

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 8, 2017

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 August 8, 2017, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release regarding its consolidated financial results for the quarter ended June 30, 2017. A copy of the Company’s August 8, 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

99.1 Press Release dated August 8, 2017.

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 8, 2017

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

Navidea Biopharmaceuticals Reports Second Quarter 2017 Financial Results

Conference call to be held Wednesday, August 9, 2017 at 8:00am ET

DUBLIN, Ohio – (BUSINESS WIRE)—Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) (Navidea or the Company), a company focused on the development of precision immunodiagnostic agents and immunotherapeutics, today announced its financial results for the second quarter of 2017. Navidea reported total revenues for the quarter of \$612,000. Net loss attributable to common stockholders was \$5.2 million. Net revenues do not include the guaranteed payments from Cardinal Health 414, LLC (Cardinal Health 414) because those are represented on the balance sheet in accounts receivable.

“2017 has been a transition year for Navidea from a commercial operation to a company focused on fully developing its best-in-class activated macrophage targeting system. With the cost savings and strengthened balance sheet enabled by this strategic reorientation, 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 great potential for the diagnosis and treatment of diseases in which macrophages play an important role,” said Michael Goldberg, M.D., Navidea’s President and Chief Executive Officer.

Dr. Goldberg continued, “On the diagnostic side, we have generated data with both intravenous (IV) and subcutaneous formulations of Tc 99m tilmanocept in rheumatoid arthritis (RA), and are very excited to be initiating dosing of an IV formulation next quarter in clinical trials in nonalcoholic steatohepatitis (NASH) and cardiovascular (CV) disease. We have also worked with outside experts to design the comprehensive plans required to pursue regulatory approval for the technology to image activated macrophages.”

Second Quarter 2017 Program Highlights and Subsequent Events

- Navidea continued enrollment in its 30-subject, multi-center phase 1/2 RA trial, initiated in February 2017. This study is evaluating the use of Tc-99m tilmanocept to diagnose RA and distinguish it from other types of inflammatory arthritis. Navidea plans to complete enrollment in the study in the fourth quarter of 2017.
 - Navidea continued enrolling subjects in an imaging study of Tc 99m tilmanocept in patients with colorectal cancer and liver metastases, also initiated in the first quarter of 2017. This study will enroll up to 12 subjects and Navidea anticipates reporting interim results by year-end.
 - MT-1002 and MT-2002 had positive results in a fourth study in a well-established mouse model of NAFLD/NASH and liver fibrosis, significantly reducing key disease assessment parameters in the *in vivo* STAMTM NASH model.
 - Navidea completed a series of predictive *in vitro* screening tests of MT-1002 and MT-2002 against the Zika and Dengue viruses, which examined infectivity and viral replication inhibition effectiveness, dose finding studies, and mechanism of action. The Company also successfully completed a series of predictive *in vivo* screening tests of MT-1002 and MT-2002 against Leishmaniasis.
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- Navidea received Institutional Review Board approval to initiate a phase 1/2 imaging study in to confirm the safety and effectiveness of IV- Tc 99m tilmanocept in patients with KS.
- On June 12, 2017, Navidea's European commercial partner, SpePharm AG, an affiliate of Norgine, B.V., launched LYMPHOSEEK® in Denmark, the Netherlands, and the United Kingdom,
- The National Cancer Institute awarded Navidea a Fast Track 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.

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.

- Navidea recorded a \$86.7 million net gain on the sale to Cardinal Health 414 for the six months ended June 30, 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 \$6.5 million in estimated taxes.
 - Total revenues were \$612,000, compared to \$1.2 million in the second quarter of 2016. These revenues are grant-related and do not include the \$1.67 million of payments from Cardinal Health 414
 - Research and development expenses for the second quarter of 2017 were \$1.2 million, compared to \$2.0 million in the second quarter of 2016. The net decrease was primarily a result of decreases in NAV4694, Tc 99m tilmanocept and NAV5001 development costs, offset by increases in Manocept development costs.
 - Selling, general and administrative expenses for the second quarter of 2017 were \$4.2 million, compared to \$1.4 million in the second quarter of 2016. Expenses for the quarter and the six months ended June 30, 2017 included several one-time charges totaling \$2.4 million.
 - Navidea's net loss attributable to common stockholders for the quarter ended June 30, 2017 was \$5.2 million, or \$0.03 per share (basic), compared to a net loss of \$6.7 million, or \$0.04 per share, for the same period in 2016.
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- Navidea ended the quarter with \$7.6 million in cash and investments, not including the quarterly guaranteed earnout payment of \$1.67 million from Cardinal Health 414 which was received after the quarter ended.
- On June 20, 2017, Navidea entered into an exclusive license and distribution agreement with Sayre Therapeutics for the development and commercialization of Tc 99m tilmanocept in India.

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. 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 2Q 2017 Financial Results Conference Call

Date/Time: Wednesday, August 9, 2017 at 8:00am ET

Webcast Link: <http://www.audio-webcast.com/cgi-bin/visitors.ssp?fn=visitor&id=4905>

Dial-In Number (US/Canada): (866) 548-4713

Conference ID: 1954322

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

Navidea Biopharmaceuticals, Inc. (NYSE MKT: 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

Navidea Biopharmaceuticals

Jed Latkin, CFO/COO

(614) 551-3416

jlatkin@navidea.com

Edison Advisors

Tirth Patel

(646) 653-7035

tpatel@edisongroup.com

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.

NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2017 (unaudited)	December 31, 2016
Assets:		
Cash	\$ 5,634,102	\$ 1,539,325
Restricted cash	-	5,001,253
Available-for-sale securities	1,998,972	-
Other current assets	9,180,992	1,141,444
Assets associated with discontinued operations, current	-	3,144,247
Guaranteed earnout receivable	8,066,868	-
Other non-current assets	1,021,281	1,530,152
Assets associated with discontinued operations	-	105,255
Total assets	\$ 25,902,215	\$ 12,461,676
Liabilities and stockholders' equity (deficit):		
Notes payable, current, net of discount	\$ 1,997,640	\$ 51,957,913
Other current liabilities	5,842,188	13,038,278
Liabilities associated with discontinued operations, current	55,059	4,865,597
Notes payable	-	9,641,179
Other liabilities	665,917	624,922
Total liabilities	8,560,804	80,127,889
Navidea stockholders' equity (deficit)	16,672,670	(68,135,123)
Noncontrolling interest	668,741	468,910
Total stockholders' equity (deficit)	17,341,411	(67,666,213)
Total liabilities and stockholders' equity (deficit)	\$ 25,902,215	\$ 12,461,676

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Six Months Ended	
	June 30, 2017 (unaudited)	June 30, 2016 (unaudited)	June 30, 2017 (unaudited)	June 30, 2016 (unaudited)
Revenue:				
Tc 99m tilmancept sales and license revenue	\$ 100,000	\$ 250,349	\$ 100,000	\$ 513,199
Grant and other revenue	511,599	916,811	1,091,629	1,602,446
Total revenue	611,599	1,167,160	1,191,629	2,115,645
Cost of goods sold	-	807	-	2,296
Gross profit	611,599	1,166,353	1,191,629	2,113,349
Operating expenses:				
Research and development	1,185,874	2,019,211	1,891,148	4,091,482
Selling, general and administrative	4,249,584	1,387,817	7,272,018	4,020,943
Total operating expenses	5,435,458	3,407,028	9,163,166	8,112,425
Loss from operations	(4,823,859)	(2,240,675)	(7,971,537)	(5,999,076)
Interest income (expense), net	44,649	(2,992)	68,761	(2,235)
Equity in the loss of joint venture	-	(2,920)	-	(15,159)
Loss on disposal of joint venture	-	(39,732)	-	(39,732)
Change in fair value of financial instruments	12,872	1,469,928	153,357	2,595,287
Loss on extinguishment of debt	-	-	(1,314,102)	-
Other, net	(16,673)	(126)	(38,277)	(37,418)
Loss before income taxes	(4,783,011)	(816,517)	(9,101,798)	(3,498,333)
Benefit from income taxes	1,631,234	-	3,085,406	-
Loss from continuing operations	(3,151,777)	(816,517)	(6,016,392)	(3,498,333)
Discontinued operations, net of tax effect:				
Loss from operations	(82,376)	(5,864,790)	(338,237)	(6,869,223)
Gain (loss) on sale	(1,953,378)	-	86,748,123	-
Net income (loss)	(5,187,531)	(6,681,307)	80,393,494	(10,367,556)
Less loss attributable to noncontrolling interest	33	(116)	(169)	(357)
Net loss attributable to common stockholders	\$ (5,187,564)	\$ (6,681,191)	\$ 80,393,663	\$ (10,367,199)
Income (loss) per common share (basic):				
Continuing operations	\$ (0.02)	\$ (0.01)	\$ (0.04)	\$ (0.03)
Discontinued operations	\$ (0.01)	\$ (0.03)	\$ 0.54	\$ (0.04)
Attributable to common stockholders	\$ (0.03)	\$ (0.04)	\$ 0.50	\$ (0.07)
Weighted average shares outstanding (basic)	161,910,792	155,382,368	161,147,873	155,345,231
Income (loss) per common share (diluted):				
Continuing operations	\$ (0.02)	\$ (0.01)	\$ (0.04)	\$ (0.03)
Discontinued operations	\$ (0.01)	\$ (0.03)	\$ 0.52	\$ (0.04)
Attributable to common stockholders	\$ (0.03)	\$ (0.04)	\$ 0.49	\$ (0.07)
Weighted average shares outstanding (diluted)	161,910,792	155,382,368	165,631,000	155,345,231