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, 2019

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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock	**NAVB**	**NYSE American**

Item 2.02 Results of Operations and Financial Condition.

On August 8, 2019, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release regarding its consolidated financial results for the quarter ended June 30, 2019. A copy of the Company's August 8, 2019 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, 2019.

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, 2019

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

Exhibit 99.1

Navidea Biopharmaceuticals Reports Second Quarter 2019 Financial Results

Conference Call to be held Thursday, August 8, 2019 at 5:00 pm EDT

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 2019. Navidea reported total revenues for the quarter of $260,000. Net loss attributable to common stockholders was $2.7 million.

"During the second quarter, Navidea continued to deliver on its renewed focus to complete its NAV 3-31 trial and raise the funding to cover it," said Mr. Jed A. Latkin, Chief Executive Officer of Navidea. "The Company furthered its partnership discussions around the globe but most importantly Navidea met its internal recruiting and enrollment goals for its ongoing RA trials. The Company remains focused on bringing its RA diagnostic to market."

Second Quarter 2019 Highlights and Subsequent Events

- Effected a one-for-twenty reverse stock split and received notification of stock price compliance from the NYSE American
- Announced that results of the Company's NAV3-21 clinical study for diagnosis of rheumatoid arthritis were presented at the Society of Nuclear Medicine and Molecular Imaging ("SNMMI") Annual Meeting by Arash Kardan, M.D.
- Completed an underwritten public offering with gross proceeds of $6.0 million
- Achieved double-digit subject enrollment in our NAV3-31 Phase 2b study and are on track with recruitment projections to date
- Received an Intent to Fund notification from the National Heart, Lung and Blood Institute for its Small Business Technology Transfer Phase 1 grant application that will support a collaboration with the University of Alabama at Birmingham titled "Gallium 68 Tilmanocept for PET Imaging of Atherosclerosis Plaques"

"We were extremely pleased with the recognition received at the annual SNMMI meeting following our Phase 1 and 2 study results, and we are pressing forward with recruitment in the ongoing Phase 2B," said Dr. Michael Rosol, Chief Medical Officer of Navidea. "This Phase 2b study will provide the fundamental test-retest and longitudinal data to validate our power calculations for the upcoming Phase 3 trial."

Financial Results

Our consolidated balance sheets, statements of operations, and statements of stockholders' equity have been restated, as required, for all periods presented to reflect the reverse stock split as if it had occurred on January 1, 2018. Our consolidated statements of cash flows were not impacted by the reverse stock split.

- Total revenues for the second quarter of 2019 were $260,000, compared to $542,000 in the same period of 2018. Total revenues for the first six months of 2019 were $302,000, compared to $819,000 in the same period of 2018. The decrease was primarily due to a decrease in license revenue related to the sublicense of our NAV4694 technology which included a non-refundable upfront payment in 2018, coupled with a reduction in grant revenue related to SBIR grants from the NIH supporting Manocept development.

- Research and development ("R&D") expenses were approximately $1.1 million in each of the second quarters of 2019 and 2018. R&D expenses for the first six months of 2019 were $1.8 million, compared to $2.1 million in the same period of 2018. The year-to-date decrease was primarily due to net decreases in drug project expenses including therapeutics, Tc99m tilmanocept, and NAV4694 development costs, offset by increased Manocept diagnostic development costs. The net decrease in R&D expenses also included decreased compensation costs resulting from net decreased salaries and headcount.
- Selling, general and administrative ("SG&A") expenses for the second quarter of 2019 were $1.9 million, compared to $1.8 million in the same period of 2018. SG&A expenses were approximately $3.6 million in each of the first six months of 2019 and 2018. Increased legal and professional services were offset by decreased compensation costs.
- Navidea's net loss attributable to common stockholders for the second quarter of 2019 was $2.7 million, or $0.24 per share, compared to a net loss attributable to common stockholders of $2.4 million, or $0.29 per share, for the same period in 2018. Navidea's net loss attributable to common stockholders for the first six months of 2019 was $5.1 million, or $0.48 per share, compared to a net loss attributable to common stockholders of $9.1 million, or $1.12 per share, for the same period in 2018.
- Navidea ended the second quarter of 2019 with $5.3 million in cash and investments.

Conference Call Details

Investors and the public are invited to dial into the earnings call through the information listed below, or participate via the audio webcast on the company website. Participants who would like to ask questions during the question and answer session will be prompted by the moderator, who will provide instructions.

Event:	Q2 2019 Earnings and Business Update Conference Call
Date:	Thursday, August 8, 2019
Time:	5:00 p.m. (EDT)
U.S. & Canada Dial-in:	877-407-0312
International Dial-in:	+1 201-389-0899
Conference ID:	13693119

Webcast Link: https://webcasts.eqs.com/navidbioph20190808/en

The recorded conference call can be replayed and will be available for 90 days following the call, available on the investor relations page of Navidea's corporate website at www.navidea.com.

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 Tc99m tilmanocept, the first product developed and commercialized by Navidea based on the platform. 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.

Forward-Looking Statements

This press 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. Forward looking statements include our expectations for the use of proceeds received from the offering. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: market and other conditions, the satisfaction of customary closing conditions related to the public offering and the impact of general economic, industry or political conditions in the United States or internationally, 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 any pending litigation; 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; our ability to maintain effective internal control over financial reporting; 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 http://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.

Contact

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NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2019 (unaudited)	December 31, 2018
Assets:		
Cash and available-for-sale securities	$ 5,263,045	$ 4,275,151
Other current assets	1,211,753	1,320,605
Non-current assets	1,655,597	1,425,771
Total assets	$ 8,130,395	$ 7,021,527
Liabilities and stockholders' equity:		
Current liabilities	$ 3,822,135	$ 3,378,518
Deferred revenue, non-current	700,000	700,000
Other liabilities	676,753	532,549
Total liabilities	5,198,888	4,611,067
Navidea stockholders' equity	2,263,201	1,742,139
Noncontrolling interest	668,306	668,321
Total stockholders' equity	2,931,507	2,410,460
Total liabilities and stockholders' equity	$ 8,130,395	$ 7,021,527

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Six Months Ended	
	June 30, 2019 (unaudited)	June 30, 2018 (unaudited)	June 30, 2019 (unaudited)	June 30, 2018 (unaudited)
Revenue:				
Royalty revenue	$ 5,940	$ 6,665	$ 9,090	$ 7,460
License revenue	9,953	257,709	9,953	257,709
Grant and other revenue	244,199	277,753	282,673	553,403
Total revenue	260,092	542,127	301,716	818,572
Cost of revenue	238	35,392	6,364	35,710
Gross profit	259,854	506,735	295,352	782,862
Operating expenses:				
Research and development	1,070,642	1,142,718	1,811,225	2,141,674
Selling, general and administrative	1,861,600	1,789,399	3,590,116	3,565,771
Total operating expenses	2,932,242	2,932,117	5,401,341	5,707,445
Loss from operations	(2,672,388)	(2,425,382)	(5,105,989)	(4,924,583)
Other (expense) income:				
Interest income (expense), net	1,630	(23,547)	11,478	7,840
Loss on extinguishment of debt	-	-	-	(4,265,434)
Other, net	(3,220)	2,828	(4,356)	(1,886)
Loss before income taxes	(2,673,978)	(2,446,101)	(5,098,867)	(9,184,063)
Benefit from (provision for) income taxes	168	10,929	(708)	10,929
Loss from continuing operations	(2,673,810)	(2,435,172)	(5,099,575)	(9,173,134)
Discontinued operations, net of tax effect:				
Gain (loss) from operations	632	(1,938)	(2,665)	(1,938)
Gain on sale	-	43,053	-	43,053
Net loss	(2,673,178)	(2,394,057)	(5,102,240)	(9,132,019)
Less loss attributable to noncontrolling interest	(3)	(16)	(15)	(25)
Net loss attributable to common stockholders	$ (2,673,175)	$ (2,394,041)	$ (5,102,225)	$ (9,131,994)
Loss per common share (basic and diluted):				
Continuing operations	$ (0.24)	$ (0.30)	$ (0.48)	$ (1.13)
Discontinued operations	$ 0.00	$ 0.01	$ (0.00)	$ 0.01
Attributable to common stockholders	$ (0.24)	$ (0.29)	$ (0.48)	$ (1.12)
Weighted average shares outstanding	11,096,834	8,135,849	10,560,265	8,124,711