventory purchases by Cardinal Health, a $500,000 milestone related to the sale of the 100,000$^{th}$ Lymphoseek dose by Cardinal Health, and receipt of a $500,000 milestone payment, and recognition of the remaining $500,000 of the upfront license fee received from SpePharm related to the positive regulatory opinion on a reduced-mass vial in Europe.

Research and development (R&D) expenses for the third quarter of 2016 were $1.3 million, compared to $3.9 million in the third quarter of last year. R&D expenses were $6.5 million for the nine months ended September 30, 2016 compared to $10.2 million in the same period of 2015. The net decreases in year-to-date R&D expenses were primarily a result of decreased headcount costs coupled with decreased project costs related to the Company's neuro assets and Lymphoseek, offset by increased project costs related to the Company's therapeutic programs. Selling, general and administrative (SG&A) expenses for the third quarter of 2016 were $2.9 million, compared to $3.9 million in the third quarter of last year. SG&A expenses were $9.9 million for the nine months ended September 30, 2016, compared to $13.5 million for the same period in 2015. The net decrease in year-to-date SG&A expenses was due primarily to decreased headcount coupled with decreased costs related to business development consulting services, contracted medical science liaisons, commercialization costs for Lymphoseek, license fees and investor relations, offset by increases in commercial and medical headcount costs related to the addition of our internal sales force and medical science liaisons coupled with increased legal and professional services. Total operating expenses were $4.2 million for the third quarter of 2016, compared to $7.8 million in the third quarter of last year. Operating expenses were $16.4 million for the nine months ended September 30, 2016, compared to $23.7 million for the same period in 2015.

Navidea's income from operations for the quarter ended September 30, 2016 was $3.4 million compared to a loss from operations of $4.3 million for the same period in 2015. For the nine months ended September 30, 2016, Navidea's income from operations was $210,000 compared to a loss from operations of $15.9 million for the same period in 2015. Navidea's net loss attributable to common stockholders for the quarter ended September 30, 2016 was $59,000, or $0.00 per share, compared to net loss attributable to common stockholders of $8.1 million, or $0.05 per share, for the same period in 2015. For the nine months ended September 30, 2016, Navidea's net loss attributable to common stockholders was $10.4 million, or $0.07 per share, compared to a net loss attributable to common stockholders of $25.1 million, or $0.17 per share, for the same period in 2015. Net losses attributable to common stockholders include fees paid to CRG (which the Company is disputing in court), the interest expense on our outstanding debt, as well as significant non-cash charges. For the nine-month periods ended September 30, 2016 and September 30, 2015, net loss attributable to common stockholders included $10.6 million and $9.1 million, respectively, in interest, debt-related fees, losses on extinguishment of debt, and changes in the fair value of financial instruments.

Navidea ended the quarter with $4.3 million in cash, $3.5 million of which was restricted related to the CRG debt.

**Conference Call Details**

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 Q3 2016 Financial Results Conference Call |
| Date/Time: | Thursday, November 3, 2016 at 8:30 a.m. ET |
| Webcast Link: | http://edge.media-server.com/m/p/on2557gm/lan/en |
| Dial-in Number – US: | (855) 897-5884 |
| Dial in Number – Int'l: | (720) 634-2940 |
| Conference ID Number: | 3723903 |
| 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**

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products and platforms including Manocept™ and NAV4694 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 in Europe in November 2014. The development activities of the Manocept immunotherapeutic platform will be conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel products and advancing the Company's pipeline through 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, our ability to repay our debt, the outcome of the CRG litigation, 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.*
*Contact: Navidea Biopharmaceuticals*

*Investors & Media*
Jed Latkin
Interim COO & CFO
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***Financial tables to follow***

**NAVIDEA BIOPHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

| | September 30, 2016 (unaudited) | December 31, 2015 |
|---|---|---|
| Assets: | | |
| Cash | $ 810,425 | $ 7,166,260 |
| Restricted cash | 3,501,247 | - |
| Other current assets | 5,119,189 | 5,410,914 |
| Non-current assets | 1,758,739 | 2,387,339 |
| Total assets | $ 11,189,600 | $ 14,964,513 |
| | | |
| Liabilities and stockholders' deficit: | | |
| Deferred revenue, current | $ 15,037 | $ 1,044,281 |
| Notes payable, current | 51,652,209 | 333,333 |
| Other current liabilities | 12,096,593 | 4,806,236 |
| Deferred revenue | 26,061 | 192,728 |
| Notes payable, net of discount | 10,549,405 | 60,746,002 |
| Other liabilities | 624,896 | 1,677,633 |
| Total liabilities | 74,964,201 | 68,800,213 |
| Navidea stockholders' deficit | (64,243,643) | (54,305,258) |
| Noncontrolling interest | 469,042 | 469,558 |
| Total stockholders' deficit | (63,774,601) | (53,835,700) |
| Total liabilities and stockholders' deficit | $ 11,189,600 | $ 14,964,513 |

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| | September 30, 2016 (unaudited) | September 30, 2015 (unaudited) | September 30, 2016 (unaudited) | September 30, 2015 (unaudited) |
| Revenue: | | | | |
| Lymphoseek sales revenue | $ 6,690,090 | $ 2,952,522 | $ 14,704,489 | $ 6,751,492 |
| Lymphoseek license revenue | 1,295,625 | 550,000 | 1,795,625 | 883,333 |
| Grant and other revenue | 511,359 | 476,755 | 2,113,995 | 1,320,816 |
| Total revenue | 8,497,074 | 3,979,277 | 18,614,109 | 8,955,641 |
| Cost of good sold | 921,817 | 457,590 | 2,017,486 | 1,239,377 |
| Gross profit | 7,575,257 | 3,521,687 | 16,596,623 | 7,716,264 |
| Operating expenses: | | | | |
| Research and development | 1,276,053 | 3,902,155 | 6,461,154 | 10,180,517 |
| Selling, general and administrative | 2,940,773 | 3,942,609 | 9,925,574 | 13,485,576 |
| Total operating expenses | 4,216,826 | 7,844,764 | 16,386,728 | 23,666,093 |
| Income (loss) from operations | 3,358,431 | (4,323,077) | 209,895 | (15,949,829) |
| Interest expense, net | (2,566,171) | (2,148,369) | (12,288,169) | (4,690,686) |
| Equity in the loss of joint venture | - | (26,785) | (15,159) | (295,217) |
| Loss on disposal of joint venture | - | - | (39,732) | - |
| Change in fair value of financial instruments | (839,298) | (1,577,275) | 1,755,989 | (1,702,902) |
| Loss on extinguishment of debt | - | - | - | (2,440,714) |
| Other income (expense), net | (12,498) | 4,402 | (49,916) | 26,100 |
| Net loss | (59,536) | (8,071,104) | (10,427,092) | (25,053,248) |
| Net loss attributable to noncontrolling interest | (159) | (340) | (516) | (681) |
| Deemed dividend on beneficial conversion feature | - | - | - | (46,000) |
| Net loss attributable to common stockholders | $ (59,377) | $ (8,070,764) | $ (10,426,576) | $ (25,098,567) |
| | | | | |
| Loss per common share (basic and diluted) | $ (0.00) | $ (0.05) | $ (0.07) | $ (0.17) |
| Weighted average shares outstanding (basic and diluted) | 155,481,278 | 150,186,131 | 155,390,911 | 150,030,638 |

*- end -*