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 24, 2021

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))

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

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 March 24, 2021, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release regarding its consolidated financial results for the quarter and twelve months ended December 31, 2020. A copy of the Company's March 24, 2021 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 24, 2021.

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 24, 2021

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 2020 Financial Results

Conference Call to be held Wednesday, March 24, 2021 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 for the period ended December 31, 2020.

"We are very excited about the progress we have made, completing all the patients in the Phase 2B NAV3-31 trial and submitting our briefing book to the FDA were milestone accomplishments this past year," said Mr. Jed A. Latkin, Chief Executive Officer of Navidea. "We are looking forward to hearing back from the FDA and continuing our due diligence discussions with Jubilant over the near term."

Fourth Quarter 2020 Highlights and Subsequent Events

- Announced positive results from continued analysis of subjects who have completed Arm 3 of the Company's NAV3-31 Phase 2B study. These data further corroborated Navidea's hypotheses that Tc99m tilmanocept imaging can provide robust, quantitative imaging in patients with active rheumatoid arthritis ("RA") and that this imaging can provide an early indicator of treatment efficacy.

- Submitted a formal Type B Meeting Request to the U.S. Food and Drug Administration ("FDA"). The FDA granted the Type B meeting and the Company has submitted the Briefing Book. The FDA is currently reviewing these formal briefing documents containing results from the NAV3-31 Phase 2B study and the proposed Phase 3 design and protocol.

- Achieved last patient, last visit in the Company's NAV3-31 Phase 2B study. Study closeout and data analysis are ongoing.

- Opened the first US site, Northwestern University, for enrollment in the Company's NAV3-32 Phase 2B trial comparing Tc99m tilmanocept imaging to histopathology of joints of patients with active RA.

- 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.

- Received notice of patent grant from the USPTO for US 10,806,803: "Compositions for targeting macrophages and other CD206 high expressing cells and methods of treating and diagnosis."

- Received a notice of allowance from the USPTO for the patent application: "Compounds and methods for diagnosis and treatment of viral infections" (US Patent Application 15/729,635).

- Performed preclinical studies that demonstrate macrophage phenotype change from an immunosuppressive to a pro-inflammatory state and a synergistic effect on tumor growth reduction using the Company's doxorubicin-containing construct with an approved checkpoint inhibitor therapy.

- Appointed Malcolm G. Witter to the Company's Board of Directors. Mr. Witter brings decades of financial and corporate governance experience to the board.

- Entered into a Stock Purchase Agreement and Letter of Investment Intent with an existing investor, pursuant to which the Company issued to the investor 50,000 shares of newly-designated Series E Redeemable Convertible Preferred Stock (the "Series E Preferred Stock") for an aggregate purchase price of $5.0 million. The Series E Preferred Stock is convertible into a maximum of 2,173,913 shares of Common Stock.

Michael Rosol, Ph.D., Chief Medical Officer for Navidea, said, “The clinical research team is working diligently to advance the technology in key disease areas, with an emphasis on our RA program. We have completed all patients and all visits in our NAV3-31 Phase 2B trial and we are eagerly anticipating feedback from the FDA on our briefing package and design of the Phase 3 trial. We continue to prepare for initiation of this trial and have also opened up enrollment for the NAV3-32 Phase 2B trial comparing tilmanocept imaging to synovial tissue biopsy samples of RA patients. Concurrent with all of this, we have made exciting progress in our therapeutics pipeline and will continue to advance these towards the clinic.”

Financial Results

- Total net revenues for the fourth quarter 2020 were $219,000, compared to $119,000 for the same period in 2019. Total net revenues for the full year of 2020 were $914,000, compared to $651,000 for 2019. The increases were primarily due to increased grant revenue related to Small Business Innovation Research grants from the National Institutes of Health supporting Manocept™ development coupled with increased license revenue from net transitional sales in Europe.

- Research and development (“R&D”) expenses for the fourth quarter of 2020 were $1.3 million, compared to $1.7 million in the same period in 2019. R&D expenses for the full year of 2020 were $4.9 million, compared to $5.3 million in the same period in 2019. The decreases were primarily due to net decreases in drug project expenses, including decreased Manocept therapeutic development costs, decreased Manocept diagnostic development costs, and decreased Tc99m development costs, offset by increased NAV4694 development costs. The net decreases also included decreased regulatory consulting and travel expenses offset by increased employee compensation.

- Selling, general and administrative (“SG&A”) expenses for the fourth quarter of 2020 were $1.7 million, compared to $1.2 million in the same period in 2019. SG&A expenses for the full year of 2020 were $6.7 million, compared to $6.3 million in 2019. The net increases were primarily due to increased legal and professional services, employee compensation, European Medicines Agency annual fees for Lymphoseek, and franchise taxes, offset by decreased travel, depreciation and amortization, losses on disposal of assets, insurance, and investor relations services.

- Navidea’s net loss attributable to common stockholders for the fourth quarter of 2020 was $3.0 million, or $0.11 per share, compared to $2.8 million, or $0.15 per share, for the same period in 2019. Navidea’s net loss attributable to common stockholders for the full year of 2020 was $11.4 million, or $0.48 per share, compared to $10.9 million, or $0.76 per share, for 2019.

- Navidea ended the fourth quarter of 2020 with $2.7 million in cash and cash equivalents. Since December 31, 2020, the Company has received $7.9 million of cash related to the Series D and Series E Preferred Stock funding transactions. To date, the Company has received over $14 million of proceeds from the issuance of Series C, Series D and Series E Preferred stock.

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 2020 Earnings and Business Update Conference Call
Date:	Wednesday, March 24, 2021
Time:	5:00 p.m. (EDT)
U.S. & Canada Dial-in:	877-407-0312
International Dial-in:	+1 201-389-0899
Conference ID:	13714810
Webcast Link:	https://webcasts.eqs.com/navidbioph20210324/en

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 operating 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; the impact of the current coronavirus pandemic; 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, 2020 (unaudited)	December 31, 2019
Assets:		
Cash and cash equivalents	$ 2,670,495	$ 1,047,159
Other current assets	3,857,833	1,868,624
Non-current assets	1,229,690	1,235,123
Total assets	$ 7,758,018	$ 4,150,906
Liabilities and stockholders' equity (deficit):		
Current liabilities	$ 4,715,105	$ 3,819,551
Deferred revenue, non-current	700,000	700,000
Other liabilities	296,006	512,344
Total liabilities	5,711,111	5,031,895
Navidea stockholders' equity (deficit)	1,315,604	(1,612,292)
Noncontrolling interest	731,303	731,303
Total stockholders' equity (deficit)	2,046,907	(880,989)
Total liabilities and stockholders' equity (deficit)	$ 7,758,018	$ 4,150,906

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Twelve Months Ended	
	December 31, 2020 (unaudited)	December 31, 2019 (unaudited)	December 31, 2020 (unaudited)	December 31, 2019
Revenue	$ 219,251	$ 119,299	$ 915,013	$ 657,826
Cost of revenue	-	108	1,048	6,667
Gross profit	219,251	119,191	913,965	651,159
Operating expenses:				
Research and development	1,271,141	1,725,484	4,930,187	5,338,267
Selling, general and administrative	1,748,680	1,165,797	6,694,959	6,275,409
Total operating expenses	3,019,821	2,891,281	11,625,146	11,613,676
Loss from operations	(2,800,570)	(2,772,090)	(10,711,181)	(10,962,517)
Other income (expense):				
Interest income (expense), net	(1,478)	1,952	11,344	25,288
Other, net	(21,078)	(1,733)	(21,855)	(7,613)
Loss before income taxes	(2,823,126)	(2,771,871)	(10,721,692)	(10,944,842)
Benefit from (provision for) income taxes	-	-	-	(707)
Loss from continuing operations	(2,823,126)	(2,771,871)	(10,721,692)	(10,945,549)
Loss from discontinued operations, net of tax effect	-	-	-	(2,665)
Net loss	(2,823,126)	(2,771,871)	(10,721,692)	(10,948,214)
Loss (income) attributable to noncontrolling interest	1	(33)	-	(17)
Deemed dividend on Series C and Series D preferred stock beneficial conversion feature	(180,556)	-	(663,889)	-
Net loss attributable to common stockholders	$ (3,003,681)	$ (2,771,904)	$ (11,385,581)	$ (10,948,231)
Loss per common share (basic and diluted):				
Continuing operations	$ (0.11)	$ (0.15)	$ (0.48)	$ (0.76)
Attributable to common stockholders	$ (0.11)	$ (0.15)	$ (0.48)	$ (0.76)
Weighted average shares outstanding (basic and diluted)	26,724,753	18,283,512	23,896,001	14,393,360