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 8, 2012

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 8, 2012, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release regarding its consolidated financial results for the three-month and nine-month periods ended September 30, 2012. A copy of the Company's November 8, 2012, 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 November 8, 2012, entitled "Navidea Biopharmaceuticals Announces Third Quarter 2012 Financial Results."

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 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, 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, Quarterly Reports on Form 10-Q, 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 8, 2012

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

Navidea BIOPHARMACEUTICALS

Press Release

FOR IMMEDIATE RELEASE

Navidea Biopharmaceuticals Announces Third Quarter 2012 Financial Results

– Business Update / Quarterly Conference Call
November 8, 2012, at 5:00 PM EST –

DUBLIN, OHIO – November 8, 2012 – 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 and nine months ended September 30, 2012.

Financial Results and Outlook

For the quarter ended September 30, 2012, Navidea reported a net loss attributable to common stockholders of $9.1 million, or $0.09 per share, compared to net income attributable to common stockholders of $19.8 million, or $0.21 per share, for the same period in 2011. For the nine months ended September 30, 2012, Navidea's net loss attributable to common stockholders was $22.0 million, or $0.23 per share, compared to net income attributable to common stockholders of $13.1 million, or $0.15 per share, for the same period in 2011. In August 2011, the Company sold its neoprobe® GDS line of gamma detection device systems to a third party. As a result, the Company recorded a net pre-tax gain on the sale of the GDS business of approximately $25 million during the third quarter of 2011.

Research and development (R&D) expenses were $6.1 million for the quarter ended September 30, 2012, compared to $3.9 million for the same period in 2011. The increase in R&D expenses was attributable to several factors, including increases in NAV4694 (previously called AZD4694) and NAV5001 (previously called CFT) development activities including $1.3 million in NAV5001 sublicense fees, Lymphoseek® manufacturing-related costs, and headcount-related costs to support our growing development activities, offset by reductions in Lymphoseek new drug application (NDA) filing fees, Lymphoseek clinical trial activities, and RIGScan™ development costs.

R&D expenses were $12.5 million for the nine months ended September 30, 2012, compared to $8.2 million for the same period in 2011. The increase in R&D expenses was primarily attributable to the same factors described above for the three-month periods as well as an option fee and diligence-related costs associated with our sublicense of NAV5001.

Selling, general and administrative (SG&A) expenses were $2.9 million for the quarters ended September 30, 2012 and 2011. During the third quarter of 2012 as compared to the same period in 2011, the Company incurred increased marketing and business development costs related to commercial launch preparations for Lymphoseek and to ongoing activities in support of advancing the Company's precision diagnostics pipeline. These costs, as well as increased SG&A headcount and other support costs incurred during the third quarter of 2012, were offset by a decrease from the third quarter of 2011 of approximately $817,000 in non-recurring charges related to the separation of the Company's former President and CEO.

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SG&A expenses were $8.5 million for the nine months ended September 30, 2012, compared to $7.5 million for the same period in 2011. The factors leading to the net increase in SG&A expenses between the two year-to-date periods were the same as described above for the three-month periods except that the offset due to the non-recurring charges related to the separation of the Company's former President and CEO totaled approximately $2.7 million for the first nine months of 2011.

As of September 30, 2012, Navidea had cash totaling approximately $11.2 million.

Brent Larson, Navidea Senior Vice President and CFO, said, "Navidea continues to maintain a strong financial position to support our pipeline development activities in advance of revenue from our first radiopharmaceutical product, Lymphoseek. We retain flexibility in timing of our expenditures and in our access to multiple available funding sources, including borrowing under the line of credit we have in place from our primary investor, Platinum-Montaur Life Sciences, LLC. We plan to work closely with Montaur to determine the optimal timing for accessing the credit facility to maintain financial strength, support the ongoing advances in our pipeline programs and fund commercial preparations for Lymphoseek. We remain focused on the prudent management of our finances as we drive toward Lymphoseek launch and revenue generation."

Lymphoseek Update

On October 30, 2012, Navidea resubmitted its Lymphoseek new drug application (NDA) to the U.S. Food and Drug Administration (FDA) in response to the complete response letter (CRL) the Company received in September 2012.

On September 10, 2012, Navidea announced that it had received a CRL from the FDA regarding the NDA for Lymphoseek (technetium Tc 99m tilmanocept) Injection. The CRL focused on current Good Manufacturing Practice (cGMP) deficiencies identified during inspections of third-party manufacturing facilities and did not cite any Lymphoseek clinical efficacy or safety issues. Since receipt of the CRL, the Company has worked diligently with its advisors, contract manufacturers and the FDA to address the deficiencies noted in the CRL. While the Company is unable to predict the timing for FDA review, it does believe that the focused scope of the CRL and the corresponding information provided in the Company's response will facilitate a timely evaluation of the resubmission.

"We continue to believe the FDA review process will involve re-evaluation of only a small portion of the NDA and that the focused information we have provided will support a potentially expeditious review," said Dr. Mark Pykett, Navidea President and CEO. "Our clear priority continues to be Lymphoseek approval and launch in the U.S. We are committed to providing this novel radiopharmaceutical for use in critical diagnostic procedures for medical professionals, cancer patients and their families."

Other Recent Business and Program Highlights

- Completed the sublicense agreement with Alseres Pharmaceuticals, Inc. for a second promising neuroimaging candidate. NAV5001 is an Iodine-123 radiolabeled imaging agent being developed as an aid in the diagnosis of Parkinson's disease and other movement disorders and a potential use as a diagnostic aid in dementia.

- Enrolled the first subject in a Phase 2 clinical trial of NAV4694, Navidea's F-18 PET imaging agent being developed as an aid in diagnosing Alzheimer's disease.

- Received a Small Business Innovation Research (SBIR) grant from the National Institutes of Health (NIH) for development of our radioimmunoguided surgery (RIGS®) agent aimed at detecting metastatic cancer, with potential funding of up to $1.5 million over three years if fully funded. The first-year Phase 1 funding of $315,000, which has already been approved, is expected to enable the Company to complete preclinical bridging activities using a RIGS tumor-antigen-targeted monoclonal antibody and prepare a standardized clinical trial protocol.

- Published the results of Lymphoseek Phase 3 clinical trials in melanoma in the online edition of the journal *Annals of Surgical Oncology*. The data indicated that Lymphoseek met the primary efficacy endpoint in the assessment of lymphatic mapping performance in patients with cutaneous melanoma. The study was titled, *"Combined Analysis of Phase III Trials Evaluating [99mTc]Tilmanocept and Vital Blue Dye for Identification of Sentinel Lymph Nodes in Clinically Node-Negative Cutaneous Melanoma,"* [DOI 10.1245/s10434-012-2612-z].

- Presented data on Lymphoseek at major scientific and medical conferences:

    - Lymphoseek Phase 3 meta-analysis data on Lymphoseek and radiolabeled colloidal agents presented at the 32nd Congress of the European Society of Surgical Oncology by Dr. Frederick Cope.

    - Additional podium and poster presentations highlighting similar Lymphoseek Phase 3 results were made at: the American Association of Pharmaceutical Scientists, the European Association of Nuclear Medicine, and the American Society for Radiation Oncology.

- Cornelia Reininger, M.D., Ph.D., joined Navidea as Chief Medical Officer. Previously, Dr. Reininger had a central role in the development of diagnostic radiopharmaceuticals for Alzheimer's and Parkinson's diseases for Bayer Healthcare Pharmaceuticals and GE Healthcare and Amersham Health – Diagnostic Imaging.

"We continue to make important progress toward a number of the clinical and regulatory objectives surrounding our product candidates," said Dr. Pykett. "We realized several important advancements in our programs this quarter and we expect to report a number of further positive achievements in the coming months, not the least of which are U.S. approval and launch for Lymphoseek, filing of a Marketing Authorization Application for approval in the European Union and advancing our discussions with potential partners outside the U.S., all in an effort to make Lymphoseek available around the world to cancer surgery patients and their physicians. We expect these Lymphoseek milestones, coupled with activities following our recent RIGS grant and the planned initiation of Phase 3 clinical trials for NAV4694 and NAV5001, to serve as demonstrable examples of the robustness of our evolving precision diagnostics pipeline as we enter 2013."

Conference Call Details

Navidea's President and CEO, Dr. Mark Pykett, Executive Vice President and Chief Business Officer, Dr. Thomas Tulip, and Senior Vice President and CFO, Brent Larson, will provide a development and business update, including responding to investor questions regarding the recent Lymphoseek NDA resubmission, and will discuss the Company's financial results for the third quarter and first nine months of 2012 during the conference call. The conference call can be accessed as follows:

CONFERENCE CALL INFORMATION			
TO PARTICPATE LIVE:		**TO LISTEN TO A REPLAY:**	
Date:	November 8, 2012	Available until:	November 22, 2012
Time:	5:00 PM ET	Toll-free (U.S.) Dial in #:	(877) 660-6853
		International Dial in #:	(201) 612-7415
Toll-free (U.S.) Dial in #:	(877) 407-8031		
International Dial in #:	(201) 689-8031	Replay passcode	
		Account #	286
		Conference ID#	403335

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®, NAV4694, NAV5001 (CFT) 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 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.

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Contact:

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

Financial tables to follow

NAVIDEA BIOPHARMACEUTICALS
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CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2012 (unaudited)	December 31, 2011
Assets:		
Cash	$ 11,211,170	$ 28,644,004
Other current assets	962,687	1,402,517
Non-current assets	1,433,861	1,147,399
Total assets	$ 13,607,718	$ 31,193,920
Liabilities and stockholders' equity:		
Note payable, net of discount, current	$ 2,425,973	$ -
Derivative liabilities, current	509,687	568,930
Other current liabilities	4,073,702	2,779,540
Note payable, net of discount	3,593,660	6,456,388
Other liabilities	250,588	257,315
Stockholders' equity	2,754,108	21,131,747
Total liabilities and stockholders' equity	$ 13,607,718	$ 31,193,920

NAVIDEA BIOPHARMACEUTICALS
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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Nine Months Ended	
	September 30, 2012 (unaudited)	September 30, 2011 (unaudited)	September 30, 2012 (unaudited)	September 30, 2011 (unaudited)
Revenue	$ -	$ 255,632	$ 71,931	$ 597,729
Operating expenses:				
Research and development	6,127,546	3,858,141	12,547,373	8,159,992
Selling, general and administrative	2,941,851	2,870,603	8,487,318	7,499,454
Total operating expenses	9,069,397	6,728,744	21,034,691	15,659,446
Loss from operations	(9,069,397)	(6,473,112)	(20,962,760)	(15,061,717)
Interest expense	(315,262)	(564)	(930,338)	(3,229)
Change in derivative liabilities	283,731	7,208	6,842	(956,933)
Other income (expense), net	2,328	6,653	(36,238)	12,058
Loss before income taxes	(9,098,600)	(6,459,815)	(21,922,494)	(16,009,821)
Benefit from income tax	-	6,403,928	-	6,403,928
Loss from continuing operations	(9,098,600)	(55,887)	(21,922,494)	(9,605,893)
Discontinued operations, net of tax effect	-	19,887,820	-	22,826,807
Net (loss) income	(9,098,600)	19,831,933	(21,922,494)	13,220,914
Preferred stock dividends	(25,000)	(25,000)	(75,000)	(75,000)
(Loss) income attributable to common stockholders	$ (9,123,600)	$ 19,806,933	$ (21,997,494)	$ 13,145,914
(Loss) income per common share (basic and diluted):				
Continuing operations	$ (0.09)	$ (0.00)	$ (0.23)	$ (0.11)
Discontinued operations	$ -	$ 0.21	$ -	$ 0.26
(Loss) income attributable to common stockholders	$ (0.09)	$ 0.21	$ (0.23)	$ 0.15
Weighted average shares outstanding:				
Basic and Diluted	102,332,983	93,070,235	97,042,832	89,410,150

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