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 23, 2022

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 23, 2022, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release regarding its consolidated financial results for the quarter and year-to-date ended December 31, 2021. A copy of the Company's March 23, 2022 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 23, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 23, 2022

By: */s/ Michael S. Rosol*
Michael S. Rosol, Ph.D.
Chief Medical Officer

Exhibit 99.1

Navidea Biopharmaceuticals Reports Fourth Quarter 2021 Financial Results

Conference Call to be held Wednesday, March 23, 2022 at 5:00 pm (EST)

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 year-to-date for the period ended December 31, 2021.

Alexander L. Cappello, Chair of Navidea's Board of Directors, said, "We remain focused on our mission of developing precision immunodiagnostic agents and immunotherapeutics to enhance patient care. We are confident that our strong management team, supported by our experienced and active Board of Directors, can continue to execute on our business plan and fulfill the vision we have for Navidea."

Fourth Quarter 2021 Highlights and Subsequent Events

- Continued to work on financing for the Company. We have engaged with an investment bank and options are being pursued.
- Initiated and enrolled into the Company's NAV3-33 Phase 3 trial in rheumatoid arthritis ("RA") titled "Evaluation of Tc 99m Tilmanocept Imaging for the Early Prediction of Anti-TNFα Therapy Response in Patients with Moderate to Severe Active Rheumatoid Arthritis."
- Continued enrollment into the Company's NAV3-32 Phase 2b trial comparing Tc99m tilmanocept imaging to histopathology of joints of patients with active RA. Eleven patients out of an originally estimated maximum of 24 based on subject pathotype are now enrolled with both imaging and biopsy performed.
- Completed enrollment in the Company's NAV3-35 Phase 2b study, "Development of a Normative Database for Rheumatoid Arthritis (RA) Imaging with Tc99m Tilmanocept."
- Completed the investigator-initiated Phase 2 trial being run at the Massachusetts General Hospital evaluating Tc99m tilmanocept uptake in atherosclerotic plaques of HIV-infected individuals. An abstract was presented at the Conference on Retroviruses and Opportunistic Infections in February 2022.
- Signed research agreement with the University of Pennsylvania evaluating Tc99m tilmanocept as a prognostic marker for glioblastoma.
- Signed a Letter of Intent with the image analysis company MIM Software, Inc., to be the Company's commercial partner for image quantification of Tc99m tilmanocept imaging in RA.
- Filed two new provisional patent applications. The first is related to new methods of attaching chemotherapeutics to the Manocept platform, and the second relates to maximizing target-tissue uptake and off-target competitive blocking. These have important implications for pipeline applications.

Michael Rosol, Ph.D., Chief Medical Officer for Navidea, said, “The clinical research team continues to work diligently to advance the technology in key disease areas, with an emphasis on our RA program. The NAV3-33 Phase 3 trial is enrolling, we continue to enroll into the NAV3-32 Phase 2b trial comparing tilmanocept imaging to synovial tissue biopsy samples of RA patients, and we have completed our normative database trial enrollment. Concurrent with all of this, we continue to make progress in our therapeutics pipeline, and we expect to keep advancing these towards the clinic.”

Financial Results

- Total net revenues for the fourth quarter of 2021 were $50,000, compared to $219,000 for the same period in 2020. Total net revenues for the full year of 2021 were $532,000, compared to $914,000 in 2020. The decrease was primarily due to decreased grant revenue related to Small Business Innovation Research grants from the National Institutes of Health supporting Manocept™ development and decreased royalty and license revenue from sales of Tc99m tilmanocept in Europe, offset by the partial recovery of debts previously written off in 2015 and receipt of reimbursement from Cardinal Health 414, LLC of certain R&D costs.

- Research and development (“R&D”) expenses for the fourth quarter of 2021 were $1.4 million, compared to $1.3 million in the same period in 2020. R&D expenses for the full year of 2021 were $5.1 million, compared to $4.9 million in 2020. The net increase during the year to date was primarily due to increased regulatory consulting, employee compensation, travel, recruiting and general office expenses, coupled with net increases in drug project expenses, including increased Manocept therapeutic and Tc99m tilmanocept development costs, offset by decreased Manocept diagnostic development costs.

- Selling, general and administrative (“SG&A”) expenses for the fourth quarter of 2021 were $2.3 million, compared to $1.7 million in the same period in 2020. SG&A expenses for the full year of 2021 were $7.5 million, compared to $6.7 million in 2020. The net increase during the year to date was primarily due to separation expenses related to the resignation of our former Chief Executive Officer, coupled with increased consulting services related to European distribution of Tc99m tilmanocept, director compensation related to additional board members and increased board compensation rates, insurance costs, losses on the abandonment of certain intellectual property, recruiting fees, travel and general office expenses, offset by decreases in legal and professional services, employee compensation, investor relations costs, European annual registration fees, facilities costs and franchise taxes.

- Navidea’s net loss attributable to common stockholders for the fourth quarter of 2021 was $3.7 million, or $0.12 per share, compared to $3.0 million, or $0.11 per share, for the same period in 2020. Navidea’s net loss attributable to common stockholders for the full year of 2021 was $11.7 million, or $0.40 per share, compared to $11.4 million, or $0.48 per share, in 2020.

- Navidea ended the fourth quarter of 2021 with $4.2 million in cash and cash equivalents.

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. Dr. Michael Rosol, Chief Medical Officer, and Erika Eves, Vice President of Finance and Administration, will host the call and webcast to discuss the financial results and provide an update on recent developments and clinical progress. Management will be available to answer questions live immediately following the earnings announcement and prepared remarks portion of the call.

To participate in the call and webcast, please refer to the information below:

Event: Fourth Quarter 2021 Earnings Conference Call and Business Update

Date: Wednesday, March 23, 2022

Time: 5:00 p.m. (EDT)

U.S. & Canada Dial-In: 877-407-0312

International Dial-In: +1 201-389-0899

Conference ID: 13726541

Webcast Link: https://www.webcast-eqs.com/navidbioph20220323/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.

Investor Relations Contact

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NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2021 (unaudited)	December 31, 2020
Assets:		
Cash and cash equivalents	$ 4,230,865	$ 2,670,495
Other current assets	1,152,420	3,857,833
Non-current assets	1,261,548	1,229,690
Total assets	$ 6,644,833	$ 7,758,018
Liabilities and stockholders' equity:		
Current liabilities	$ 5,299,802	$ 4,715,105
Deferred revenue, non-current	700,000	700,000
Other liabilities	20,288	296,006
Total liabilities	6,020,090	5,711,111
Navidea stockholders' (deficit) equity	(106,556)	1,315,604
Noncontrolling interest	731,299	731,303
Total stockholders' equity	624,743	2,046,907
Total liabilities and stockholders' equity	$ 6,644,833	$ 7,758,018

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Twelve Months Ended	
	December 31, 2021 (unaudited)	December 31, 2020 (unaudited)	December 31, 2021 (unaudited)	December 31, 2020
Revenue	$ 50,348	$ 219,251	$ 531,513	$ 915,013
Cost of revenue	-	-	-	1,048
Gross profit	50,348	219,251	531,513	913,965
Operating expenses:				
Research and development	1,372,314	1,271,141	5,141,910	4,930,187
Selling, general and administrative	2,317,285	1,748,680	7,450,015	6,694,959
Total operating expenses	3,689,599	3,019,821	12,591,925	11,625,146
Loss from operations	(3,639,251)	(2,800,570)	(12,060,412)	(10,711,181)
Other income (expense):				
Interest income (expense), net	(1,938)	(1,478)	(6,361)	11,344
Gain on extinguishment of debt	-	-	366,000	-
Other, net	(10,974)	(21,077)	(14,115)	(21,854)
Loss before income taxes	(3,652,163)	(2,823,125)	(11,714,888)	(10,721,691)
Provision for income taxes	-	-	(16,043)	-
Net loss	(3,652,163)	(2,823,125)	(11,730,931)	(10,721,691)
Loss attributable to noncontrolling interest	-	1	4	-
Deemed dividend on Series C and Series D preferred stock beneficial conversion feature	-	(180,556)	-	(663,889)
Net loss attributable to common stockholders	$ (3,652,163)	$ (3,003,680)	$ (11,730,927)	$ (11,385,580)
Loss attributable to common stockholders per common shares (basic and diluted)	$ (0.12)	$ (0.11)	$ (0.40)	$ (0.48)
Weighted average shares outstanding (basic and diluted)	30,161,825	26,724,753	29,343,542	23,896,001