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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) May 9, 2017

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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>5600 Blazer Parkway, Suite 200, Dublin, Ohio</u> (Address of principal executive offices)		<u>43017</u> (Zip Code)

Registrant's telephone number, including area code (614) 793-7500

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(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))
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**Item 2.02 Results of Operations and Financial Condition.**

On May 9, 2017, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release regarding its consolidated financial results for the quarter ended March 31, 2017. A copy of the Company’s May 9, 2017 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*

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99.1 [Press Release dated May 9, 2017.](#)

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## 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: May 9, 2017

By: /s/ Jed A. Latkin  
Jed A. Latkin, Chief Operating Officer and  
Chief Financial Officer

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## Navidea Biopharmaceuticals Reports First Quarter 2017 Financial Results

*Conference call with investment community to be held tomorrow, May 10, 2017, at 8:00 a.m. ET*

DUBLIN, Ohio--(BUSINESS WIRE)—May 9, 2017-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) (“Navidea” or “the Company”), a company focused on the development and commercialization of precision immunodiagnostic agents, today announced its financial results for the first quarter of 2017. Navidea reported total revenue (excluding discontinued operations) for the quarter of \$580,000. Net income attributable to common stockholders was \$85.6 million.

“Navidea ended the first quarter with strong momentum built upon the strategic plan developed over the past two quarters. Our strategy is designed to maximize the value of our proprietary macrophage-targeting technology by developing and out-licensing promising imaging and therapeutic products,” said Michael Goldberg, M.D., Navidea’s President and CEO. Dr. Goldberg continued, “Our completed sale of the North American rights to Lymphoseek® to Cardinal Health 414, LLC ensures that our focus remains on product development going forward. We are confident that our Manocept platform, properly developed, will yield both diagnostics and therapeutics that can generate significant value for our stockholders.”

### Product, Pipeline, and Business Updates

#### *Lymphoseek®*

- On March 3, 2017, Navidea completed the sale of the North American rights to Lymphoseek® to Cardinal Health 414, receiving approximately \$82 million at closing.
- Navidea will have the opportunity to earn up to \$227 million of additional consideration through 2026, with \$17.1 million guaranteed over the next three years.
- As a result of this closing, all liens on Navidea’s assets have been released, all frozen accounts have been transferred to Navidea’s control, and the majority of the loan from Platinum Partners has been repaid.

#### *Manocept Immunodiagnostic Pipeline*

The flexible and versatile Manocept platform acts as an engine for the design of targeted imaging molecules applicable to a range of diagnostic modalities, including single photon emission computed tomography (“SPECT”), positron emission tomography (“PET”), gamma-scanning (both imaging and topical) and intra-operative and/or optical-fluorescence detection. We have active clinical diagnostic programs in cardiovascular disease, rheumatoid arthritis, Kaposi’s sarcoma and colorectal cancer, diseases representing both major macrophage activation states.

Cardiovascular Disease – The results of a study to evaluate diagnostic imaging of emerging atherosclerosis plaque with Tc 99m tilmanocept were published in early release in the *Journal of Infectious Diseases* on January 16, 2017, confirming that the Tc 99m tilmanocept product can both quantitatively and qualitatively target non-calcified plaque in the aortic arch.

Colorectal Cancer and Synchronous Liver Metastases – During the first quarter of 2017, we initiated an imaging study in subjects with colorectal cancer and liver metastases via intravenous administration of Tc 99m tilmanocept.

#### *Manocept Immunotherapeutic Development Pipeline (Macrophage Therapeutics)*

Navidea’s majority-owned subsidiary, Macrophage Therapeutics, Inc. (“MT”), has developed processes for producing the first two therapeutic Manocept immunoconstructs consisting of a therapeutic molecule conjugated to moieties targeting CD206+ macrophages:

1. MT-1002, designed to specifically target and kill activated CD206+ macrophages by delivering doxorubicin; and
2. MT-2002, designed to inhibit the inflammatory activity of activated CD206+ macrophages by delivering a potent anti-inflammatory agent.

In the first quarter of 2017, MT completed its third vivo study dosing either MT-1002 or MT-2002 in a well-established mouse model of nonalcoholic fatty liver disease/nonalcoholic steatohepatitis and liver fibrosis, in which both compounds significantly reduced key disease parameters.

Also in the first quarter of 2017, we completed a series of predictive in vitro screening tests of the MT-1002 and MT-2002 therapeutic conjugates against the Zika and Dengue viruses and against Leishmaniosis. These evaluations were positive and MT will begin in vivo testing in the second or third quarter of 2017.

### Financials

Our consolidated balance sheets and statements of operations have been reclassified, as required by current accounting standards, for all periods presented to reflect the line of business sold to Cardinal Health 414 as a discontinued operation. Accordingly, this discussion focuses on describing results of our operations as if we had not operated the discontinued operation during the periods being disclosed.

We recorded a net gain on the sale to Cardinal Health 414 of \$88.7 million for the first quarter of 2017, including \$16.5 in guaranteed consideration, which was discounted to the present value of future cash flows. The proceeds were offset by \$3.3 million in estimated fair value of warrants issued to Cardinal Health 414, \$2.0 million in legal and other fees related to the sale, \$800,000 in net balance sheet dispositions and write-offs, and \$4.6 million in estimated taxes.

Total revenues for the quarter ended March 31, 2017 were \$580,000 compared to \$948,000 in the first quarter of last year. Total operating expenses for the first quarter of 2017 were \$3.7 million, compared to \$4.7 million in the first quarter of last year. Research and development expenses for the first quarter of 2017 were \$705,000, compared to \$2.1 million in the first quarter of last year. The net decrease from 2016 to 2017 was primarily a result of decreases in NAV4694, Tc 99m tilmanocept and NAV5001 development costs, offset by increases in Manocept and therapeutics development costs, coupled with decreased compensation and related support costs. Selling, general, and administrative expenses for the first quarter of 2017 were \$3.0 million, compared to \$2.6 million in the first quarter of last year. The net increase was primarily due to increased legal and professional services, offset by decreased investor relations services, compensation and related support costs.

Navidea’s net income attributable to common stockholders for the quarter ended March 31, 2017 was \$85.6 million, or \$0.53 per share (basic), compared to a net loss of \$3.7 million, or \$0.02 per share, for the same period in 2016.

Navidea ended the quarter with \$13.4 million in cash.



## Conference Call Details

Investors and the public are invited to access the live audio webcast through the link below. Participants who would like to ask questions during the question and answer session must participate by telephone also. Participants are encouraged to log-in and/or dial-in fifteen minutes before the conference call begins. The webcast replay is expected to be available on our investor website, <http://ir.navidea.com>, approximately two to four hours after the live event.

**Event:** Navidea Q1 2017 Financial Results Conference Call

**Date/Time:** Wednesday, May 10, 2017 at 8:00 a.m. ET

**Webcast Link:** <http://edge.media-server.com/m/p/zjm948a2/lan/en>

**Dial-In Number (US):** (855) 897-5884

**Dial-In Number (International):** (720) 634-2940

**Conference ID:** 20720582

**Replay:** A webcast replay will be available on the Investor Relations section of our website at <http://ir.navidea.com> following the event

## About

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products based on its Manocept™ platform to enhance patient care by identifying the sites and pathways of disease and enable better diagnostic accuracy, clinical decision-making, and targeted treatment. Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Tc 99m tilmanocept, the first product developed and commercialized by Navidea based on the platform. The development activities of the Manocept immunotherapeutic platform are being conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics, Inc. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel products and advancing the Company's pipeline through global partnering and commercialization efforts. For more information, please visit [www.navidea.com](http://www.navidea.com).

## Financial Tables

*Condensed Consolidated Balance Sheets*

*Condensed Consolidated Statements of Operations*

## Contact

Navidea Biopharmaceuticals  
Jed Latkin (investors & media)  
Chief Operating Officer & Chief Financial Officer  
[jlatkin@navidea.com](mailto:jlatkin@navidea.com)

or

Edison Advisors  
Tirth Patel (investors)  
[tpatel@edisongroup.com](mailto:tpatel@edisongroup.com)

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**NAVIDEA BIOPHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

	March 31, 2017 (unaudited)	December 31, 2016
Assets:		
Cash	\$ 13,440,618	\$ 1,539,325
Restricted cash	-	5,001,253
Other current assets	8,258,377	1,141,444
Assets associated with discontinued operations, current	-	3,144,247
Guaranteed earnout receivable	9,437,599	-
Other non-current assets	1,788,993	1,530,152
Assets associated with discontinued operations	-	105,255
Total assets	<u>\$ 32,925,587</u>	<u>\$ 12,356,421</u>
Liabilities and stockholders' equity (deficit):		
Notes payable, current, net of discount	\$ 2,103,000	\$ 51,957,913
Other current liabilities	4,319,104	13,038,278
Liabilities associated with discontinued operations, current	3,554,320	4,865,597
Notes payable	-	9,641,179
Other liabilities	583,849	624,922
Total liabilities	<u>10,560,273</u>	<u>80,127,889</u>
Navidea stockholders' equity (deficit)	21,696,606	(68,135,123)
Noncontrolling interest	668,708	468,910
Total stockholders' equity (deficit)	<u>22,365,314</u>	<u>(67,666,213)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 32,925,587</u>	<u>\$ 12,461,676</u>

**NAVIDEA BIOPHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended	
	March 31, 2017 (unaudited)	March 31, 2016 (unaudited)
Revenue:		
Te 99m tilmanocept sales and license revenue	\$ -	\$ 262,850
Grant and other revenue	580,030	685,635
Total revenue	<u>580,030</u>	<u>948,485</u>
Cost of goods sold	-	1,489
Gross profit	<u>580,030</u>	<u>946,996</u>
Operating expenses:		
Research and development	705,274	2,072,271
Selling, general and administrative	3,022,434	2,633,126
Total operating expenses	<u>3,727,708</u>	<u>4,705,397</u>
Loss from operations	<u>(3,147,678)</u>	<u>(3,758,401)</u>
Other (expense) income:		
Interest income, net	24,112	757
Equity in the loss of joint venture	-	(12,239)
Change in fair value of financial instruments	140,485	1,125,359
Loss on extinguishment of debt	(1,314,102)	-
Other, net	(21,604)	(37,292)
Loss before income taxes	<u>(4,318,787)</u>	<u>(2,681,816)</u>
Benefit from income taxes	1,454,172	-
Loss from continuing operations	<u>(2,864,615)</u>	<u>(2,681,816)</u>
Discontinued operations, net of tax effect:		
Loss from operations	(255,861)	(1,004,433)
Gain on sale	88,701,501	-
Net income (loss)	<u>85,581,025</u>	<u>(3,686,249)</u>
Less loss attributable to noncontrolling interest	(202)	(241)
Net income (loss) attributable to common stockholders	<u>\$ 85,581,227</u>	<u>\$ (3,686,008)</u>
Income (loss) per common share (basic):		
Continuing operations	\$ (0.02)	\$ (0.02)
Discontinued operations	\$ 0.55	\$ 0.00
Attributable to common stockholders	\$ 0.53	\$ (0.02)
Weighted average shares outstanding (basic)	160,376,476	155,308,094
Income (loss) per common share (diluted):		
Continuing operations	\$ (0.02)	\$ (0.02)
Discontinued operations	\$ 0.54	\$ 0.00
Attributable to common stockholders	\$ 0.52	\$ (0.02)
Weighted average shares outstanding (diluted)	164,871,955	155,308,094