

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 5, 2018

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.)

4995 Bradenton Avenue, Suite 240, 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))

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 March 8, 2018, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release regarding its consolidated financial results for the fourth quarter and full year ended December 31, 2017. A copy of the Company’s March 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

Effective March 5, 2018, the Company appointed Dr. Claudine Bruck as a director, effective immediately. Dr. Bruck was appointed to fill a vacancy on the Board of Directors in the class with terms expiring at the annual meeting of stockholders to be held in 2018. Dr. Bruck was not appointed to serve on a committee of the Board, although she may be appointed to a committee at a later date.

Similar to other non-employee directors, Dr. Bruck will receive compensation for her service as director in accordance with the Company’s non-employee director compensation program.

There is no arrangement or understanding between Dr. Bruck and any other person pursuant to which she was selected as a director of the Company and there are no family relationships between Dr. Bruck and any of the Company’s directors or executive officers. There are no transactions to which the Company is a party and in which Dr. Bruck has a direct or indirect material interest that would be required to be disclosed under Item 404(a) of Regulation S-K.

In connection with her appointment, Dr. Bruck entered into a standard Director Agreement with the Company, a form of which was previously filed by the Company with the U.S. Securities and Exchange Commission on May 10, 2016, and which is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	<u>Press Release, dated March 8, 2018.</u>

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 8, 2018

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

Navidea Biopharmaceuticals Reports Fourth Quarter and Full Year 2017 Financial Results

Conference Call to be held Thursday, March 8, 2018 at 4:30 p.m. 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 fourth quarter of 2017. Navidea reported total revenues for the quarter of \$395,000. Net loss attributable to common stockholders for the quarter was \$4.1 million. Total revenues for 2017 were \$1.8 million, and net income attributable to common stockholders was \$74.9 million.

“It’s been quite a transition year for Navidea going from a commercial operation, with its own dedicated sales force, to a development-focused company leveraging its best-in-class activated macrophage targeting system,” said Michael Goldberg, M.D., Navidea’s President and Chief Executive Officer.

Dr. Goldberg continued, “I am more excited today than I have ever been as we push forward on the three key pillars of our business; CD206 biomarker identification, diagnostic imaging and therapeutics. I expect that the coming year will be characterized by the release of data that confirms our strategy that focusing on the targeting of activated macrophages with our proprietary imaging agents in humans and our proprietary therapeutics in animals has the potential to generate significant commercial opportunities for Navidea in the short term.”

Fourth Quarter 2017 Highlights and Subsequent Events

- Selected as 1 of 25 from 1100 applicants to present a late-breaking poster at the American College of Rheumatology Annual Meeting detailing the results of an intravenous (“IV”)-administered study in rheumatoid arthritis (“RA”) patients;
 - Completed the Phase 2 IV RA study;
 - Commenced dosing and imaging in the 12-subject nonalcoholic steatohepatitis (“NASH”) diagnostic study at Kettering Medical Center in Ohio;
 - Commenced dosing and imaging in the 24-subject visceral Kaposi’s Sarcoma (“KS”) diagnostic study at the University of California, San Francisco;
 - Commenced dosing and imaging in the 24-subject HIV+ Cardiovascular trial at Massachusetts General Hospital-Harvard University under the direction of Dr. Steven Grinspoon;
 - Commenced dosing and imaging in the 12-subject colorectal cancer trial with synchronous liver metastases at the University of Alabama at Birmingham;
 - Submitted an extensive grant to support broad expansion of both Navidea’s and the Massachusetts General Hospital’s work in Cardiovascular imaging;
 - The National Cancer Institute awarded Navidea a Fast Track Small Business Innovation Research (“SBIR”) grant that will provide up to \$1.8 million to fund preclinical and subsequent clinical studies examining the safety and efficacy of IV Tc 99m tilmanocept to identify and quantify both skin- and organ-associated KS lesions;
 - Completed regulatory strategies for imaging and inflammation for Phase 3 trials (pending meeting with the U.S. Food & Drug Administration); and
 - Appointed Claudine Bruck, Ph.D. as a member of the board of directors of the Company effective March 5, 2018.
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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, LLC (“Cardinal Health 414”) on March 3, 2017 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 \$89.2 million net gain on the line of business sold to Cardinal Health 414 for the year ended December 31, 2017, including \$16.5 million 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 \$4.1 million in estimated taxes.
 - Total revenues for the fourth quarter of 2017 were \$395,000, compared to \$1.0 million in the fourth quarter of 2016. Revenues for the full year of 2017 were \$1.8 million, compared to \$5.0 million in 2016. Revenues were primarily related to grants and licenses, and do not include the guaranteed earnout payments received from Cardinal Health 414 during 2017.
 - Research and development (“R&D”) expenses for the fourth quarter of 2017 were \$1.7 million, compared to \$2.1 million in the fourth quarter of 2016. R&D expenses for the full year of 2017 were \$4.5 million, compared to \$7.1 million in 2016. The net decrease was primarily a result of decreases in Tc99m tilmanocept, NAV4694 and NAV5001 development costs coupled with decreased net compensation costs, offset by increases in Manocept platform development costs.
 - Selling, general and administrative (“SG&A”) expenses for the fourth quarter of 2017 were \$2.2 million, compared to \$2.1 million in the fourth quarter of 2016. SG&A expenses for the full year of 2017 were \$11.2 million, compared to \$7.9 million in 2016. The net increase was primarily due to several non-recurring charges, including a \$2.0 increase in legal expenses due to CRG and other concluded legal matters, \$949,000 of other items including the FTI settlement, the Cardinal deal completion bonuses, severance payouts and asset disposal costs.
 - Navidea’s net loss attributable to common stockholders for the quarter ended December 31, 2017 was \$4.1 million, or \$0.03 per share (basic), compared to a net loss of \$3.9 million, or \$0.02 per share (basic), for the same period in 2016. Navidea’s net income attributable to common stockholders for the year ended December 31, 2017 was \$74.9 million, or \$0.47 per share (basic), compared to a net loss of \$14.3 million, or \$0.09 per share (basic), for the same period in 2016.
 - Navidea ended the quarter with \$4.6 million in cash and investments.
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Full Year 2017 Highlights and Subsequent Events

- 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;
- Presented two papers at the Society of Nuclear Medicine and Molecular Imaging Annual Meeting detailing initial results from the SC-administered study in RA;
- Initiated Biomarker Qualification with FDA biomarker division;
- Selected by NIH/NIAMS as one of 24 from 1200 awardees to present business development and RA clinical results at the International Biotechnology Innovation Organization 2017 meeting in June, 2017;
- Initiated series of regular investor-focused Q&A conference calls to strengthen investor relations;
- Presented a late-breaking poster presented at the American College of Rheumatology Annual Meeting detailing the results of an IV-administered study in RA patients;
- Transferred three clinical trials in sentinel node biopsy to Cardinal Health 414, including cervical, anal/rectal and pediatric trials;
- Completed filings or disclosures on multiple new intellectual property constructs and usages; and
- Completed preclinical testing of therapeutic constructs in Zika, Dengue, leishmaniosis, KS, tumor models and NASH model systems.

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:	Q4 and Full Year 2017 Earnings and Business Update Conference Call
Date:	Thursday, March 8, 2018
Time:	4:30 p.m. (Eastern Time)
U.S. & Canada Dial-in:	646-828-8143 (toll free)
Conference ID:	1826783

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.

NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2017 (unaudited)	December 31, 2016
Assets:		
Cash and securities	\$ 4,592,610	\$ 1,539,325
Restricted cash	-	5,001,253
Accounts and other receivables	8,137,872	203,016
Other current assets	1,101,923	938,428
Assets associated with discontinued operations, current	-	3,144,247
Guaranteed earnout receivable	4,809,376	-
Other assets	2,139,655	1,530,152
Assets associated with discontinued operations	-	105,255
Total assets	<u>\$ 20,781,436</u>	<u>\$ 12,461,676</u>
Liabilities and stockholders' equity (deficit):		
Notes payable, current	\$ 2,353,639	\$ 51,957,913
Other current liabilities	5,707,672	13,038,278
Liabilities associated with discontinued operations, current	7,092	4,865,597
Notes payable	-	9,641,179
Other liabilities	664,703	624,922
Total liabilities	<u>8,733,106</u>	<u>80,127,889</u>
Navidea stockholders' equity (deficit)	11,379,630	(68,135,123)
Noncontrolling interest	668,700	468,910
Total stockholders' equity (deficit)	<u>12,048,330</u>	<u>(67,666,213)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 20,781,436</u>	<u>\$ 12,461,676</u>

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Twelve Months Ended	
	December 31,	December 31,	December 31,	December 31,
	2017	2016	2017	2016
	(unaudited)	(unaudited)	(unaudited)	
Revenue:				
Tc99m tilmanocept sales, license and royalty revenue	\$ 9,126	\$ 8,801	\$ 109,126	\$ 1,835,226
Grant and other revenue	386,013	1,022,988	1,701,311	3,136,408
Total revenue	395,139	1,031,789	1,810,437	4,971,634
Cost of good sold	3,651	57,075	3,651	62,260
Gross profit	391,488	974,714	1,806,786	4,909,374
Operating expenses:				
Research and development	1,748,147	2,127,157	4,513,842	7,138,080
Selling, general and administrative	2,163,226	2,087,413	11,169,951	7,920,036
Total operating expenses	3,911,373	4,214,570	15,683,793	15,058,116
Loss from operations	(3,519,885)	(3,239,856)	(13,877,007)	(10,148,742)
Other income (expense):				
Interest income (expense), net	24,160	(2,790)	168,971	(4,866)
Equity in the loss of joint venture	-	-	-	(15,159)
Loss on disposal of joint venture	-	-	-	(39,732)
Change in fair value of financial instruments	-	1,102,535	153,357	2,858,524
Loss on extinguishment of debt	(2,887,566)	-	(4,201,668)	-
Other, net	11,917	21,997	(33,339)	(27,919)
Loss before income taxes	(6,371,374)	(2,118,114)	(17,789,686)	(7,377,894)
Benefit from income taxes	201,333	-	4,062,489	-
Loss from continuing operations	(6,170,041)	(2,118,114)	(13,727,197)	(7,377,894)
Discontinued operations, net of tax effect:				
Loss from discontinued operations	(157,920)	(1,763,825)	(490,758)	(6,931,137)
Gain on sale	2,269,811	-	89,163,811	-
Net income (loss)	(4,058,150)	(3,881,939)	74,945,856	(14,309,031)
Less loss attributable to noncontrolling interest	(18)	(132)	(210)	(648)
Net income (loss) attributable to common stockholders	\$ (4,058,132)	\$ (3,881,807)	\$ 74,946,066	\$ (14,308,383)
Income (loss) per common share (basic):				
Continuing operations	\$ (0.04)	\$ (0.01)	\$ (0.08)	\$ (0.05)
Discontinued operations	\$ 0.01	\$ (0.01)	\$ 0.55	\$ (0.04)
Attributable to common stockholders	\$ (0.03)	\$ (0.02)	\$ 0.47	\$ (0.09)
Weighted average shares outstanding (basic)	162,053,385	155,516,120	161,592,569	155,422,384
Income (loss) per common share (diluted):				
Continuing operations	\$ (0.04)	\$ (0.01)	\$ (0.08)	\$ (0.05)
Discontinued operations	\$ 0.01	\$ (0.01)	\$ 0.53	\$ (0.04)
Attributable to common stockholders	\$ (0.03)	\$ (0.02)	\$ 0.45	\$ (0.09)
Weighted average shares outstanding (diluted)	166,465,741	155,516,120	166,016,458	155,422,384

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 include our expectations regarding future diagnostic and therapeutic results; 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; and anticipated trends in 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; 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.