

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 6, 2013

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.)

425 Metro Place North, Suite 450, 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 6, 2013, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the third quarter ended September 30, 2013. A copy of the Company’s November 6, 2013, 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 7.01. Regulation FD Disclosure

During a conference call held by the Company on November 6, 2013, the Company discussed consolidated financial results for the third quarter ended September 30, 2013, announced that it has selected Norgine BV and affiliates (“Norgine”) as its specialty pharmaceutical partner for Europe and other selected regions, and disclosed that it will appoint Dr. Michael Goldberg to the Company’s Board of Directors (the “Board”). The Company expects to consummate a formal agreement with Norgine before the end of the year and to appoint Dr. Goldberg to the Board following the completion of customary agreements with Dr. Goldberg and other governance requirements associated with the appointment of members of the Board.

The information in this Item 7.01 will not be treated as filed for the purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section. 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 November 6, 2013, entitled “Navidea Biopharmaceuticals Announces Third Quarter 2013 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: November 6, 2013

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



Press Release

FOR IMMEDIATE RELEASE**Navidea Biopharmaceuticals Announces Third Quarter 2013 Results****– Business Update / Quarterly Conference Call Today, November 6, 2013 at 8:30 am EST –**

DUBLIN, OHIO – November 6, 2013 – Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced business highlights and consolidated results for the third quarter ended September 30, 2013.

“We view the third quarter as continuing on the track toward success that we’ve envisioned for several years now,” said Dr. Mark Pykett, Navidea CEO. “We are pleased with the initial stages of Lymphoseek[®] commercialization at launch and believe that Lymphoseek continues to hold the promise to become the standard of care in lymphatic mapping. In the first several quarters of launch, we have indicated that success would be measured primarily by important qualitative evidence of Lymphoseek adoption, especially in advance of reimbursement. We believe we are seeing good momentum in many of these key parameters. Our optimism stems from witnessing evidence of progress in many positive measures, including multi-fold increases in unit sales quarter over quarter, a high frequency of repeat and multi-dose ordering, an increase in total accounts ordering, strong new user accrual, and encouraging formulary placement activity. We anticipate further growth in the current quarter and going forward facilitated by the October 1st implementation of the unique Lymphoseek reimbursement code received from the Centers for Medicare & Medicaid Services (CMS).”

Dr. Pykett added, “Our recent equity offering enhances our ability to advance several efforts underway, including commercial opportunities for Lymphoseek outside the U.S., the continued development of our innovative neurodegenerative imaging portfolio, and further evaluation of our recently announced Manocept[™] platform initiatives. During the fourth quarter of 2013, we expect additional value enhancing events, including submission of the Lymphoseek sNDA, EMA feedback on our Marketing Authorization Application in Europe, initiation of the NAV5001 Phase 3 trial in Parkinson’s disease and additional disclosures regarding the advance of our Manocept platform.”

Third Quarter 2013 Financial Results

For the quarter ended September 30, 2013, Navidea reported a net loss attributable to common stockholders of \$11.3 million, or \$0.09 per share, compared with a net loss attributable to common stockholders of \$9.1 million, or \$0.09 per share, for the same period in 2012. For the nine months ended September 30, 2013, Navidea’s net loss attributable to common stockholders was \$28.9 million, or \$0.25 per share, compared to a net loss attributable to common stockholders of \$22.0 million, or \$0.23 per share, for the same period in 2012.

Revenue for the quarter ended September 30, 2013 was \$400,000 compared with no revenue for the same period in 2012. For the nine months ended September 30, 2013, Navidea’s revenue was \$596,000, compared to revenue of \$72,000 for the same period in 2012. Revenue for the third quarter of 2013 consisted of \$144,000 derived primarily from the procedural-based sale of Lymphoseek and \$256,000 from various federal and state grants. The increase in procedural revenue was due to an increase in unit dose sales of over 600% during the third quarter as compared to the second quarter, which resulted in part from a high repeat-order rate of approximately 90% coupled with increasing incidence of multi-dose ordering.

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Research and development (R&D) expenses were \$6.3 million for the quarter ended September 30, 2013, compared to \$6.1 million for the same period in 2012. The net increase of \$151,000 was primarily a result of increased NAV4694 product development costs, compensation and other support costs related to increased headcount, and Manocept platform product development costs, offset by decreased NAV5001, Lymphoseek and potential pipeline product development costs. R&D expenses were \$14.3 million for the nine months ended September 30, 2013, compared to \$12.5 million for the same period in 2012. The increase of \$1.8 million was attributable to the same primary factors noted for the third quarter.

Selling, general and administrative (SG&A) expenses were \$4.0 million for the quarter ended September 30, 2013, compared to \$2.9 million for the same period in 2012. The net increase of \$1.1 million was primarily a result of increased medical education costs, compensation and other support costs related to increased headcount, and legal and professional services costs, offset by decreased out-of-pocket marketing costs to support the commercial launch of Lymphoseek. SG&A expenses were \$11.5 million for the nine months ended September 30, 2013, compared to \$8.5 million for the same period in 2012. The SG&A increase of \$3.0 million between the two periods was primarily attributable to increased medical education costs, compensation and other support costs related to increased headcount, out-of-pocket business development costs related to NAV4694, investor and public relations costs, pharmacovigilance costs related to Lymphoseek, and legal and professional services costs, offset by decreased out-of-pocket marketing costs to support the commercial launch of Lymphoseek.

Other expenses were \$1.4 million for the quarter ended September 30, 2013, compared to \$29,000 for the same period in 2012. Other expenses were \$3.6 million for the nine months ended September 30, 2013, compared to \$960,000 for the same period in 2012. The net increases in other expenses between the quarter and year-to-date periods were primarily the result of accounting charges classified as loss on extinguishment of debt related to the payoff of one note payable and the restructuring of another note, the majority of which were non-cash in nature, coupled with increased interest on higher notes payable balances.

As of September 30, 2013, Navidea had cash totaling approximately \$44.6 million.

“The recent equity transaction provides us with a stronger balance sheet position than we have had in several years,” said Brent Larson, Navidea CFO. “This strengthened balance sheet, augmented by our available line of credit, our ability to control many expenses, and other financial tools at our disposal, continue to provide us with a great deal of financial strength and flexibility during the expected ramp up of revenue from Lymphoseek.”

Third Quarter 2013 and Recent Business Highlights
Products and Pipeline

- Lymphoseek
 - o CMS issued a Lymphoseek reimbursement pass-through “C Code” that became effective October 1, 2013, establishing a reimbursement mechanism for healthcare providers.
 - o Researchers highlighted additional results from a Lymphoseek Phase 3 clinical trial in head and neck cancer at the American College of Surgeons 2013 Annual Clinical Congress. Lymphoseek successfully identified Sentinel Lymph Nodes when compared with the pathology Gold Standard to meet the primary and secondary endpoints.

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- o Independent investigators at The Ohio State University published Lymphoseek Phase 3 clinical trial results in *JAMA Otolaryngology Head and Neck Surgery*.

· **Development Programs**

- o Data focused on CD206 receptor-targeted precision diagnostic imaging for multiple disorders using agents from the recently announced Manoecept platform were featured in *Nature Outlook: Medical Imaging* and appeared in the October 31st issue of *Nature*.
- o The Manoecept Advisory Board was formed and is comprised of renowned scientific and medical advisors in the field of macrophage science and macrophage-mediated diseases as Navidea seeks to prioritize and advance encouraging early stage results.
- o Two National Institutes of Health Small Business Innovation Research grants were awarded for studies of NAV4694 in mild cognitive impairment and for the Phase 3 program in Alzheimer's disease. The grants have the potential to provide up to \$4.1 million in support, if fully funded.
- o Special Protocol Assessments for the NAV5001 Phase 3 program were agreed upon with the FDA.
- o U.S. manufacturing and supply agreement for clinical trial doses of NAV4694 was signed with Siemens' PETNET Solutions.

Corporate/Financial

- A \$30 million registered direct offering of common stock led by Crede CG III, Ltd., a wholly-owned subsidiary of Crede Capital Group, LLC, a U.S.-based accredited, institutional investor, closed in September.

Conference Call Details

Navidea's Chief Executive Officer, Dr. Mark Pykett, President and Chief Business Officer, Dr. Thomas Tulip, and Executive Vice President and Chief Financial Officer, Brent Larson, will provide a development and business update and will discuss the Company's financial results for the third quarter of 2013 during the conference call. The conference call can be accessed as follows:

Investors and the public are invited to listen to the conference call via telephone or live webcast.

Event:	Navidea Biopharmaceuticals Q3 2013 Financial Results Conference Call
Date/Time:	Wednesday, November 6, 2013 at 8:30 a.m. ET
Webcast Link:	http://edge.media-server.com/m/p/tarnovqu/lan/en
Dial-in Number – US:	888-713-4214
Dial in Number – Int'l:	617-213-4866
Participant Passcode:	42425304
Replay	A webcast replay will be available on the Investor Relations section of our website under Calendar of Events until December 6, 2013.

Participants who would like to ask questions during the question and answer portion of the call must participate by telephone. For faster service on the day of the call, participants may pre-register for the telephonic call at: <https://www.theconferencingservice.com/prereg/key.process?key=PLWG4YRTQ>. Pre-registrants will be issued a PIN number to use along with the Passcode when dialing into the live call which will provide quicker access to the conference by bypassing the operator upon connection. If not pre-registered, participants are encouraged to dial-in fifteen minutes before the conference call begins. Pre-registration is not necessary to listen to the live webcast or webcast replay. The webcast replay is expected to be available on our website approximately two to four hours after the live event.

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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 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 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.

Contact: Navidea Biopharmaceuticals

Brent Larson, 614-822-2330

Executive VP & CFO

Sharon Correia, 978-655-2686

Associate Director, Corporate Communications

Financial tables to follow

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NAVIDEA BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2013 (unaudited)	December 31, 2012
Assets:		
Cash	\$ 44,632,604	\$ 9,118,564
Other current assets	2,990,766	1,498,819
Non-current assets	<u>2,313,338</u>	<u>1,355,014</u>
Total assets	<u>\$ 49,936,708</u>	<u>\$ 11,972,397</u>
Liabilities and stockholders' equity (deficit):		
Notes payable, net of discount, current	\$ 1,692,091	\$ 2,756,718
Other current liabilities	4,613,909	3,433,821
Notes payable, net of discount	26,087,219	6,930,112
Derivative liabilities	7,675,446	--
Other liabilities	1,005,310	257,122
Stockholders' equity (deficit)	<u>8,862,733</u>	<u>(1,405,376)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 49,936,708</u>	<u>\$ 11,972,397</u>

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NAVIDEA BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Nine Months Ended	
	September 30, 2013	September 30, 2012	September 30, 2013	September 30, 2012
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenue:				
Net sales	\$ 143,799	\$ --	\$ 271,620	\$ 71,931
Grant and other revenue	256,575	--	324,031	--
Total revenue	400,374	--	595,651	71,931
Cost of goods sold	75,422	--	180,860	--
Gross profit	324,952	--	414,791	71,931
Operating expenses:				
Research and development	6,278,459	6,127,546	14,295,049	12,547,373
Selling, general and administrative	3,971,172	2,941,851	11,505,099	8,487,318
Total operating expenses	10,249,631	9,069,397	25,800,148	21,034,691
Loss from operations	(9,924,679)	(9,069,397)	(25,385,357)	(20,962,760)
Interest expense	(976,226)	(315,262)	(1,804,576)	(930,338)
Loss on extinguishment of debt	--	--	(1,372,266)	--
Change in fair value of financial instruments	(377,474)	283,731	(377,474)	6,842
Other income (expense), net	(27,828)	2,328	(7,904)	(36,238)
Net loss	(11,306,207)	(9,098,600)	(28,947,577)	(21,922,494)
Preferred stock dividends	--	(25,000)	--	(75,000)
Loss attributable to common stockholders	\$ (11,306,207)	\$ (9,123,600)	\$ (28,947,577)	\$ (21,997,494)
Loss per common share (basic and diluted)	\$ (0.09)	\$ (0.09)	\$ (0.25)	\$ (0.23)
Weighted average shares outstanding (basic and diluted)	121,117,562	102,332,983	117,740,754	97,042,832

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