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)	March 11, 2020

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, par value $.001 per share	NAVB	NYSE American

Item 2.02 Results of Operations and Financial Condition.

On March 11, 2020, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release regarding its consolidated financial results for the quarter ended December 31, 2019. A copy of the Company's March 11, 2020 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 March 11, 2020.

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: March 11, 2020

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

Exhibit 99.1

Navidea Biopharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results

Conference Call to be held Wednesday, March 11, 2020 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 fourth quarter and full year ended December 31, 2019.

"During the fourth quarter, Navidea made great strides in its enrollment of the NAV 3-31 Phase 2B trial in patients with rheumatoid arthritis," said Mr. Jed A. Latkin, Chief Executive Officer of Navidea. "The Company continued its dialogue with several key potential partners and we anticipate providing updates on those initiatives in the very near future. Furthermore, with the most recent financing, the Company put in place the steps necessary to launch the next critical trials."

Fourth Quarter 2019 Highlights and Subsequent Events

- Continued with double-digit subject enrollment in the Company's NAV3-31 Phase 2b study in rheumatoid arthritis ("RA") and completed enrollment of subjects in Arms 1 and 2.
- Announced positive results of the first interim analysis of the NAV3-31 Phase 2b study, demonstrating that Tc99m tilmanocept imaging can provide robust, quantitative imaging in healthy controls and in patients with active RA, and that this imaging is stable, reproducible, and can define joints with and without RA-involved inflammation.
- Completed enrollment in NAV3-24, a Phase 1 Kaposi's Sarcoma trial; All imaging has been completed and the Company is currently compiling results.
- Continued enrollment in the Investigator Initiated Phase 2 trial being run at the Massachusetts General Hospital evaluating Tc99m tilmanocept uptake in atherosclerotic plaques of HIV-infected individuals.
- Entered into a collaboration agreement with IMV Inc., a clinical-stage immuno-oncology company, to explore the combinatory effect of Navidea's and IMV's proprietary immuno-oncology platforms.
- Converted the Tilmanocept Uptake Value quantitative imaging analysis provisional patent to an A1 patent application, and filed an additional provisional patent relevant to both imaging and therapeutic applications.
- Executed agreements with five investors, including an existing investor, to purchase approximately 2.1 million shares of the Company's common stock in a private placement for aggregate gross proceeds to Navidea of approximately $1.9 million.
- Won summary judgment in the Court of Common Pleas for Franklin County, Ohio (the "Ohio Court") related to the Company's ongoing litigation with Capital Royalty Partners II, L.P., et al ("CRG"), in the amount of $4.3 million plus interest (the "Judgment"). The Ohio Court also found that there was no unjust enrichment or conversion by CRG. The decision is a final appealable order and terminated the case.
- Executed a binding term sheet to sell the Judgment for $4.2 million of proceeds to Navidea.
- Executed agreements with two existing investors to purchase approximately 4.0 million shares of the Company's common stock for aggregate gross proceeds to Navidea of approximately $3.4 million.
- Following the funding transactions described above, the Company regained compliance with the NYSE American's continued listing standards with stockholders' equity of $6.0 million.

Michael Rosol, Ph.D., Chief Medical Officer for Navidea, said, “The clinical research team has been working diligently to advance the technology in key disease areas, with an emphasis on our ongoing RA trials. We continue to advance our Phase 2B trial in RA, building upon last quarter’s announced interim analysis results, and with an eye towards the second interim analysis. We are also planning for the start of our second Phase 2B trial comparing tilmanocept imaging to synovial tissue biopsy samples of RA patients as well as the Phase 3 trial.”

Financial Results

Navidea’s consolidated balance sheets, statements of operations, and statements of stockholders’ equity have been restated, as required, for all periods presented to reflect the April 2019 reverse stock split as if it had occurred on January 1, 2018. The consolidated statements of cash flows were not impacted by the reverse stock split.

- Total revenues for the fourth quarters of both 2018 and 2019 were $119,000. Total revenues for fiscal 2019 were $658,000, compared to $1.2 million in 2018. The year-to-year decrease was primarily due to a decrease in license revenue related to the sublicense of the Company’s NAV4694 technology, which included a non-refundable upfront payment in 2018, coupled with a reduction in grant revenue related to Small Business Innovation Research grants from the National Institutes of Health supporting Manocept development.
- Research and development (“R&D”) expenses for the fourth quarter of 2019 were $1.7 million, compared to $854,000 in the same period of 2018. R&D expenses in 2019 were $5.3 million, compared to $4.2 million in 2018. The increase was primarily due to net increases in drug project expenses, which includes Manocept™ diagnostic and Tc99m tilmanocept development costs, offset by decreased Manocept therapeutic and NAV4694 development costs.
- Selling, general and administrative (“SG&A”) expenses for the fourth quarter of 2019 were $1.2 million, compared to $1.4 million in the same period of 2018. SG&A expenses for 2019 were $6.3 million, compared to $7.7 million in 2018. The decrease was primarily related to the resignation of the Company’s former CEO in 2018, coupled with net decreases in salaries and bonuses, investor relations, general office expenses and taxes, offset by increased legal and professional services, primarily related to litigation with the Company’s former CEO.
- Navidea’s net loss attributable to common stockholders for the fourth quarter of 2019 was $2.8 million, or $0.15 per share, compared to a net loss attributable to common stockholders of $3.2 million, or $0.33 per share, for the same period in 2018. Navidea’s net loss attributable to common stockholders for 2019 was $10.9 million, or $0.76 per share, compared to a net loss attributable to common stockholders of $16.1 million, or $1.89 per share, for 2018.
- Navidea ended the fourth quarter of 2019 with $1.0 million in cash and investments. Per Navidea’s recent filings with the SEC, the Company executed funding transactions totaling $7.6 million in proceeds during the first quarter of 2020.

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:	Q4 2019 Earnings and Business Update Conference Call
Date:	Wednesday, March 11, 2020
Time:	5:00 p.m. (EDT)
U.S. & Canada Dial-in:	877-407-0312
International Dial-in:	+1 201-389-0899
Conference ID:	13699935
Webcast Link:	https://webcasts.eqs.com/navidbioph20200311

A live audio webcast of the conference call will also be available on the investor relations page of Navidea's corporate website atwww.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 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 regarding pending litigation and other matters. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: 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; dependence on royalties and grant revenue; our ability to implement our growth strategy; anticipated trends in our business; our limited product line and distribution channels; advances in technologies and development of new competitive products; 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.

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NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2019 (unaudited)	December 31, 2018
Assets:		
Cash and available-for-sale securities	$ 1,047,159	$ 4,275,151
Other current assets	1,868,624	1,320,605
Non-current assets	1,235,123	1,425,771
Total assets	$ 4,150,906	$ 7,021,527
Liabilities and stockholders' (deficit) equity:		
Current liabilities	$ 3,819,551	$ 3,378,518
Deferred revenue, non-current	700,000	700,000
Other liabilities	512,344	532,549
Total liabilities	5,031,895	4,611,067
Navidea stockholders' (deficit) equity	(1,612,292)	1,742,139
Noncontrolling interest	731,303	668,321
Total stockholders' (deficit) equity	(880,989)	2,410,460
Total liabilities and stockholders' (deficit) equity	$ 4,150,906	$ 7,021,527

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Twelve Months Ended	
	December 31, 2019 (unaudited)	December 31, 2018 (unaudited)	December 31, 2019 (unaudited)	December 31, 2018
Revenue:				
Royalty revenue	$ 2,680	$ 5,505	$ 16,665	$ 15,347
License revenue	-	29,535	9,953	307,174
Grant and other revenue	116,619	84,281	631,208	846,830
Total revenue	119,299	119,321	657,826	1,169,351
Cost of revenue	108	22,825	6,667	96,636
Gross profit	119,191	96,496	651,159	1,072,715
Operating expenses:				
Research and development	1,725,484	854,437	5,338,267	4,221,881
Selling, general and administrative	1,165,797	1,443,661	6,275,409	7,698,135
Total operating expenses	2,891,281	2,298,098	11,613,676	11,920,016
Loss from operations	(2,772,090)	(2,201,602)	(10,962,517)	(10,847,301)
Other income (expense):				
Interest income (expense), net	1,952	(10,565)	25,288	(30,799)
Loss on extinguishment of debt	-	(1,026,182)	-	(5,291,616)
Other, net	(1,733)	(509)	(7,613)	1,145
Loss before income taxes	(2,771,871)	(3,238,858)	(10,944,842)	(16,168,571)
Benefit from (provision for) income taxes	-	75,083	(707)	9,753
Loss from continuing operations	(2,771,871)	(3,163,775)	(10,945,549)	(16,158,818)
Discontinued operations, net of tax effect:				
Income (loss) from discontinued operations	-	3,387	(2,665)	1,449
Gain on sale	-	-	-	43,053
Net loss	(2,771,871)	(3,160,388)	(10,948,214)	(16,114,316)
Less loss attributable to noncontrolling interest	(1)	(46)	(17)	(379)
Net loss attributable to common stockholders	$ (2,771,870)	$ (3,160,342)	$ (10,948,197)	$ (16,113,937)
Loss per common share (basic and diluted):				
Continuing operations	$ (0.15)	$ (0.33)	$ (0.76)	$ (1.90)
Discontinued operations	$ -	$ 0.00	$ (0.00)	$ 0.01
Attributable to common stockholders	$ (0.15)	$ (0.33)	$ (0.76)	$ (1.89)
Weighted average shares outstanding (basic and diluted)	18,283,512	9,501,763	14,393,360	8,526,767