

**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) November 7, 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 November 7, 2018, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release regarding its consolidated financial results for the quarter ended September 30, 2018. A copy of the Company’s November 7, 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.

<i>Exhibit Number</i>	<i>Exhibit Description</i>
99.1	<a href="#"><u>Press Release dated November 7, 2018.</u></a>

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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: November 7, 2018

By: /s/ Jed A. Latkin

Jed A. Latkin  
Chief Executive Officer, Chief  
Operating Officer and  
Chief Financial Officer

## Navidea Biopharmaceuticals Reports Third Quarter 2018 Financial Results

*Conference Call to be held Wednesday, November 7<sup>th</sup>, 2018 at 4:30 pm 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 third quarter of 2018. Navidea reported total revenues for the quarter of \$231, 000. Net loss attributable to common stockholders was \$3.8 million.

"Navidea had a productive quarter as we advanced the business and our novel imaging pipeline," said Mr. Jed A. Latkin, Chief Executive Officer of Navidea. "We also continued to gain recognition from the scientific and medical communities, receiving acceptance into the National Institutes of Health's ("NIH") Commercialization Accelerator Program and presenting encouraging data on Tc99m tilmanocept, the first product developed and commercialized by the Company based on the Manocept platform, at the American College of Rheumatology ("ACR") Annual Meeting. The Company also presented its Phase II data to the U.S. Food and Drug Administration ("FDA") at the end of September. These accomplishments reflect the strength of our team and the potential of our pipeline of innovative diagnostics. Importantly, acceptance into the NIH's program in addition to a \$3 million private placement by a long-term investor provides us with assistance to advance our Rheumatoid Arthritis ("RA") program and product portfolio. I am pleased with our progress and look forward to a strong finish to the year."

### **Third Quarter 2018 Highlights and Subsequent Events**

- Closed \$3 million private placement with an existing investor
- Announced acceptance into the NIH's Commercialization Accelerator Program for 2018-2019
- Presented data on the Manocept platform at the 2018 ACR Annual Meeting
- Presented at the 2018 BIO Investor Forum in California
- Held meeting with the FDA to discuss the results from the Phase II RA trial and activated macrophage data and next steps for the program
- Announced leadership transition in which Dr. Michael Goldberg stepped down as CEO and Board member of Navidea and Mr. Jed Latkin was appointed CEO of Navidea
- Held the Annual Shareholder Meeting

### **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 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 third quarter of 2018 were \$231,000 compared to \$224,000 in the third quarter of 2017. The increase was primarily due to a royalty revenue related to our license agreement with SpePharm in Europe as well as a license revenue for activities related to the sublicense of NAV4694 to Meilleur Technologies, Inc. and the sublicense of Tc99m tilmanocept to Beijing Sinotau Medical Research Co., Ltd. No royalty revenue or license revenue was recognized during the third quarter of 2017. Total revenues for the first nine months of 2018 were \$1.1 million compared to \$1.4 million for the same period in 2017. Revenue included royalty and license revenue as well as grant revenue, primarily related to SBIR grants from the NIH supporting Manocept development. Other revenue for the first nine months of 2018 was from our marketing partners in Europe and China related to development work performed at their request.
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- Research and development (“R&D”) expenses for the third quarter of 2018 were \$1.2 million compared to \$875,000 in the third quarter of 2017. R&D expenses for the first nine months of 2018 were \$3.4 million compared to \$2.8 million during the same period in 2017. The increase was primarily due to net increases in drug project expenses related to increased therapeutics development costs from research consulting, regulatory consulting, and preclinical testing.
  - Selling, general and administrative (“SG&A”) expenses for the third quarter of 2018 were \$2.7 million, compared to \$1.7 million in the third quarter of 2017. The net increase was primarily due to increased compensation including incentive-based awards as well as termination costs associated with the resignation of our former CEO. SG&A expenses for the first nine months of 2018 were \$6.3 million, compared to \$9.0 million during the same period in 2017. The net decrease was primarily due to decreased legal and professional services, as well as decreased general office, insurance, depreciation, rent, and travel expenses.
  - Navidea’s net loss attributable to common stockholders for the quarter ended September 30, 2018 was \$3.8 million, or \$0.02 per share (basic), compared to a net loss attributable to common stockholders of \$1.4 million, or \$0.01 per share, for the same period in 2017. Navidea’s net loss attributable to common stockholders for the nine-month period ended September 30, 2018 was \$13.0 million, or \$0.08 per share (basic), compared to net income attributable to common stockholders of \$79.0 million, or \$0.49 per share, for the same period in 2017.
  - Navidea ended the third quarter of 2018 with \$6.5 million in cash and investments.
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## **Conference Call Details**

Investors and the public are invited to dial into the earnings call through the information listed below. Participants who would like to ask questions during the question and answer session must participate by telephone.

<b>Event:</b>	Third Quarter 2018 Earnings and Business Update Conference Call
<b>Date:</b>	Wednesday, November 7, 2018
<b>Time:</b>	4:30 pm (Eastern Time)
<b>U.S. &amp; Canada Dial-in:</b>	877-407-0312
<b>Conference ID:</b>	13684819

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](http://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](http://www.navidea.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: any future actions by Platinum-Montaur; 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 and Ohio; 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; our ability to comply with the NYSE American continued listing standards; and other risk factors 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](http://www.sec.gov) or at <http://ir.navidea.com>.

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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.

**Contacts:**

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Or

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**NAVIDEA BIOPHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

	September 30, 2018 (unaudited)	December 31, 2017
<b>Assets:</b>		
Cash and securities	\$ 6,506,413	\$ 4,592,610
Accounts and other receivables	86,928	8,137,872
Other current assets	547,027	1,101,923
Guaranteed earnout receivable	-	4,809,376
Other non-current assets	1,968,674	2,139,655
<b>Total assets</b>	<b>\$ 9,109,042</b>	<b>\$ 20,781,436</b>
<b>Liabilities and stockholders' equity:</b>		
Notes payable, current	\$ 2,164,330	\$ 2,353,639
Accrued loss for CRG litigation	-	2,887,566
Other current liabilities	3,682,565	2,827,198
Deferred revenue	700,000	11,024
Other liabilities	552,084	653,679
<b>Total liabilities</b>	<b>7,098,979</b>	<b>8,733,106</b>
Navidea stockholders' equity	1,341,696	11,379,630
Noncontrolling interest	668,367	668,700
<b>Total stockholders' equity</b>	<b>2,010,063</b>	<b>12,048,330</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 9,109,042</b>	<b>\$ 20,781,436</b>

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended September 30, 2018 (unaudited)	September 30, 2017 (unaudited)	Nine Months Ended September 30, 2018 (unaudited)	September 30, 2017 (unaudited)
<b>Revenue:</b>				
Tc99m tilmanocept royalty revenue	\$ 2,382	\$ -	\$ 9,842	\$ -
License revenue	19,930	-	277,639	100,000
Grant and other revenue	209,146	223,669	762,549	1,315,298
<b>Total revenue</b>	<b>231,458</b>	<b>223,669</b>	<b>1,050,030</b>	<b>1,415,298</b>
Cost of revenue	38,101	-	73,811	-
<b>Gross profit</b>	<b>193,357</b>	<b>223,669</b>	<b>976,219</b>	<b>1,415,298</b>
<b>Operating expenses:</b>				
Research and development	1,225,770	874,547	3,367,444	2,765,695
Selling, general and administrative	2,688,703	1,734,707	6,254,474	9,006,725
<b>Total operating expenses</b>	<b>3,914,473</b>	<b>2,609,254</b>	<b>9,621,918</b>	<b>11,772,420</b>
Loss from operations	(3,721,116)	(2,385,585)	(8,645,699)	(10,357,122)
<b>Other income (expense):</b>				
Interest (expense) income, net	(28,074)	76,050	(20,234)	144,811
Change in fair value of financial instruments	-	-	-	153,357
Loss on extinguishment of debt	-	-	(4,265,434)	(1,314,102)
Other, net	3,540	(6,979)	1,654	(45,256)
<b>Loss before income taxes</b>	<b>(3,745,650)</b>	<b>(2,316,514)</b>	<b>(12,929,713)</b>	<b>(11,418,312)</b>
(Provision for) benefit from income taxes	(76,259)	775,750	(65,330)	3,861,156
Loss from continuing operations	(3,821,909)	(1,540,764)	(12,995,043)	(7,557,156)
<b>Discontinued operations, net of tax effect:</b>				
Income (loss) from operations	-	5,399	(1,938)	(332,838)
Gain (loss) on sale	-	145,877	43,053	86,894,000
Net (loss) income	(3,821,909)	(1,389,488)	(12,953,928)	79,004,006
Less loss attributable to noncontrolling interest	(308)	(23)	(333)	(192)
<b>Net (loss) income attributable to common stockholders</b>	<b>\$ (3,821,601)</b>	<b>\$ (1,389,465)</b>	<b>\$ (12,953,595)</b>	<b>\$ 79,004,198</b>
<b>(Loss) income per common share (basic):</b>				
Continuing operations	\$ (0.02)	\$ (0.01)	\$ (0.08)	\$ (0.05)
Discontinued operations	\$ -	\$ 0.00	\$ 0.00	\$ 0.54
Attributable to common stockholders	\$ (0.02)	\$ (0.01)	\$ (0.08)	\$ 0.49
<b>Weighted average shares outstanding (basic)</b>	<b>166,855,420</b>	<b>162,006,646</b>	<b>163,963,940</b>	<b>161,437,276</b>
<b>(Loss) income per common share (diluted):</b>				
Continuing operations	\$ (0.02)	\$ (0.01)	\$ (0.08)	\$ (0.05)
Discontinued operations	\$ -	\$ 0.00	\$ 0.00	\$ 0.52
Attributable to common stockholders	\$ (0.02)	\$ (0.01)	\$ (0.08)	\$ 0.47

Weighted average shares outstanding (diluted)	166,855,420	162,006,646	163,963,940	165,914,473
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