

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) March 6, 2013

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.)
--	---	---

<u>425 Metro Place North, Suite 450, Dublin, Ohio</u> (Address of principal executive offices)	<u>43017</u> (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 March 6, 2013, Navidea Biopharmaceuticals, Inc., a Delaware corporation (the “Company”), issued a press release regarding its consolidated financial results for the fourth quarter of 2012, and for the year ended December 31, 2012. A copy of the Company’s March 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 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

*Exhibit  
Number*

*Exhibit Description*

99.1	Navidea Biopharmaceuticals, Inc. press release dated March 6, 2013, entitled “Navidea Announces Fourth Quarter and Full-Year 2012 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 Securities and Exchange Commission filings. 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: March 7, 2013

By: /s/ Brent L. Larson

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



Press Release

**FOR IMMEDIATE RELEASE****NAVIDEA ANNOUNCES FOURTH QUARTER AND FULL-YEAR 2012 RESULTS***– Management hosting conference call on March 7, 2013 at 8:30 a.m. EST –*

DUBLIN, OHIO – March 6, 2013 – Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced consolidated results for the fourth quarter of 2012 and for the year ended December 31, 2012.

**Financial Results**

Navidea's revenues for 2012 relate primarily to reimbursement of certain Lymphoseek<sup>®</sup> commercialization activities by our U.S. distribution partner. Revenues for 2011 relate to grants received in support of the Company's drug development activities. Revenues for the year ended December 31, 2012 were \$79,000 compared to \$598,000 for 2011. Costs related to these reimbursements and grants received in support of development activities were recorded in operating expenses.

Fourth quarter 2012 operating expenses were \$7.0 million compared to \$9.0 million for the fourth quarter of 2011. Operating expenses for the year ended December 31, 2012 were \$28.1 million compared to \$24.7 million for 2011.

Research and development expenses decreased \$2.7 million to \$4.3 million during the fourth quarter of 2012 from \$7.0 million for the same period in 2011. The net decrease was primarily a result of net decreases in NAV4694 costs, which included a \$5.0 million license fee in the fourth quarter of 2011, and RIGScan<sup>™</sup> development costs, offset by increases in Lymphoseek and NAV5001 development costs as well as increased headcount and related costs to support our expanded development efforts. Research and development expenses increased \$1.7 million to \$16.9 million during 2012 from \$15.2 million during 2011. The net increase from 2011 to 2012 was primarily a result of net increases in NAV5001 and Lymphoseek development costs, including NAV5001 option and sublicense fees of \$1.8 million (\$1.1 million of which was non-cash in nature), increased costs related to potential pipeline products, and increased headcount and related costs as described above, offset by decreases in NAV4694 and RIGScan development costs.

Selling, general and administrative expenses increased \$642,000 to \$2.7 million for the fourth quarter of 2012 from \$2.0 million for the same period in 2011. The net increase was primarily a result of our formation of a marketing and business development team during the second half of 2011 to prepare for the commercial launch of Lymphoseek, resulting in increased marketing costs related to the pending commercial launch of Lymphoseek and increased headcount and related costs in 2012. Selling, general and administrative expenses increased \$1.7 million to \$11.2 million during 2012 from \$9.5 million in 2011. The net increase from 2011 to 2012 was primarily a result of increased marketing costs related to the pending commercial launch of Lymphoseek coupled with increased headcount and related costs as described above, offset by decreased separation costs of \$2.7 million related to our former President and CEO which were recorded in 2011.

Navidea's loss from operations for the fourth quarter of 2012 was \$7.0 million compared to \$9.0 million for the fourth quarter of 2011. Navidea's loss from operations for the year ended December 31, 2012 was \$28.0 million compared to \$24.1 million for the same period of 2011. For the fourth quarter of 2012, Navidea reported a loss attributable to common stockholders of \$7.2 million, or \$0.07 per share, compared to a loss attributable to common stockholders of \$7.6 million, or \$0.08 per share, for the fourth quarter of 2011. For the year ended December 31, 2012, Navidea reported a loss attributable to common stockholders of \$29.2 million, or \$0.29 per share, compared to income attributable to common stockholders of \$5.5 million, or \$0.06 per share, for the same period in 2011. Income attributable to common stockholders in 2011 was the result of the sale of Navidea's line of medical devices, the neoprobe<sup>®</sup> GDS gamma detection systems, to Devicor Medical Products, Inc. in August 2011 for approximately \$30 million.

- MORE -

---

## Business Update

Key milestones achieved by Navidea in 2012 and to date in 2013 include:

### Corporate/Financial

- Neoprobe Corporation became Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) reflecting the Company's biopharmaceutical focus on precision diagnostics development and commercialization.
- Implemented a \$50 million credit facility with Platinum-Montaur Life Sciences LLC (Montaur), of which \$15 million was made immediately available, to provide flexible financial resources to fund short- and long-term development and growth plans. To date the Company has drawn a total of \$4 million under the credit facility. Montaur also exercised certain warrants in December 2012 and March 2013, providing \$1.9 million and \$1.4 million in proceeds, respectively.
- Completed an underwritten public offering of 1.5 million shares of common stock in February 2013, resulting in net proceeds to the Company of approximately \$4.4 million after deducting expenses associated with the offering.
- Appointed pharma industry veteran Cornelia Reininger, MD, PhD, as Chief Medical Officer to lead ongoing development of our pipeline agents, playing a key role in medical strategy, protocol design, product positioning and regulatory direction. Formerly, Dr. Reininger spearheaded development and registration of the neuroimaging agents, florbetaben for Alzheimer's disease and DaTScan<sup>TM</sup> for Parkinson's disease.
- Augmented management with the addition of key strategic positions to strengthen the Company's global regulatory, commercial and manufacturing functions including William Regan, Senior Vice President, Global Regulatory Strategy; David Pendleton, Vice President, Marketing and New Product Planning; Stephen Haber, Vice President, Development; and David Casebier, Vice President, Chemistry, Manufacturing and Control.

### Pipeline

- Lymphoseek
  - o Designation of April 30, 2013 as a Prescription Drug User Fee Act goal date for Lymphoseek by the U.S. Food and Drug Administration's (FDA). On September 10, 2012, the Company received a Complete Response Letter (CRL) from the FDA citing manufacturing deficiencies with the Company's contract manufacturers. The Company stated the CRL was not related to Lymphoseek safety or efficacy, and as a result, was able to quickly resubmit the New Drug Application for Lymphoseek to the FDA on October 30, 2012.
  - o Submitted the Lymphoseek Marketing Authorization Application to the European Medicines Agency in December 2012.

- MORE -

---

- o Reached the interim analysis point of the NEO3-06 Phase 3 head and neck cancer study of Lymphoseek with results from the interim statistical analysis and reporting of the findings expected later in 2013.
- o Initiated a collaboration with Maimonides Medical Center on an investigator-initiated clinical trial utilizing Lymphoseek for lymphatic mapping in colorectal cancer.
- o Presented data from Lymphoseek clinical trials at more than 15 major medical meetings, including: Society of Surgical Oncology, European Society of Surgical Oncology, American Society of Clinical Oncology, Society of Nuclear Medicine, International Conference on Head and Neck Cancer, European Association of Nuclear Medicine, American Society for Radiation Oncology and Radiology Society of North America.
- o Published data from the Lymphoseek Phase 3 Clinical Trial for Intraoperative Lymphatic Mapping of Lymph Nodes in Breast Cancer Compared to Sulfur Colloid and Vital Blue Dye in the *Journal of Clinical Oncology Online* (2012; e21066).
- o Published results from the Lymphoseek Phase 3 Clinical Trials in Melanoma in the *Annals of Surgical Oncology* (DOI 10.1245/s10434-012-2612-z).
- NAV4694
  - o Initiated a Phase 2 clinical trial of NAV4694 as an aid in diagnosing Alzheimer’s disease (AD) with the goal to compare images from subjects with probable AD with similarly aged and young healthy volunteers.
  - o Presented data from the NAV4694 studies at six major neurological medical meetings including: Human Amyloid Imaging meeting, Alzheimer’s Disease Neuroimaging Initiative, Society of Nuclear Medicine and the Alzheimer’s Association International Conference on Alzheimer’s Disease.
- NAV5001
  - o Licensed NAV5001, an Iodine-123 radiolabeled imaging agent being developed as a potential aid in the diagnosis of Parkinson’s disease, dementia with Lewy Bodies (DLB) and other movement disorders, thus expanding the Company’s neuroimaging pipeline.
- RIGScan
  - o Awarded a Small Business Innovation Research grant from the National Institutes of Health for development of a radio-immuno-guided surgery agent aimed at detecting metastatic cancer, with potential for grant money up to a total of \$1.5 million over three years if fully funded.

**Management Commentary**

“Through flexible access to multiple available funding sources, we have maintained a strong financial position in advance of expected revenue from our first radiopharmaceutical product, Lymphoseek,” said Brent Larson, Navidea’s Senior Vice President and CFO. “We believe that our cash flow and available financial resources are sufficient to support the ongoing advances in our pipeline programs and operating needs for the foreseeable future. In addition, we have spent considerable effort in 2012 to build relationships with potential institutional investors and catalyze interest in Navidea. As an example, our recent transaction led by J.P. Morgan Asset Management has provided us the opportunity to expand our institutional base with additional outstanding investors.”

- MORE -

---

**NAVIDEA BIOPHARMACEUTICALS**  
**ADD – 4**

“During 2012, we continued to make important progress positioning Navidea as a leader in the area of precision diagnostics,” said Dr. Mark Pykett, Navidea’s President and CEO. “We are looking forward to an even more exciting year in 2013.”

Dr. Pykett, Executive Vice President and CBO, Dr. Thomas Tulip, Senior Vice President, Pharmaceutical Research and Clinical Development, Dr. Frederick Cope, and Mr. Larson, will provide a business update and discuss the fourth quarter and full year 2012 financial results during a conference call with the investment community scheduled for Thursday, March 7, 2013 at 8:30 a.m. EST. The conference call can be accessed as follows:

<b>Conference Call Information</b>			
<b>TO PARTICIPATE LIVE:</b>		<b>TO LISTEN TO A REPLAY:</b>	
Date:	March 7, 2013	Available until:	March 21, 2013
Time:	8:30 a.m. EST	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 #:	410082

**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<sup>®</sup>, NAV4694, NAV5001 and RIGScan<sup>™</sup> – to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. 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](http://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, the ability to obtain, and timing of, regulatory approvals of the Company’s products, the timing and anticipated results of commercialization efforts, and anticipated 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 regulatory approvals for and 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, 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:**

Navidea Biopharmaceuticals, Inc. – Brent Larson, Sr. VP & CFO – (614) 822-2330

*Financial tables to follow*

- MORE -

---

NAVIDEA BIOPHARMACEUTICALS  
ADD – 5

NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2012 (unaudited)	December 31, 2011
<b>Assets:</b>		
Cash	\$ 9,118,564	\$ 28,644,004
Other current assets	1,498,819	1,402,517
Non-current assets	<u>1,355,014</u>	<u>1,147,399</u>
<b>Total assets</b>	<b><u>\$ 11,972,397</u></b>	<b><u>\$ 31,193,920</u></b>
<b>Liabilities and stockholders' (deficit) equity:</b>		
Notes payable, net of discount, current	\$ 2,756,718	\$ -
Derivative liabilities, current	-	568,930
Other current liabilities	3,433,821	2,779,540
Notes payable, net of discount	6,930,112	6,456,388
Other liabilities	257,122	257,315
Stockholders' (deficit) equity	<u>(1,405,376)</u>	<u>21,131,747</u>
<b>Total liabilities and stockholders' (deficit) equity</b>	<b><u>\$ 11,972,397</u></b>	<b><u>\$ 31,193,920</u></b>

- MORE -

---



CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Twelve Months Ended	
	December 31, 2012 (unaudited)	December 31, 2011 (unaudited)	December 31, 2012 (unaudited)	December 31, 2011
Revenue	\$ 6,807	\$ -	\$ 78,738	\$ 597,729
Operating expenses:				
Research and development	4,343,109	6,994,373	16,890,482	15,154,365
Selling, general and administrative	2,690,241	2,048,325	11,177,559	9,547,779
Total operating expenses	7,033,350	9,042,698	28,068,041	24,702,144
Loss from operations	(7,026,543)	(9,042,698)	(27,989,303)	(24,104,415)
Interest expense	(235,994)	(10,101)	(1,166,332)	(13,330)
Change in derivative liabilities	25,268	4,558	32,110	(952,375)
Other income, net	2,559	10,486	(33,679)	22,544
Loss before income taxes	(7,234,710)	(9,037,755)	(29,157,204)	(25,047,576)
Benefit from income taxes	-	1,476,215	-	7,880,143
Loss from continuing operations	(7,234,710)	(7,561,540)	(29,157,204)	(17,167,433)
Discontinued operations, net of income tax effect	-	(46,382)	-	22,780,425
Net (loss) income	(7,234,710)	(7,607,922)	(29,157,204)	5,612,992
Preferred stock dividends	31,667	(25,000)	(43,333)	(100,000)
(Loss) income attributable to common stockholders	\$ (7,203,043)	\$ (7,632,922)	\$ (29,200,537)	\$ 5,512,992
(Loss) income per common share (basic and diluted):				
Continuing operations	\$ (0.07)	\$ (0.08)	\$ (0.29)	\$ (0.17)
Discontinued operations	\$ -	\$ (0.00)	\$ -	\$ 0.23
(Loss) income attributable to common stockholders	\$ (0.07)	\$ (0.08)	\$ (0.29)	\$ 0.06
Weighted average shares outstanding:				
Basic and diluted	105,067,640	93,766,560	99,059,997	90,509,326

###

- END -