**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) May 12, 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 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 May 12, 2022, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release regarding its consolidated financial results for the quarter ended March 31, 2022. A copy of the Company's May 12, 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 May 12, 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: May 12, 2022

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

**Exhibit 99.1**

# Navidea Biopharmaceuticals Reports First Quarter 2022 Financial Results

*Conference Call to be held Thursday, May 12, 2022 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 first quarter for the period ended March 31, 2022.

**First 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."
- Announced positive preliminary results from the Company's ongoing NAV3-32 Phase 2b trial comparing Tc99m tilmanocept imaging to histopathology of joints of patients with active RA. Two non-overlapping classes that align with the fibroid and non-fibroid histological pathotypes were identified, supporting the hypothesis that these classes can be identified by Tc99m tilmanocept imaging.
- Received regulatory approval for Lymphoaim in India.
- Filed two new provisional patent applications. Both are related to new methods to maximize target-tissue uptake and reduce off-target binding. These have important implications for pipeline applications.
- Received Notices of Allowed Claims for patent applications in the United States, Israel, Australia, and Japan.
- Closed on a $1.5 million bridge loan from the Company's Vice Chair of the Board of Directors, John K. Scott, Jr.
- Adopted a plan designed to protect the Company's net operating loss and tax credit carryforwards.
- Continued to work on financing for the Company. We have engaged with multiple investment banks and options are being pursued.
- Settled litigation with Platinum-Montaur Life Sciences LLC.

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 and NAV3-32 Phase 2b trials continue to enroll. 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 the clinic."

**Financial Results**

- Total net revenues for the first quarter of 2022 were $0, compared to $124,000 for the same period in 2021. The decrease was primarily due to the 2021 partial recovery of debts previously written off in 2015 coupled with recognition of license revenue related to transitional sales in Europe in 2021.

- Research and development expenses for the first quarters of both 2022 and 2021 were $1.2 million. Decreases in Manocept diagnostic and Tc99m tilmanocept development costs and decreased regulatory consulting expenses were offset by increased Manocept therapeutic development costs, employee compensation including fringe benefits and incentive-based awards, and recruiting expenses.

- Selling, general and administrative expenses for the first quarter of 2022 were $1.8 million, compared to $2.2 million in the same period in 2021. Decreases in employee compensation including fringe benefits and incentive-based awards, legal and professional services, general office expenses, travel, franchise taxes and investor relations costs were offset by increased director fees, losses on the abandonment of certain intellectual property and increased insurance costs.

- Navidea's net loss attributable to common stockholders for the first quarter of 2022 was $3.0 million, or $0.10 per share, compared to $3.0 million, or $0.11 per share, for the same period in 2021.

- Navidea ended the first quarter of 2022 with $1.2 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: First Quarter 2022 Earnings Conference Call and Business Update

Date: Thursday, May 12, 2022

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

U.S. & Canada Dial-In: 800-285-6670

International Dial-In: +1 713-481-1320

Conference ID: 512400

Webcast Link: https://www.webcast-eqs.com/navidbioph20220512/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**

| | March 31, 2022 (unaudited) | December 31, 2021 |
|---|---|---|
| Assets: | | |
| Cash and cash equivalents | $ 1,217,114 | $ 4,230,865 |
| Other current assets | 1,106,276 | 1,152,420 |
| Non-current assets | 1,278,735 | 1,261,548 |
| Total assets | $ 3,602,125 | $ 6,644,833 |
| | | |
| Liabilities and stockholders' (deficit) equity: | | |
| Current liabilities | $ 4,900,268 | $ 5,299,802 |
| Deferred revenue, non-current | 800,000 | 700,000 |
| Other liabilities | 11,299 | 20,288 |
| Total liabilities | 5,711,567 | 6,020,090 |
| Total stockholders' deficit | (2,401,960) | (106,556) |
| Noncontrolling interest | 292,518 | 731,299 |
| Navidea stockholders' (deficit) equity | (2,109,442) | 624,743 |
| Total liabilities and stockholders' (deficit) equity | $ 3,602,125 | $ 6,644,833 |

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

| | Three Months Ended | |
|---|---|---|
| | March 31, 2022 (unaudited) | March 31, 2021 (unaudited) |
| Revenue | $ - | $ 123,737 |
| Cost of revenue | - | - |
| Gross profit | - | 123,737 |
| Operating expenses: | | |
| Research and development | 1,169,254 | 1,222,754 |
| Selling, general and administrative | 1,810,029 | 2,230,745 |
| Total operating expenses | 2,979,283 | 3,453,499 |
| Loss from operations | (2,979,283) | (3,329,762) |
| Other income (expense): | | |
| Interest expense, net | (3,662) | (2,875) |
| Gain on extinguishment of debt | - | 366,000 |
| Other, net | (4,299) | (255) |
| Net loss | (2,987,244) | (2,966,892) |
| Loss attributable to noncontrolling interest | 2 | 2 |
| Loss attributable to common stockholders | $ (2,987,242) | $ (2,966,890) |
| | | |
| Loss attributable to common stockholders per common share (basic and diluted) | $ (0.10) | $ (0.11) |
| Weighted average shares outstanding (basic and diluted) | 30,207,746 | 28,066,296 |