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 10, 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 November 10, 2021, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release regarding its consolidated financial results for the quarter and year-to-date ended September 30, 2021. A copy of the Company's November 10, 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 November 10, 2021.
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: November 10, 2021

By: /s/ Michael S. Rosol
Michael S. Rosol, Ph.D.
Senior Vice President and
Chief Medical Officer

Exhibit 99.1

Navidea Biopharmaceuticals Reports Third Quarter 2021 Financial Results

Conference Call to be held Wednesday, November 10, 2021 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 third quarter and year-to-date for the period ended September 30, 2021.

Alexander L. Cappello, Chair of Navidea's Board of Directors, said, "During this time of transition in our leadership, 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 execute on our business plan and fulfill the vision we have for Navidea."

Third Quarter 2021 Highlights and Subsequent Events

- Submitted draft Clinical Study Report to the U.S. Food and Drug Administration ("FDA") for the Company's completed NAV3-31 Phase 2b study in Rheumatoid Arthritis ("RA") as part of the briefing package for an End-of-Phase 2 Type B meeting.
- Held an End-of-Phase 2 Type B meeting with the FDA to discuss the Company's ongoing program in RA and advancement to the pivotal Phase 3 trial September 1, 2021 via conference call.
- Opened a third site for enrollment in the Company's NAV3-32 Phase 2b trial comparing Tc99m tilmanocept imaging to histopathology of joints of patients with active RA. Enrollment is ongoing and biopsy specimens are in the process of analysis.
- Nearly completed enrollment in the Company's NAV3-35 Phase 2b study, "Development of a Normative Database for Rheumatoid Arthritis (RA) Imaging with Tc99m Tilmanocept." Arm 1 is 4 subjects from completion and Arm 2 is fully enrolled.
- Completed enrollment and imaging data analysis 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.
- Converted the provisional patent application "Synthesis of Uniformly Defined Molecular Weight Mannosylated Dextrans and Derivatives Thereof" to an A1 application on July 9, 2021.
- Appointed Alexander L. Cappello and John K. Scott, Jr. to the Board of Directors. Mr. Scott is the Company's largest shareholder and Mr. Cappello brings over 30 years of banking and public board experience to the Company.
- Appointed Thomas F. Farb and Agnieszka Winkler to the Board of Directors. Mr. Farb has over three decades of experience as an investor in and senior executive of numerous life science and information technology companies both in the U.S. and internationally, and Ms. Winkler has extensive professional and board experience with start-up, mid-cap and Fortune 500 companies.

- Appointed Michel Mikhail, Ph.D. as Chief Regulatory Officer of Navidea. Dr. Mikhail brings more than 30 years of experience in the pharmaceutical industry and a track record of achievement in research and development ("R&D") and international regulatory affairs at large multinational research-based pharmaceutical companies.

- Jed A. Latkin resigned as Chief Executive Officer, Chief Financial Officer and Chief Operating Officer of the Company and as a member of the Company's Board of Directors. The Company's Board of Directors has established an Executive Leadership Committee to lead the Company on an interim basis while its next CEO is identified. The Executive Leadership Committee includes Michael Rosol, Ph.D., the Company's Senior Vice President and Chief Medical Officer; Erika Eves, the Company's Vice President of Finance and Administration; and Jeffrey Smith, the Company's Vice President of Operations. The Executive Leadership Committee will work with a newly established Board Oversight Committee, consisting of independent directors Alexander Cappello, Thomas Farb and John K. Scott, Jr.

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. We have had a constructive dialogue with the FDA over the results of the completed NAV3-31 Phase 2b trial as well as our proposed plan for the NAV3-33 Phase 3 study, and we continue to prepare for initiation of this trial. We also have active enrollment in the NAV3-32 Phase 2b trial comparing tilmanocept imaging to synovial tissue biopsy samples of RA patients, and have near full enrollment in the NAV3-35 normative database study. Concurrent with all of this, we continue to make exciting progress in our therapeutics pipeline, and we expect to keep advancing these towards the clinic."

Financial Results

- Total net revenues for the third quarter of 2021 were $96,000, compared to $268,000 for the same period in 2020. Total net revenues for the first nine months of 2021 were $481,000, compared to $695,000 for the same period 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, offset by receipt of reimbursement from Cardinal Health 414, LLC of certain R&D costs and the partial recovery of debts previously written off in 2015.

- R&D expenses for the third quarter of 2021 were $1.0 million, compared to $1.4 million in the same period in 2020. R&D expenses for the first nine months of 2021 were $3.8 million, compared to $3.7 million in the same period in 2020. The net increase during the year to date was primarily due to net increases in drug project expenses, including increased Manocept therapeutic and Tc99m tilmanocept development costs, offset by decreased Manocept diagnostic development costs. The net increase in research and development expenses also included increased regulatory consulting and general office expenses offset by decreased employee compensation including incentive-based awards.

- Selling, general and administrative ("SG&A") expenses for the third quarter of 2021 were $1.5 million, compared to $1.8 million in the same period in 2020. SG&A expenses for the first nine months of 2021 were $5.1 million, compared to $4.9 million in the same period in 2020. The net increase during the year to date was primarily due to increased consulting services related to preparation for European distribution of Tc99m tilmanocept, increased employee compensation including incentive-based awards, increased insurance cost, increased director fees related to additional board members, increased travel costs, increased European license fees, increased general office expenses, and a loss on the third quarter 2021 abandonment of certain intellectual property, offset by decreased legal and professional services, decreased investor relations costs, decreased facilities costs and decreased franchise taxes.

- Navidea's net loss attributable to common stockholders for the third quarter of 2021 was $2.4 million, or $0.08 per share, compared to $3.3 million, or $0.13 per share, for the same period in 2020. Navidea's net loss attributable to common stockholders for the first nine months of 2021 was $8.1 million, or $0.28 per share, compared to $8.4 million, or $0.37 per share, for the same period in 2020.

- Navidea ended the third quarter of 2021 with $7.2 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. As noted in the Company's press release dated November 3, 2021, questions will not be taken during the conference call. Previously-submitted questions will be read aloud and answered during the Q&A portion of the conference call, and we may also respond to questions on an individual basis or by posting answers on our website after the call.

Event: Third Quarter 2021 Earnings Conference Call and Business Update

Date: Wednesday, November 10, 2021

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

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

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

Conference ID: 13724382

Webcast Link: https://webcast-eqs.com/navidbioph20211110/en

A live audio webcast of the conference call will 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 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

Navidea Biopharmaceuticals, Inc.
Jeff Smith
Vice President of Operations
614-822-2365
jsmith@navidea.com

NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2021 (unaudited)	December 31, 2020
Assets:		
Cash and cash equivalents	$ 7,176,211	$ 2,670,495
Other current assets	480,749	3,857,833
Non-current assets	1,302,586	1,229,690
Total assets	$ 8,959,546	$ 7,758,018
Liabilities and stockholders' equity:		
Current liabilities	$ 4,096,516	$ 4,715,105
Deferred revenue, non-current	700,000	700,000
Other liabilities	29,036	296,006
Total liabilities	4,825,552	5,711,111
Navidea stockholders' equity	3,402,695	1,315,604
Noncontrolling interest	731,299	731,303
Total stockholders' equity	4,133,994	2,046,907
Total liabilities and stockholders' equity	$ 8,959,546	$ 7,758,018

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Nine Months Ended	
	September 30, 2021 (unaudited)	September 30, 2020 (unaudited)	September 30, 2021 (unaudited)	September 30, 2020 (unaudited)
Revenue	$ 96,382	$ 268,389	$ 481,165	$ 695,762
Cost of revenue	-	82	-	1,048
Gross profit	96,382	268,307	481,165	694,714
Operating expenses:				
Research and development	1,048,786	1,377,998	3,769,596	3,659,046
Selling, general and administrative	1,469,375	1,788,934	5,132,730	4,946,279
Total operating expenses	2,518,161	3,166,932	8,902,326	8,605,325
Loss from operations	(2,421,779)	(2,898,625)	(8,421,161)	(7,910,611)
Other income (expense):				
Interest income (expense), net	(2,814)	(149)	(4,423)	12,822
Gain on extinguishment of debt	-	-	366,000	-
Other, net	2,800	(564)	(3,141)	(777)
Loss before income taxes	(2,421,793)	(2,899,338)	(8,062,725)	(7,898,566)
Provision for income taxes	(16,043)	-	(16,043)	-
Net loss	(2,437,836)	(2,899,338)	(8,078,768)	(7,898,566)
Loss (income) attributable to noncontrolling interest	1	-	4	(1)
Deemed dividend on Series C and Series D preferred stock beneficial conversion feature	-	(405,555)	-	(483,333)
Net loss attributable to common stockholders	$ (2,437,835)	$ (3,304,893)	$ (8,078,764)	$ (8,381,900)
Loss attributable to common stockholders per common share (basic and diluted)	$ (0.08)	$ (0.13)	$ (0.28)	$ (0.37)
Weighted average shares outstanding (basic and diluted)	30,122,549	25,843,732	29,067,784	22,946,201