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, 2017

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, 2017, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release regarding its consolidated financial results for the quarter ended September 30, 2017. A copy of the Company's November 7, 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 November 7, 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: November 7, 2017

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

Exhibit 99.1

Navidea Biopharmaceuticals Reports Third Quarter 2017 Financial Results

Conference Call to be held Wednesday, November 8, 2017 at 8:30 am 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 third quarter of 2017. Navidea reported total revenues for the quarter of $224,000. Net loss attributable to common stockholders was $1.5 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 and were already included in the gain on sale of the line of business sold to Cardinal Health 414 for the nine months ended September 30, 2017.

“We’ve made significant advancements in our pipeline, both on the diagnostic and therapeutics side so far this year. Efforts undertaken since the closing of the Cardinal Health 414 transaction to implement the new strategy have enabled the more rapid development of our proprietary technology. We have demonstrated significant market expansion potential with our imaging agent. We are actively pursuing an approval to utilize our activated macrophage technology as a biomarker. We have formally contacted the U.S. Food and Drug Administration (“FDA”) and have scheduled our first meeting with them. In parallel, we are also pursuing an additional approval for our agent so we can administer it intravenously (“IV”). The FDA and many major pharmaceutical companies have indicated their significant interest in developing biomarkers that can assist in developing new therapeutics and in enabling objective monitoring of performance of existing therapies. 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,” 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 IV and subcutaneous formulations of Tc99m tilmanocept in rheumatoid arthritis (“RA”). We have completed all but a few of the control dosings in the Phase 1/2 dose escalation registrational study and expect to finalize the report on this study in the fourth quarter of this year. In nonalcoholic steatohepatitis (“NASH”) and cardiovascular (“CV”) disease, we will also be initiating dosing of an IV formulation shortly. For CV, we are working with the same team at Massachusetts General Hospital in Boston who designed, managed and published the subcutaneous CV study that has attracted so much interest. In the IV study we will also explore the ability to image central nervous system inflammation. With Kettering Medical Center in Ohio, we will shortly be dosing in NASH patients. On the therapeutic side we have synthesized and tested delivery backbones that are one-tenth the size of the existing agents. As we explore formulation opportunities with our therapeutics, smaller agents provide better opportunities for creating therapeutics than can be delivered orally and topically. The newer agents retain the same very high binding we have achieved with our larger constructs. Finally, we have dosed in cancer models our MT1000 class of therapeutics, much more frequently (twice per day as opposed to twice per week) with the same total dose and as expected this resulted in much improved activity. “

Third Quarter 2017 Highlights and Subsequent Events

- Executed a letter of intent for a sublicensing contract for worldwide research and development results with Cerveau Technologies, Inc. (“Cerveau”) for using NAV4694, a beta-amyloid imaging agent being evaluated as an aid in the differential diagnosis of early-onset Alzheimer’s disease
- Executed a letter of intent for an exclusive license with Cerveau for the development and commercialization of NAV4694 in Australia, Canada, China, and Singapore
- Presented a late-breaking poster at the American College of Rheumatology Annual Meeting detailing the results of an IV-administered study in RA patients
- Initiated series of regular investor-focused Q&A conference calls to improve Investor Relations strategy
- IV-administration RA trial to complete enrollment in fourth quarter 2017
- Launched NASH imaging study launch this quarter at Kettering Medical Center in Ohio
- Initiate dosing in Phase 1/2 clinical imaging study in Kaposi’s Sarcoma

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.

- We recorded a $86.7 million net gain on the line of business sold to Cardinal Health 414 for the nine months ended September 30, 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 $6.5 million in estimated taxes.

- Total revenues for the third quarter of 2017 were $224,000, compared to $1.8 million in the third quarter of 2016. These revenues are grant-related and do not include the $1.7 million of payments received from Cardinal Health 414.

- Research and development expenses for the third quarter of 2017 were $875,000, compared to $919,000 in the third quarter of 2016. The net decrease was primarily a result of decreases in net compensation costs coupled with decreased NAV4694 and NAV5001 development costs, offset by increases in Manocept development costs.

- Selling, general and administrative expenses for the third quarter of 2017 were $1.7 million, compared to $1.8 million in the third quarter of 2016. The net decrease was primarily due to decreases in general support costs such as rent and depreciation, coupled with decreased net compensation costs, offset by net increased legal and professional services.

- Navidea's net loss attributable to common stockholders for the quarter ended September 30, 2017 was $1.5 million, or a $0.01 loss per share (basic), compared to a net loss of $59,000, or a $0.00 loss per share, for the same period in 2016.

- Navidea ended the quarter with $6.6 million in cash and investments, not including the quarterly guaranteed earnout payment of $1.7 million from Cardinal Health 414 which was received after the quarter ended.

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:	Q3 2017 Earnings and Business Update Conference Call
Date:	Wednesday, November 8, 2017
Time:	8:30 am (Eastern Time)
U.S. & Canada Dial-in:	1-866-548-4713 (toll free)
Conference ID:	6714834
Webcast	http://www.audio-webcast.com/cgi-bin/visitors.ssp?fn=visitor&id=5121

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 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

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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

	September 30, 2017 (unaudited)	December 31, 2016
Assets:		
Cash and securities	$ 6,618,449	$ 1,539,325
Restricted cash	-	5,001,253
Accounts receivable	8,042,691	203,016
Other current assets	504,971	938,428
Assets associated with discontinued operations, current	-	3,144,247
Guaranteed earnout receivable	6,445,390	-
Other assets	994,206	1,530,152
Assets associated with discontinued operations	-	105,255
Total assets	$ 22,605,707	$ 12,461,676
Liabilities and stockholders' equity (deficit):		
Notes payable, current	$ 1,981,676	$ 51,957,913
Other current liabilities	4,026,867	13,038,278
Liabilities associated with discontinued operations, current	33,141	4,865,597
Notes payable	-	9,641,179
Other liabilities	706,295	624,922
Total liabilities	6,747,979	80,127,889
Navidea stockholders' equity (deficit)	15,189,010	(68,135,123)
Noncontrolling interest	668,718	468,910
Total stockholders' equity (deficit)	15,857,728	(67,666,213)
Total liabilities and stockholders' equity (deficit)	$ 22,605,707	$ 12,461,676

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Nine Months Ended	
	September 30, 2017 (unaudited)	September 30, 2016 (unaudited)	September 30, 2017 (unaudited)	September 30, 2016 (unaudited)
Revenue:				
Tc99m tilmanocept sales and license revenue	$ -	$ 1,313,226	$ 100,000	$ 1,826,425
Grant and other revenue	223,669	510,974	1,315,298	2,113,420
Total revenue	223,669	1,824,200	1,415,298	3,939,845
Cost of good sold	-	2,889	-	5,185
Gross profit	223,669	1,821,311	1,415,298	3,934,660
Operating expenses:				
Research and development	874,547	919,441	2,765,695	5,010,923
Selling, general and administrative	1,734,707	1,811,680	9,006,725	5,832,623
Total operating expenses	2,609,254	2,731,121	11,772,420	10,843,546
Loss from operations	(2,385,585)	(909,810)	(10,357,122)	(6,908,886)
Other income (expense):				
Interest income (expense), net	76,050	159	144,811	(2,076)
Equity in the loss of joint venture	-	-	-	(15,159)
Loss on disposal of joint venture	-	-	-	(39,732)
Change in fair value of financial instruments	-	(839,298)	153,357	1,755,989
Loss on extinguishment of debt	-	-	(1,314,102)	-
Other, net	(6,979)	(12,498)	(45,256)	(49,916)
Loss before income taxes	(2,316,514)	(1,761,447)	(11,418,312)	(5,259,780)
Benefit from income taxes	776,068	-	3,861,474	-
Loss from continuing operations	(1,540,446)	(1,761,447)	(7,556,838)	(5,259,780)
Discontinued operations, net of tax effect:				
Income (loss) from discontinued operations	5,998	1,701,911	(332,239)	(5,167,312)
Gain (loss) on sale	(12,486)	-	86,735,637	-
Net income (loss)	(1,546,934)	(59,536)	78,846,560	(10,427,092)
Less loss attributable to noncontrolling interest	(23)	(159)	(192)	(516)
Net income (loss) attributable to common stockholders	$ (1,546,911)	$ (59,377)	$ 78,846,752	$ (10,426,576)
Income (loss) per common share (basic):				
Continuing operations	$ (0.01)	$ (0.01)	$ (0.05)	$ (0.03)
Discontinued operations	$ (0.00)	$ 0.01	$ 0.54	$ (0.04)
Attributable to common stockholders	$ (0.01)	$ (0.00)	$ 0.49	$ (0.07)
Weighted average shares outstanding (basic)	162,006,646	155,481,278	161,437,276	155,390,911
Income (loss) per common share (diluted):				
Continuing operations	$ (0.01)	$ (0.01)	$ (0.05)	$ (0.03)
Discontinued operations	$ (0.00)	$ 0.01	$ 0.52	$ (0.04)
Attributable to common stockholders	$ (0.01)	$ (0.00)	$ 0.47	$ (0.07)
Weighted average shares outstanding (diluted)	162,006,646	155,481,278	165,914,473	155,390,911