

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, 2018

NAVIDEA BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-35076 (Commission File Number)	31-1080091 (IRS Employer Identification No.)
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4995 Bradenton Avenue, Suite 240, Dublin, Ohio (Address of principal executive offices)	43017 (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, 2018, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release regarding its consolidated financial results for the quarter ended June 30, 2018. A copy of the Company’s August 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 August 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: August 9, 2018

By: /s/ Jed A. Latkin

Jed A. Latkin

Chief Operating Officer and Chief Financial
Officer

Navidea Biopharmaceuticals Reports Second Quarter 2018 Financial Results

Conference Call to be held Thursday, August 16th, 2018 at 5:00 pm ET following the Annual Meeting

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 second quarter of 2018. Navidea reported total revenues for the quarter of \$542,000. Net loss attributable to common stockholders was \$2.4 million.

Michael Goldberg, M.D., President and Chief Executive Officer of Navidea BioPharmaceuticals, commented, “During the first half of the year, we continued to make significant progress executing on our strategy to develop imaging and therapeutics based on our activated macrophage targeting technology. We have generated additional clinical data with our imaging agents and progressed with our development efforts towards additional regulatory approvals. Macrophage Therapeutics is seeking to develop treatments for diseases where inflammation is a major contributing factor. Macrophage Therapeutics has an exclusive license from Navidea for all therapeutic uses of our propriety Manocept platform, while our diagnostics business is focused on the development and commercialization of precision imaging products for a large range of inflammatory related conditions. With the benefit of these corporate changes, we are well-positioned to create long-term value for our stakeholders as we focus the business and execute our mission of developing innovative immunodiagnostic agents and therapies that improve patient care.”

Second Quarter 2018 Highlights and Subsequent Events

- Signed exclusive license with Meilleur Technologies, Inc. (“Meilleur”) 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
- Presented at the 8th Annual LD Micro Invitational Conference
- Presented at the 2nd Annual NASH conference in Boston, MA

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 in March 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.

- Total revenues for the second quarter of 2018 were \$542,000 compared to \$612,000 in the second quarter of 2017. Total revenues for the first six months of 2018 were \$819,000 compared to \$1.2 million for the same period in 2017. License revenue in 2018 was primarily related to the sublicense of NAV4694 to Meilleur; license revenue during 2017 was primarily related to the license of Tc99m tilmanocept to Sayre Therapeutics in India. Grant revenue in both 2018 and 2017 was primarily related to Small Business Innovation Research (“SBIR”) grants from the National Institutes of Health (“NIH”) supporting Manocept development.
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- Research and development (“R&D”) expenses for the second quarter of 2018 were \$1.1 million compared to \$1.2 million in the second quarter of 2017. The net decrease was primarily due to reductions in drug project expenses related to NAV4694 and Manocept development costs, offset by increased therapeutics and Tc99m tilmanocept development costs. R&D expenses for the first six months of 2018 were \$2.1 million compared to \$1.9 million during the same period in 2017. The net increase was primarily due to net increases in drug project expenses related to NAV4694 and therapeutics development costs, offset by decreased Manocept and Tc99m tilmanocept development costs. The change in R&D expenses for both periods also included net decreased compensation related to decreased headcount.
- Selling, general and administrative (“SG&A”) expenses for the second quarter of 2018 were \$1.8 million, compared to \$4.2 million in the second quarter of 2017. SG&A expenses for the first six months of 2018 were \$3.6 million, compared to \$7.3 million during the same period in 2017. The net decrease for both periods was primarily due to decreased legal and professional services, a loss on disposal of assets related to our previous office space, termination costs related to the arbitration award to our former CEO, a loss on termination of our previous office lease, and decreased general office expenses such as depreciation, insurance and rent.
- Navidea’s net loss attributable to common stockholders for the quarter ended June 30, 2018 was \$2.4 million, or \$0.02 per share (basic), compared to a net loss attributable to common stockholders of \$5.2 million, or \$0.03 per share, for the same period in 2017. Navidea’s net loss attributable to common stockholders for the six-month period ended June 30, 2018 was \$9.1 million, or \$0.06 per share (basic), compared to net income attributable to common stockholders of \$80.4 million, or \$0.50 per share, for the same period in 2017.
- Navidea ended the second quarter of 2018 with \$5.5 million in cash and investments, including the accelerated earnout payment of \$6.0 million from Cardinal Health 414 which was received during the quarter.

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: Second Quarter 2018 Earnings and Business Update Conference Call
Date: Thursday, August 16, 2018
Time: 5:00 pm (Eastern Time)
U.S. & Canada
Dial-in: 877-407-0312
Conference ID: 13682395
Webcast <https://webcasts.eqs.com/navidea20180816>

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.

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

	June 30, 2018 (unaudited)	December 31, 2017
Assets:		
Cash and securities	\$ 5,488,909	\$ 4,592,610
Accounts and other receivables	373,876	8,137,872
Other current assets	737,336	1,101,923
Guaranteed earnout receivable	-	4,809,376
Other non-current assets	2,060,371	2,139,655
Total assets	\$ 8,660,492	\$ 20,781,436
Liabilities and stockholders' equity:		
Notes payable, current	\$ 2,200,353	\$ 2,353,639
Accrued loss for CRG litigation	-	2,887,566
Other current liabilities	2,428,590	2,827,198
Deferred revenue	700,000	11,024
Other liabilities	544,677	653,679
Total liabilities	5,873,620	8,733,106
Navidea stockholders' equity	2,118,197	11,379,630
Noncontrolling interest	668,675	668,700
Total stockholders' equity	2,786,872	12,048,330
Total liabilities and stockholders' equity	\$ 8,660,492	\$ 20,781,436

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Six Months Ended	
	June 30, 2018 (unaudited)	June 30, 2017 (unaudited)	June 30, 2018 (unaudited)	June 30, 2017 (unaudited)
Revenue:				
Tc99m tilmanocept royalty revenue	\$ 6,665	\$ -	\$ 7,460	\$ -
License revenue	257,709	100,000	257,709	100,000
Grant and other revenue	277,753	511,599	553,403	1,091,629
Total revenue	<u>542,127</u>	<u>611,599</u>	<u>818,572</u>	<u>1,191,629</u>
Cost of revenue	35,392	-	35,710	-
Gross profit	<u>506,735</u>	<u>611,599</u>	<u>782,862</u>	<u>1,191,629</u>
Operating expenses:				
Research and development	1,142,718	1,185,874	2,141,674	1,891,148
Selling, general and administrative	1,789,399	4,249,584	3,565,771	7,272,018
Total operating expenses	<u>2,932,117</u>	<u>5,435,458</u>	<u>5,707,445</u>	<u>9,163,166</u>
Loss from operations	<u>(2,425,382)</u>	<u>(4,823,859)</u>	<u>(4,924,583)</u>	<u>(7,971,537)</u>
Other income (expense):				
Interest (expense) income, net	(23,547)	44,649	7,840	68,761
Change in fair value of financial instruments	-	12,872	-	153,357
Loss on extinguishment of debt	-	-	(4,265,434)	(1,314,102)
Other, net	2,828	(16,673)	(1,886)	(38,277)
Loss before income taxes	<u>(2,446,101)</u>	<u>(4,783,011)</u>	<u>(9,184,063)</u>	<u>(9,101,798)</u>
Benefit from income taxes	10,929	1,631,234	10,929	3,085,406
Loss from continuing operations	<u>(2,435,172)</u>	<u>(3,151,777)</u>	<u>(9,173,134)</u>	<u>(6,016,392)</u>
Discontinued operations, net of tax effect:				
Loss from operations	(1,938)	(82,376)	(1,938)	(338,237)
Gain (loss) on sale	43,053	(1,953,378)	43,053	86,748,123
Net (loss) income	<u>(2,394,057)</u>	<u>(5,187,531)</u>	<u>(9,132,019)</u>	<u>80,393,494</u>
Less (loss) income attributable to noncontrolling interest	(16)	33	(25)	(169)
Net (loss) income attributable to common stockholders	<u>\$ (2,394,041)</u>	<u>\$ (5,187,564)</u>	<u>\$ (9,131,994)</u>	<u>\$ 80,393,663</u>
(Loss) income per common share (basic):				
Continuing operations	\$ (0.02)	\$ (0.02)	\$ (0.06)	\$ (0.04)
Discontinued operations	\$ 0.00	\$ (0.01)	\$ 0.00	\$ 0.54
Attributable to common stockholders	\$ (0.02)	\$ (0.03)	\$ (0.06)	\$ 0.50
Weighted average shares outstanding (basic)	162,716,988	161,910,792	162,494,238	161,147,873
(Loss) income per common share (diluted):				
Continuing operations	\$ (0.02)	\$ (0.02)	\$ (0.06)	\$ (0.04)
Discontinued operations	\$ 0.00	\$ (0.01)	\$ 0.00	\$ 0.52
Attributable to common stockholders	\$ (0.02)	\$ (0.03)	\$ (0.06)	\$ 0.49
Weighted average shares outstanding (diluted)	162,716,988	161,910,792	162,494,238	165,631,000