

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) August 7, 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 August 7, 2013, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release regarding its consolidated financial results for the second quarter ended June 30, 2013. A copy of the Company’s August 7, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<i>Exhibit Number</i>	<i>Exhibit Description</i>
99.1	Navidea Biopharmaceuticals, Inc. press release dated August 7, 2013, entitled “Navidea Biopharmaceuticals Announces Second 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: August 7, 2013

By: /s/ Brent L. Larson

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



Press Release

FOR IMMEDIATE RELEASE

Navidea Biopharmaceuticals Announces Second Quarter 2013 Results

**– Business Update / Quarterly Conference Call Today, August 7, 2013
at 8:30 am EDT –**

DUBLIN, OHIO – August 7, 2013 – Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced business highlights and consolidated results for the second quarter ended June 30, 2013.

“The most significant event for Navidea this quarter was the launch of our first product, Lymphoseek[®]. Our launch is off to a great start and we are advancing our innovative portfolio with the initiation of the Phase 3 study of NAV4694 in Alzheimer’s disease. During the second half of 2013, we expect to further enhance our long-term growth with additional value enhancing pipeline events,” said Dr. Mark Pykett, Navidea CEO.

“We are tracking well in the initial weeks of launch and feel strongly that we have the right strategy to drive adoption. The commercialization plan we are executing with our partner is on target based on key measures of success: repeat and multiple dose ordering, adoption at top-tier medical institutions, formulary placement, excellent product performance, and high customer satisfaction,” added Dr. Pykett. “We are looking forward to the expected pass-through C code to further facilitate reimbursement starting in the fourth quarter.”

With the objective of strengthening the existing label and as a result of a recent constructive meeting with the U.S. Food and Drug Administration (FDA), Navidea announced today that it is formally closing its Phase 3 clinical study in subjects with head and neck cancer. The Company plans to submit a supplemental New Drug Application (sNDA) later this year.

The Company also continues to make progress related to Lymphoseek outside the U.S.; Navidea received positive Day 120 feedback on its Marketing Authorization Application from the European Medicines Agency and expects a positive opinion by year-end 2013.

Second Quarter 2013 Financial Results

For the quarter ended June 30, 2013, Navidea reported a net loss attributable to common stockholders of \$10.3 million, or \$0.09 per share, compared with a net loss attributable to common stockholders of \$5.9 million, or \$0.06 per share, for the same period in 2012. For the six months ended June 30, 2013, Navidea’s net loss attributable to common stockholders was \$17.6 million, or \$0.15 per share, compared to a net loss attributable to common stockholders of \$12.9 million, or \$0.14 per share, for the same period in 2012.

Revenue for the quarter ended June 30, 2013 was \$195,000 compared with revenue of \$60,000 for the same period in 2012. For the six months ended June 30, 2013, Navidea’s revenue was \$195,000, compared to revenue of \$72,000 for the same period in 2012. Revenue for the second quarter of 2013 consisted primarily of approximately \$128,000 derived from the sale of Lymphoseek, including initial stocking of our partner’s radiopharmacies.

Research and development (R&D) expenses were \$4.4 million for the quarter ended June 30, 2013, compared to \$2.5 million for the same period in 2012. The increase of \$1.9 million was primarily a result of increased NAV4694 and NAV5001 product development costs, offset by decreased Lymphoseek and potential pipeline product development costs. R&D expenses were \$8.0 million for the six months ended June 30, 2013, compared to \$6.4 million for the same period in 2012. The increase of \$1.6 million was primarily attributable to increased NAV4694 product development costs, offset by decreased Lymphoseek, NAV5001, RIGScan[™], and potential pipeline development costs.

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Selling, general and administrative (SG&A) expenses were \$4.2 million for the quarter ended June 30, 2013, compared to \$3.0 million for the same period in 2012. The increase of \$1.2 million was primarily a result of increased medical education and investor and public relations costs, offset by decreased out-of-pocket marketing costs, to support the commercial launch of Lymphoseek. SG&A expenses were \$7.5 million for the six months ended June 30, 2013, compared to \$5.5 million for the same period in 2012. The net SG&A increase of \$2.0 million between the two periods was attributable to the same primary factors noted for the second quarter.

Other expenses were \$1.8 million for the quarter ended June 30, 2013, compared to \$448,000 for the same period in 2012. Other expenses were \$2.2 million for the six months ended June 30, 2013, compared to \$931,000 for the same period in 2012. The net increases in other expenses between the quarter and year-to-date periods were related primarily to accounting charges classified as loss on extinguishment of debt related to the payoff of one note payable and the restructuring of another. The majority of these losses on extinguishment were non-cash in nature.

As of June 30, 2013, Navidea had cash and cash equivalents totaling approximately \$25.6 million compared to \$9.8 million in cash and cash equivalents as of March 31, 2013.

“Meeting our goals for successful commercialization of Lymphoseek and advancing our pipeline remain our primary focus,” said Brent Larson, Navidea CFO. “During this initial quarter of launch, margins on Lymphoseek sales were negatively impacted by two primary factors: the high proportion of revenue derived from inventory-stocking at lower margins and costs related to certain post-production testing required by regulatory authorities. These testing activities are charged to cost of goods sold in the period they are incurred rather than recognized as inventory is sold. Gross margins are expected to increase as these charges diminish as a proportion of revenue in line with previous guidance. Additionally, we believe the recent closing of a \$25 million debt financing with GE Capital, Healthcare Financial Services strengthens our financial position. We continue to maintain financial flexibility through access to available funding sources and expense control as we execute our business plan and support our pipeline.”

Second Quarter 2013 and Recent Business Highlights

Pipeline

- Lymphoseek
 - o Navidea announced the commercial launch of Lymphoseek (technetium Tc 99m tilmanocept) Injection in May, with U.S. marketing partner, Cardinal Health.
 - o Researchers highlighted results from Lymphoseek clinical trials in 20 presentations and a sponsored lymphatic mapping symposium at the Joint International Oncology Congress, the Annual Meeting of the American Society of Clinical Oncology and the Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging.
 - o Positive top-line results from an interim analysis of Lymphoseek Phase 3 clinical trial in head and neck cancer which met its primary endpoint in identification of sentinel lymph nodes against the pathology gold standard were reported.

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- o Navidea closed enrollment in the NEO3-06 study in head and neck cancers following a constructive FDA meeting and made plans to submit a sNDA based on the current interim data analysis.
- NAV4694 and NAV5001
 - o Navidea’s global Phase 3 trial of NAV4694 PET imaging agent was initiated with the first patient enrolled at the Southern Illinois University School of Medicine.
 - o AIBL, a leading Australian-based neurodegenerative disease and imaging research consortium, announced that it is converting to NAV4694 from gold-standard Pittsburgh Compound-B (PiB) for its comprehensive research initiative in Alzheimer’s disease (AD) and Mild Cognitive Impairment.
 - o Researchers from the McGill Centre for Studies in Aging, Douglas Research Institute, and Montreal Neurological Institute presented results at the annual Alzheimer’s Association International Conference showing NAV4694 better differentiated amyloid deposition associated with AD in post-mortem brains than PiB.
 - o Navidea co-sponsored the 2013 Alzheimer’s Imaging Consortium in July which featured leading international experts including presentations by Drs. Gil Rabinovici, University of California, San Francisco and Christopher Rowe, Austin Health, Melbourne, Australia.
 - o Christopher Rowe et al published results in the *Journal of Nuclear Medicine* from a NAV4694 clinical trial demonstrating positive results from a head-to-head comparison of NAV4694 and β -Amyloid imaging gold standard PiB in AD and dementia. The study was conducted by collaborators at Austin Health in Melbourne, Australia.
 - o A manufacturing and supply agreement with Nordion, Inc. (Canada) was executed to produce and distribute supplies of ^{123}I -labeled NAV5001 for late-phase clinical trials.
 - o A clinical study commenced to investigate the performance of NAV5001 in a SPECT imaging procedure of the brain in connection with Navidea’s program to evaluate NAV5001 in dementia with Lewy bodies.

Corporate/Financial

- A \$25 million debt financing transaction led by GE Capital, Healthcare Financial Services closed in June.
- An underwritten public offering of 2.1 million shares of common stock, resulting in net proceeds to the Company of approximately \$4.8 million was completed in April.

Conference Call Details

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

CONFERENCE CALL INFORMATION			
TO PARTICIPATE LIVE:		TO LISTEN TO A REPLAY:	
Date:	August 7, 2013	Available until:	August 21, 2013
Time:	8:30 a.m. EDT	Toll-free (U.S.) Dial in #:	(877) 660-6853
		International Dial in #:	(201) 612-7415
Toll-free (U.S.) Dial in #:	(877) 407-8031	Replay passcode:	
International Dial in #:	(201) 689-8031	Account #:	268
		Conference ID #:	418275

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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 actively developing four radiopharmaceutical agent platforms – Lymphoseek®(technetium 99m tilmanocept) Injection, NAV4694, NAV5001 and RIGScan™ – to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. Navidea’s first commercial agent, Lymphoseek, 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.

Contact:

Source: Navidea Biopharmaceuticals, Inc.
Navidea Biopharmaceuticals
Brent Larson, 614-822-2330
Executive VP & CFO

Stern Investor Relations, Inc.
Beth DelGiacco, 212-362-1200

- Financial Tables to follow -

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NAVIDEA BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2013 (unaudited)	December 31, 2012
Assets:		
Cash	\$ 25,638,305	\$ 9,118,564
Other current assets	3,089,281	1,498,819
Non-current assets	<u>2,390,682</u>	<u>1,355,014</u>
Total assets	<u>\$ 31,118,268</u>	<u>\$ 11,972,397</u>
Liabilities and stockholders' deficit:		
Notes payable, net of discount, current	\$ 80,820	\$ 2,756,718
Other current liabilities	4,638,665	3,433,821
Notes payable, net of discount	27,225,620	6,930,112
Other liabilities	1,005,875	257,122
Stockholders' deficit	<u>(1,832,712)</u>	<u>(1,405,376)</u>
Total liabilities and stockholders' deficit	<u>\$ 31,118,268</u>	<u>\$ 11,972,397</u>

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Six Months Ended	
	June 30, 2013 (unaudited)	June 30, 2012 (unaudited)	June 30, 2013 (unaudited)	June 30, 2012 (unaudited)
Revenue:				
Net sales	\$ 127,821	\$ -	\$ 127,821	\$ -
Grant and other revenue	67,456	60,000	67,456	71,931
Total revenue	<u>195,277</u>	<u>60,000</u>	<u>195,277</u>	<u>71,931</u>
Cost of goods sold	<u>105,438</u>	<u>-</u>	<u>105,438</u>	<u>-</u>
Gross profit	<u>89,839</u>	<u>60,000</u>	<u>89,839</u>	<u>71,931</u>
Operating expenses:				
Research and development	4,376,833	2,476,113	8,016,590	6,419,827
Selling, general and administrative	4,169,437	2,970,837	7,533,927	5,545,467
Total operating expenses	<u>8,546,270</u>	<u>5,446,950</u>	<u>15,550,517</u>	<u>11,965,294</u>
Loss from operations	<u>(8,456,431)</u>	<u>(5,386,950)</u>	<u>(15,460,678)</u>	<u>(11,893,363)</u>
Interest expense	(465,268)	(321,405)	(828,350)	(615,076)
Loss on extinguishment of debt	(1,372,266)	-	(1,372,266)	-
Change in derivative liabilities	-	(92,805)	-	(276,889)
Other income (expense), net	(6,386)	(33,662)	19,924	(38,566)
Net loss	<u>(10,300,351)</u>	<u>(5,834,822)</u>	<u>(17,641,370)</u>	<u>(12,823,894)</u>
Preferred stock dividends	<u>-</u>	<u>(25,000)</u>	<u>-</u>	<u>(50,000)</u>
Loss attributable to common stockholders	<u>\$ (10,300,351)</u>	<u>\$ (5,859,822)</u>	<u>\$ (17,641,370)</u>	<u>\$ (12,873,894)</u>
Loss per common share (basic and diluted)	\$ (0.09)	\$ (0.06)	\$ (0.15)	\$ (0.14)
Weighted average shares outstanding (basic and diluted)	118,260,288	94,664,659	116,024,366	94,368,690

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