

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 6, 2012

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.)
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<u>425 Metro Place North, Suite 450, Dublin, Ohio</u> (Address of principal executive offices)	<u>43017</u> (Zip Code)
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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 6, 2012, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release regarding its consolidated financial results for the second quarter ended June 30, 2012. A copy of the Company’s August 6, 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 August 6, 2012, entitled “Navidea Biopharmaceuticals Announces Second Quarter 2012 Results.”
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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: August 7, 2012

By: /s/Brent L. Larson

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



Press Release

FOR IMMEDIATE RELEASE

Navidea Biopharmaceuticals Announces Second Quarter 2012 Financial Results

*– Business Update / Quarterly Conference Call Set for Tomorrow, August 7, 2012,
at 8:00 AM EDT –*

DUBLIN, OHIO – August 6, 2012 – 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 and six months ended June 30, 2012.

Financial Results and Outlook

For the quarter ended June 30, 2012, Navidea reported a net loss attributable to common stockholders of \$5.9 million, or \$0.06 per share, compared to a net loss attributable to common stockholders of \$2.2 million, or \$0.02 per share, for the same period in 2011. For the six months ended June 30, 2012, Navidea's net loss attributable to common stockholders was \$12.9 million, or \$0.14 per share, compared to a net loss attributable to common stockholders of \$6.7 million, or \$0.08 per share, for the same period in 2011.

Brent Larson, Navidea Senior Vice President and CFO, said: "In continuing to facilitate the growth and diversification of our business, Navidea achieved a number of milestones during the first half of 2012 that we believe will enhance shareholder value, including activities related to Lymphoseek[®] commercialization and the addition of the [¹²³I]-E-IACFT (CFT) neuro-imaging agent to our pipeline. To achieve these accomplishments, we incurred a number of non-recurring expenses including costs related to regulatory support of Lymphoseek registration activities, launch preparation costs, expenses incurred addressing manufacturing matters, and the option fee for the CFT asset. Along the way, we have maintained a strong balance sheet and have taken incremental steps to further strengthen our financial position. Access to a non-dilutive, \$50 million credit facility demonstrates yet another facet of the financial flexibility we have established to help ensure that our development programs continue to advance and to support potential additional pipeline growth as we approach revenue generation from Lymphoseek. We will continue to evaluate high-value opportunities to enhance our pipeline and, as with the CFT license, seek to constructively approach these agreements with back-end milestone-driven payments."

Research and development (R&D) expenses were \$2.5 million for the quarter ended June 30, 2012, compared to \$1.9 million for the same period in 2011. The increase in R&D expenses was attributable to several factors, including increases in AZD4694 development activities, Lymphoseek manufacturing-related costs, other pipeline and headcount-related costs to support our growing pipeline and development activities, offset by reductions in Lymphoseek clinical trial activities and RIGScan[™] development costs.

R&D expenses were \$6.4 million for the six months ended June 30, 2012, compared to \$4.3 million for the same period in 2011. The increase in R&D expenses was attributable to primarily the same factors as the 2nd quarter plus option fee and diligence-related costs associated with our recent license of CFT.

Selling, general and administrative (SG&A) expenses were \$3.0 million for the quarter ended June 30, 2012, compared to \$1.7 million for the same period in 2011. The net SG&A increase of \$1.3 million between the two periods was primarily due to increased marketing and business development costs in preparation for the commercial launch of Lymphoseek and efforts to continue to build the Company's pipeline, coupled with increased general and administrative headcount and other support costs, offset by decreased professional services costs.

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SG&A expenses were \$5.5 million for the six months ended June 30, 2012, compared to \$4.6 million for the same period in 2011. The net SG&A increase of \$917,000 between the two periods was primarily due to increased marketing and business development costs in preparation for the commercial launch of Lymphoseek and efforts to continue to build the Company's pipeline, coupled with increased general and administrative headcount and other support costs, but was offset by approximately \$1.9 million in non-recurring charges related to the separation of the Company's former President and CEO incurred in the first half of 2011 and decreased professional services costs.

As of June 30, 2012, Navidea had cash and cash equivalents totaling approximately \$17.0 million.

"We remain focused on supporting our expected U.S. Lymphoseek approval and commercial launch as well as the planned advancement of its global registration process this year," said Dr. Mark Pykett, Navidea President and CEO. "In collaboration with our U.S. marketing partner, Cardinal Health, we are making important strides to support commercial introduction and market penetration, completing competitive product and launch analyses, customer surveys, and marketing and medical education plans. We also continue to build relationships with key opinion leaders, early adopters, and patient advocacy groups in support of a successful launch."

Recent business and program highlights:

- Completed a \$50 million credit facility with Platinum-Montaur Life Sciences providing the Company with significant, yet flexible, financial resources to fund short- and long-term development and growth plans.
- Completed the license agreement with Alseres Pharmaceuticals, Inc. for a second promising neuroimaging candidate. [¹²³I]-E-IACFT Injection, an Iodine-123 radiolabeled imaging agent will be 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.
- Received approval for the Phase 2 Brent Larson, Navidea Senior Vice President and CFO protocol from the New England Institutional Review Board (IRB), a centralized IRB that oversees the approval of clinical protocols for investigational drugs for multiple research organizations. Trial enrollment is expected to commence in the coming months.
- Presented data on Lymphoseek and AZD4694 at major scientific and medical conferences:
 - o Lymphoseek data was presented by three independent investigators at 8th International Conference on Head and Neck Cancer. Investigators from the University of Texas MD Anderson Cancer Center, The Ohio State University and the University of Miami reported their personal experiences with the use of Lymphoseek in head and neck squamous cell carcinoma
 - o Head-to-head study comparing Navidea's AZD4694 to the gold standard for imaging beta amyloid protein deposits was presented at Alzheimer's Association International Conference and the Society of Nuclear Medicine. Results from Austin Health, Melbourne, Australia clinical trial examined and reported AZD4694 performance characteristics and blinded reader confidence when used as an aid in diagnosing Alzheimer's disease. Results demonstrated strong similarity of AZD4694 to the long-standing agent of choice, PiB. A poster and another podium talk from investigators at Banner Alzheimer Institute and Astra Zeneca were also presented.

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- o Additional podium and poster presentations highlighting similar Lymphoseek Phase 3 results were made at: the European Association for Cancer Research, the Society for Nuclear Medicine, European Society for Therapeutic Radiology and Oncology, Australasian Lymphology Association and International Symposium on Sentinel Node Biopsy in Head and Neck Cancer.
- o Additional Early clinical development AZD4694 data was presented by Astra Zeneca at 12th International Stockholm/Springfield Symposium on Advances in Alzheimer Therapy.
- o Meta-analysis of Lymphoseek Phase 3 data compared to standard of care techniques was published in conjunction with the ASCO Annual Meeting. Data from the Phase 3 trial for Intraoperative Lymphatic Mapping (ILM) of lymph nodes in breast cancer compared to sulfur colloid and vital blue dye was reviewed in this online abstract publication.

Published data developed from Phase 3 trials of Lymphoseek (99m-Tc-Tilmanocept) demonstrating important performance characteristics of Lymphoseek compared to a commercially available radiolabeled colloid used in intra-operative lymphatic mapping. The analysis evaluated the performance of Lymphoseek to a meta-analysis of published data for 99m-Tc-labeled nanocolloid human serum albumin (Nanocoll[®]), commercially available and considered the standard of care in Europe. The difference between Lymphoseek and Nanocoll in the parameters analyzed was statistically significant. (p < 0.0001) The study, *“The efficacy of Tilmanocept in sentinel lymph node mapping and identification in breast cancer patients: a comparative review and meta-analysis of the 99m-Tc-labeled nanocolloid human serum albumin standard of care,”* can found in the current online edition of the peer-reviewed journal *Clinical and Experimental Metastasis* [DOI 10.1007/s10585-012-9497-x].

"Navidea's 2012 accomplishments demonstrate our great momentum as we continue our progress to achieve the Company's clinical and regulatory objectives," said Dr. Pykett. "As evidenced in the licensing of our second neuroimaging agent, CFT, we expect to continue efforts to grow the company through robust drug development, global partnering and commercialization efforts, and select licenses and acquisitions. We look forward to commencing additional Phase 2 studies of AZD4694 during 2012 and to beginning Phase 3 clinical studies for this agent in early 2013. As we look toward the remainder of 2012 and beyond, we will continue our efforts to deliver superior growth and shareholder return by bringing novel radiopharmaceuticals through development and registration – and ultimately, to market."

Conference Call Details

Navidea's President and CEO, Dr. Mark Pykett, Executive Vice President and Chief Business Officer, Dr. Thomas Tulip, Senior Vice President, Pharmaceutical Research and Clinical Development, Dr. Fred Cope and Senior Vice President and CFO, Brent Larson, will provide a development and business update and will discuss the Company's financial results for the second quarter and first six months of 2012 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, 2012	Available until:	August 21, 2012
Time:	8:00 AM EDT	Toll-free (U.S.) Dial in # :	(877) 660-6853
		International Dial in # :	(201) 612-7415
Toll-free (U.S.) Dial in # :	(877) 407-8033		
International Dial in # :	(201) 689-8033	Replay passcode:	
		Account #	286
		Conference ID #:	398463

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About Navidea Biopharmaceuticals

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®, AZD4694, E-IACFT, and RIGScan™ – to help identify the presence and status 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.

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:

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

- Financial Tables to follow -

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CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2012 (unaudited)	December 31, 2011
Assets:		
Cash	\$ 16,952,671	\$ 28,644,004
Other current assets	1,741,251	1,402,517
Non-current assets	<u>1,320,641</u>	<u>1,147,399</u>
Total assets	<u>\$ 20,014,563</u>	<u>\$ 31,193,920</u>
Liabilities and stockholders' equity:		
Note payable, net of discount, current	\$ 2,341,151	\$ -
Derivative liabilities, current	793,418	568,930
Other current liabilities	2,466,449	2,779,540
Note payable, net of discount	4,232,391	6,456,388
Other liabilities	252,247	257,315
Stockholders' equity	<u>9,928,907</u>	<u>21,131,747</u>
Total liabilities and stockholders' equity	<u>\$ 20,014,563</u>	<u>\$ 31,193,920</u>

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Six Months Ended	
	June 30, 2012 (unaudited)	June 30, 2011 (unaudited)	June 30, 2012 (unaudited)	June 30, 2011 (unaudited)
Revenue	\$ 60,000	\$ 6,135	\$ 71,931	\$ 342,097
Operating expenses:				
Research and development	2,476,113	1,866,252	6,419,827	4,301,851
Selling, general and administrative	2,970,837	1,727,145	5,545,467	4,628,853
Total operating expenses	<u>5,446,950</u>	<u>3,593,397</u>	<u>11,965,294</u>	<u>8,930,704</u>
Loss from operations	<u>(5,386,950)</u>	<u>(3,587,262)</u>	<u>(11,893,363)</u>	<u>(8,588,607)</u>
Interest expense	(321,405)	(1,058)	(615,076)	(2,665)
Change in derivative liabilities	(92,805)	(10,352)	(276,889)	(964,141)
Other income (expense), net	<u>(33,662)</u>	<u>2,598</u>	<u>(38,566)</u>	<u>5,406</u>
Loss before income taxes	(5,834,822)	(3,596,074)	(12,823,894)	(9,550,007)
Benefit from income tax	<u>-</u>	<u>478,444</u>	<u>-</u>	<u>999,257</u>
Loss from continuing operations	(5,834,822)	(3,117,630)	(12,823,894)	(8,550,750)
Discontinued operations, net of tax effect	<u>-</u>	<u>928,740</u>	<u>-</u>	<u>1,939,731</u>
Net loss	(5,834,822)	(2,188,890)	(12,823,894)	(6,611,019)
Preferred stock dividends	<u>(25,000)</u>	<u>(25,000)</u>	<u>(50,000)</u>	<u>(50,000)</u>
Loss attributable to common stockholders	<u>\$ (5,859,822)</u>	<u>\$ (2,213,890)</u>	<u>\$ (12,873,894)</u>	<u>\$ (6,661,019)</u>
Loss per common share (basic and diluted):				
Continuing operations	\$ (0.06)	\$ (0.03)	\$ (0.14)	\$ (0.10)
Discontinued operations	\$ -	\$ 0.01	\$ -	\$ 0.02
Attributable to common stockholders	\$ (0.06)	\$ (0.02)	\$ (0.14)	\$ (0.08)
Weighted average shares outstanding:				
Basic and diluted	94,664,659	89,660,089	94,368,690	87,549,776

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