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 21, 2023

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 exchange on which registered
Common Stock	NAVB	NYSE American
Preferred Stock Purchase Rights	N/A	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 21, 2023, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release regarding its consolidated financial results for the quarter and year ended December 31, 2022. A copy of the Company's March 21, 2023 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 21, 2023.
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 21, 2023

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

Exhibit 99.1

Navidea Biopharmaceuticals Reports Fourth Quarter 2022 Financial Results

Conference Call to be held Tuesday, March 21, 2023 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 three-month and twelve-month periods ended December 31, 2022.

Fourth Quarter 2022 Highlights and Subsequent Events

- Continued enrollment 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." The Company announced enrollment of the 50th participant in NAV3-33 in November 2022.

- Presented positive results from the Company's completed NAV3-31 Phase 2B clinical study as well as the positive preliminary results of its ongoing NAV3-32 Phase 2B study at the Annual Meeting of the American College of Rheumatology held November 10-14, 2022 in Philadelphia, PA.

- Presented results from the Company's ongoing preclinical studies evaluating targeted immunotherapy for cancer based on the Manocept platform at the 37th Annual Meeting of the Society for Immunotherapy of Cancer held November 8-12, 2022 in Boston, MA. Results demonstrate efficacy of new constructs at macrophage phenotype change and in a mouse tumor model.

- Received notification of issuance of U.S. Patent No. 11,590,236 from the United States Patent and Trademark Office for the Company's application titled, "Compositions And Methods For Altering Macrophage Phenotype." This patent covers the ability of the Company's constructs to stimulate an immune response against tumors through targeted delivery of payloads that change the nature of macrophages to make them more proinflammatory. Efficacy of these constructs has been demonstrated in preclinical studies.

- Received notifications of issuance for Company patent applications in the state of Israel for the application titled, "Compounds And Compositions For Treating Leishmaniasis And Methods Of Diagnosis And Treating Using Same" (State of Israel Patent No. 265830; U.S. counterpart application issued in June 2022 as U.S. Patent No. 11,369,680) and in Canada for Canadian Patent No. 2,955,441 titled, "Compositions, Methods, and Kits for Diagnosing and Treating CD206 Expressing Cell-Related Disorders." (U.S. counterpart application issued in October 2020 as U.S. Patent No. 10,806,803.)

- Filed a provisional patent application describing a different chemical linker used in a critical step in the Manocept synthesis process, one which is more stable and easier to manufacture than the current linker that is used. This could have significant implications for both diagnostic and therapeutic applications.

- Converted several provisional patent applications to reviewable patent applications in the U.S. and Patent Cooperation Treaty countries.

- The Company's work performed in collaboration with investigators from the University of Alabama at Birmingham and titled, "In vivo Assessment of the Impact of Molecular Weight on Constructs of 68Ga-DOTA-Manocept in a Syngeneic Mouse Tumor Model" was published in the journal *Molecular Imaging and Biology* (2023 Mar. 7. Online ahead of print.).

Michael Rosol, Ph.D., Chief Medical Officer for Navidea, said, "The Phase 3 and Phase 2B trials in RA continue to enroll and advance towards completion. The company continues to work diligently to advance its technology in key disease areas, with an emphasis on our RA program. We are pleased with the preliminary positive results from the NAV3-32 study that thus far support our hypothesis that we can distinguish between fibroid and non-fibroid pathotypes of RA with a single scan." Dr. Rosol continued, "Concurrent with all of this, we continue to make progress in our therapeutics pipeline, and we expect to keep advancing these towards IND filing and clinical trials. The promising results to date of our RA trials and the preclinical studies of our therapeutics demonstrate the significant potential of our macrophage-targeting Manocept platform."

Financial Results

- Total revenues for the three-month period ended December 31, 2022 were approximately $1,000, compared to $50,000 for the same period in 2021. Total revenues for the year ended December 31, 2022 were $66,000, compared to $532,000 for the same period in 2021. The decrease was primarily due to the 2021 partial recovery of debts previously written off in 2015, the 2021 receipt of reimbursement from Cardinal Health 414, LLC of certain research and development ("R&D") costs, decreased grant revenue related to Small Business Innovation Research grants from the National Institutes of Health supporting Manocept development, and decreased license revenue from transitional sales of Tc99m tilmanocept in Europe.

- Research and development expenses for the three-month period ended December 31, 2022 were $1.9 million, compared to $1.4 million for the same period in 2021. R&D expenses for the year ended December 31, 2022 were $6.0 million, compared to $5.1 million for the same period in 2021. The year-over-year increase was primarily due to increased drug project expenses and increased employee compensation including incentive-based awards, offset by decreased regulatory consulting expenses.

- Selling, general and administrative ("SG&A") expenses for the three-month period ended December 31, 2022 were $1.3 million, compared to $2.3 million for the same period in 2021. SG&A expenses for the year ended December 31, 2022 were $8.0 million, compared to $7.5 million for the same period in 2021. Following the ruling by the Texas Court in August 2022, the Company recorded $2.6 million of legal fees in SG&A pursuant to the CRG judgment. The year-over-year increase was also due to increases in insurance and depreciation and amortization, partially offset by decreases in employee compensation including fringe benefits and incentive-based awards, expenses related to European operations, travel, legal and professional services, investor relations and shareholder services, general office expenses, facilities costs, losses on the abandonment of certain intellectual property and franchise taxes.

- Navidea's net loss attributable to common stockholders for the three-month period ended December 31, 2022 was $3.5 million, or $0.11 per share, compared to $3.7 million, or $0.12 per share, for the same period in 2021. Navidea's net loss attributable to common stockholders for the year ended December 31, 2022 was $17.2 million, or $0.56 per share, compared to $11.7 million, or $0.40 per share, for the same period in 2021.

- Navidea ended the fourth quarter of 2022 with approximately $2.0 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 2022 Earnings Conference Call and Business Update

Date: Tuesday, March 21, 2023

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

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

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

Conference ID: 13736745

Webcast Link: https://www.webcast-eqs.com/navidbioph20230321/en

A live audio webcast of the conference call will also 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

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NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2022 (unaudited)	December 31, 2021
Assets:		
Cash and cash equivalents	$ 1,995,860	$ 4,230,865
Other current assets	1,208,084	1,152,420
Non-current assets	1,167,662	1,261,548
Total assets	$ 4,371,606	$ 6,644,833
Liabilities and stockholders' equity:		
Current liabilities	$ 9,941,889	$ 5,299,802
Note payable to related party, net of discount	1,871,715	-
Deferred revenue, non-current	700,000	700,000
Other liabilities	1,312	20,288
Total liabilities	12,514,916	6,020,090
Navidea stockholders' (deficit) equity	(8,435,828)	(106,556)
Noncontrolling interest	292,518	731,299
Total stockholders' equity	(8,143,310)	624,743
Total liabilities and stockholders' equity	$ 4,371,606	$ 6,644,833

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Twelve Months Ended	
	December 31, 2022 (unaudited)	December 31, 2021 (unaudited)	December 31, 2022 (unaudited)	December 31, 2021
Revenue	$ 610	$ 50,348	$ 65,652	$ 531,513
Cost of revenue	50,036	-	184,947	-
Gross (loss) profit	(49,426)	50,348	(119,295)	531,513
Operating expenses:				
Research and development	1,890,113	1,372,314	5,969,774	5,141,910
Selling, general and administrative	1,258,681	2,317,285	7,961,826	7,450,015
Total operating expenses	3,148,794	3,689,599	13,931,600	12,591,925
Loss from operations	(3,198,220)	(3,639,251)	(14,050,895)	(12,060,412)
Other (expense) income:				
Interest (expense) income, net	(245,620)	(1,938)	(1,098,322)	(6,361)
Gain on extinguishment of debt	-	-	-	366,000
Other, net	(38,788)	(10,974)	(27,939)	(14,115)
Loss before income taxes	(3,482,628)	(3,652,163)	(15,177,156)	(11,714,888)
Provision for income taxes	-	-	-	(16,043)
Net loss	(3,482,628)	(3,652,163)	(15,177,156)	(11,730,931)
Net (income) loss attributable to noncontrolling interest	(1)	-	3	4
Net loss attributable to Navidea and subsidiaries	(3,482,629)	(3,652,163)	(15,177,153)	(11,730,927)
Deemed dividend on preferred stock exchanged for Units	-	-	(2,037,886)	-
Net loss attributable to common stockholders	$ (3,482,629)	$ (3,652,163)	$ (17,215,039)	$ (11,730,927)
Loss attributable to common stockholders per common shares (basic and diluted)	$ (0.11)	$ (0.12)	$ (0.56)	$ (0.40)
Weighted average shares outstanding (basic and diluted)	32,376,900	30,161,825	30,901,869	29,343,542