

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 8, 2018

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>4995 Bradenton Avenue, Suite 240, 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 8, 2018, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release regarding its consolidated financial results for the quarter ended March 31, 2018. A copy of the Company’s May 8, 2018 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 [Press Release dated May 8, 2018.](#)

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 8, 2018

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

Navidea Biopharmaceuticals Reports First Quarter 2018 Financial Results*Conference Call to be held Wednesday, May 9, 2018 at 8:30 am ET*

DUBLIN, Ohio--(BUSINESS WIRE)--Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) (“Navidea” or the “Company”), a company focused on the development of precision immunodiagnostic agents and immunotherapeutics, today announced its financial results for the first quarter of 2018. Navidea reported total revenues for the quarter of \$276,000. Net loss attributable to common stockholders was \$6.7 million.

Michael Goldberg, M.D., President and Chief Executive Officer of Navidea, commented, “We were able to advance our core technology on multiple fronts and we experienced a year free from the severe financial constraints the company labored under for over a decade. Navidea had been pursuing a strategy to become a major player in the development and commercialization of precision medicine diagnostic products and took on too much debt to fund the development of in-licensed products and to develop the commercial infrastructure to market and sell its Lymphoseek product. We continue to also drive the process with the FDA and their agents to seek approval of CD206 as a qualified biomarker, thus advancing the use of Tc99m tilmanocept on a broad front for clinical trials. With our best-in-class activated macrophage targeting system, we have been able to generate significant human imaging data and promising animal data with our therapeutic agents, reinforcing our optimism that this platform holds potential for the diagnosis and treatment of diseases in which macrophages play an important role.”

First Quarter 2018 Highlights and Subsequent Events

- Entered an Amendment to the Asset Purchase Agreement with Cardinal Health 414, LLC (“Cardinal Health 414”) in April 2018, pursuant to which Cardinal Health 414 paid the Company approximately \$6.0 million and agreed to pay the Company an amount equal to the unused portion of the letter of credit (not to exceed approximately \$7.1 million) promptly after the earlier of (i) the expiration of the letter of credit and (ii) the receipt by Cardinal Health 414 of evidence of the return and cancellation of the letter of credit. In exchange, the obligation of Cardinal Health 414 to make any further contingent payments has been eliminated. Cardinal Health 414 is still obligated to make the milestone payments in accordance with the terms of the earnout provisions of the Purchase Agreement.
 - Presented strong preclinical results in Navidea’s nonalcoholic steatohepatitis (“NASH”) research at the 2nd Annual NASH Summit in April
 - Signed exclusive license with Meilleur Technologies, Inc. a wholly-owned subsidiary of Cerveau Technologies, Inc. to conduct research using NAV4694, as well as an exclusive license for the development and commercialization of NAV4694 in Australia, Canada, China, and Singapore
 - Completed two clinical imaging studies of intravenous (“IV”)-administered Tc99m tilmanocept in subjects with rheumatoid arthritis and results will be included in a package to be submitted to the U.S. Food and Drug Administration (“FDA”) regarding a Phase 3 clinical plan
 - Continued enrollment in IV-administered Tc99m tilmanocept trial in NASH. Enrollment is anticipated to complete by the end of this year.
 - Continued enrollment in 27-patient Phase 2 cardiovascular clinical study
 - Completed a preclinical plan for Kaposi’s Sarcoma to be reviewed by the FDA
 - Initiated a pilot study for imaging Crohn’s Disease with IV-administered Tc99m tilmanocept and evaluation of archival biopsies of Crohn’s patients for CD206 biomarker analysis
 - Continued series of regular investor-focused Q&A conference calls to improve Investor Relations strategy
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Financial Results

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.

- Total revenues for the first quarter of 2018 were \$276,000, compared to \$580,000 in the first quarter of 2017. These revenues were primarily grant-related in both periods.
 - Research and development expenses for the first quarter of 2018 were \$999,000, compared to \$705,000 in the first quarter of 2017. The net increase was primarily a result of increased NAV4694 development costs due to the 2017 reversal of previously accrued expenses, offset by decreased Tc99m tilmanocept, Manocept, and therapeutics development costs coupled with decreased net compensation costs.
 - Selling, general and administrative expenses for the first quarter of 2018 were \$1.8 million, compared to \$3.0 million in the first quarter of 2017. The net decrease was primarily due to decreases in legal and professional services, general office expenses such as insurance, depreciation, rent and travel, and investor relations services.
 - Navidea's net loss attributable to common stockholders for the quarter ended March 31, 2018 was \$6.7 million, or \$0.04 per share (basic), compared to net income attributable to common stockholders of \$85.6 million, or \$0.53 per share, for the same period in 2017.
 - Navidea ended the quarter with \$2.2 million in cash and investments, not including the accelerated earnout payment of \$6.0 million from Cardinal Health 414 which was received after the quarter ended.
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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. Participants are encouraged to log-in and/or dial-in fifteen minutes before the conference call begins.

Event: Q1 2018 Earnings and Business Update Conference Call
Date: Wednesday, May 9, 2018
Time: 8:30 am (Eastern Time)
U.S. & Canada Dial-in: 1-929-477-0448
Conference ID: 9493945
Webcast <http://www.audio-webcast.com/cgi-bin/visitors.ssp?fn=visitor&id=5603>

A live audio webcast of the conference call will also be available on the investor relations page of Navidea's corporate website at www.navidea.com. In addition, the recorded conference call can be replayed and will be available for 90 days following the call on Navidea's website.

About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) is a biopharmaceutical company focused on the development 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.

Contacts

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Forward-Looking Statements

This release and any oral statements made with respect to the information contained in this release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: general economic and business conditions, both nationally and in our markets; our history of losses and uncertainty of future profitability; the final outcome of the CRG litigation in Texas; our ability to successfully complete research and further development of our drug candidates; the timing, cost and uncertainty of obtaining regulatory approvals of our drug candidates; our ability to successfully commercialize our drug candidates; our expectations and estimates concerning future financial performance, financing plans and the impact of competition; our ability to raise capital sufficient to fund our development and commercialization programs; our ability to implement our growth strategy; anticipated trends in our business; advances in technologies; and other risk factors set forth in this report and detailed in our most recent Annual Report on Form 10-K and other SEC filings. You are urged to carefully review and consider the disclosures found in our SEC filings, which are available at www.sec.gov or at <http://ir.navidea.com>.

Investors are urged to consider statements that include the words “will,” “may,” “could,” “should,” “plan,” “continue,” “designed,” “goal,” “forecast,” “future,” “believe,” “intend,” “expect,” “anticipate,” “estimate,” “project,” and similar expressions, as well as the negatives of those words or other comparable words, to be uncertain forward-looking statements. You are cautioned not to place undue reliance on any forward-looking statements, any of which could turn out to be incorrect. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this report. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2018 (unaudited)	December 31, 2017
Assets:		
Cash and securities	\$ 2,214,444	\$ 4,592,610
Accounts and other receivables	12,954,997	8,137,872
Other current assets	1,058,069	1,101,923
Guaranteed earnout receivable	-	4,809,376
Other non-current assets	2,094,717	2,139,655
Total assets	\$ 18,322,227	\$ 20,781,436
Liabilities and stockholders' equity:		
Notes payable, current	\$ 2,276,926	\$ 2,353,639
Accrued loss for CRG litigation	7,153,000	2,887,566
Other current liabilities	2,604,981	2,827,198
Deferred revenue	700,000	11,024
Other liabilities	637,963	653,679
Total liabilities	13,372,870	8,733,106
Navidea stockholders' equity	4,280,666	11,379,630
Noncontrolling interest	668,691	668,700
Total stockholders' equity	4,949,357	12,048,330
Total liabilities and stockholders' equity	\$ 18,322,227	\$ 20,781,436

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended	
	March 31, 2018 (unaudited)	March 31, 2017 (unaudited)
Revenue:		
Tc99m tilmanocept sales, license and royalty revenue	\$ 795	\$ -
Grant and other revenue	275,650	580,030
Total revenue	<u>276,445</u>	<u>580,030</u>
Cost of goods sold	318	-
Gross profit	<u>276,127</u>	<u>580,030</u>
Operating expenses:		
Research and development	998,956	705,274
Selling, general and administrative	1,776,372	3,022,434
Total operating expenses	<u>2,775,328</u>	<u>3,727,708</u>
Loss from operations	<u>(2,499,201)</u>	<u>(3,147,678)</u>
Other income (expense):		
Interest income, net	31,387	24,112
Change in fair value of financial instruments	-	140,485
Loss on extinguishment of debt	(4,265,434)	(1,314,102)
Other, net	(4,714)	(21,604)
Loss before income taxes	<u>(6,737,962)</u>	<u>(4,318,787)</u>
Benefit from income taxes	-	1,454,172
Loss from continuing operations	<u>(6,737,962)</u>	<u>(2,864,615)</u>
Discontinued operations, net of tax effect:		
Loss from operations	-	(255,861)
Gain on sale	-	88,701,501
Net (loss) income	<u>(6,737,962)</u>	<u>85,581,025</u>
Less loss attributable to noncontrolling interest	(9)	(202)
Net (loss) income attributable to common stockholders	<u>\$ (6,737,953)</u>	<u>\$ 85,581,227</u>
(Loss) income per common share (basic):		
Continuing operations	\$ (0.04)	\$ (0.02)
Discontinued operations	\$ -	\$ 0.56
Attributable to common stockholders	\$ (0.04)	\$ 0.53
Weighted average shares outstanding (basic)	162,269,012	160,376,476
(Loss) income per common share (diluted):		
Continuing operations	\$ (0.04)	\$ (0.02)
Discontinued operations	\$ -	\$ 0.55
Attributable to common stockholders	\$ (0.04)	\$ 0.52
Weighted average shares outstanding (diluted)	162,269,012	164,871,955