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 21, 2020

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))

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. ☐

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	NAVB	NYSE American

Item 8.01 Other Events.

On May 21, 2020, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release announcing the results of its second interim analysis of its Phase 2B Study in rheumatoid arthritis. A copy of the Company's May 21, 2020 press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	*Exhibit Description*
99.1	Press Release dated May 21, 2020

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 21, 2020

By: */s/ Jed A. Latkin*
Jed A. Latkin
Chief Executive Officer, Chief Operating Officer and
Chief Financial Officer

Exhibit 99.1

Navidea Biopharmaceuticals Announces Positive Results ofSecond Interim Analysis of Ongoing Phase 2B Study in Rheumatoid Arthritis

Conference Call to be held Thursday, May 21, 2020 at 5:30 pm EDT

Data Support Hypothesis that Tc99m Tilmanocept Imaging Can Provide Early Indicator of Treatment Response

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, is pleased to announce positive preliminary results from the Company's second interim analysis of its ongoing NAV3-31 Phase 2B study. Analysis demonstrates that these interim data further corroborate Navidea's hypotheses that Tc99m tilmanocept imaging can provide robust, quantitative imaging in healthy controls and in patients with active rheumatoid arthritis ("RA"), and that this imaging can provide an early indicator of treatment efficacy in patients with active RA.

Navidea's NAV3-31 Phase 2B trial titled "Evaluation of the Precision and Sensitivity of Tilmanocept Uptake Value (TUV) on Tc99m Tilmanocept Planar Imaging" has three arms: Arm 1 consists of healthy subjects, Arm 2 is comprised of patients with active, moderate-to-severe RA who are on stable therapy, and Arm 3 is a pilot arm of the upcoming Phase 3 trial assessing the ability of Tc99m tilmanocept to provide an early indicator of efficacy of anti-tumor necrosis factor ("TNF") alpha treatment in RA patients.

This second interim analysis was designed to examine data from Arm 3 of the study in order to evaluate the magnitude of change of Tc99m tilmanocept signal localized to RA-involved joints in patients before and after treatment with an anti-TNF alpha therapy as well as to examine whether this change in localization, if any, can serve as an early, quantifiable predictor of treatment efficacy.

A total of 15 subjects with active moderate-to-severe RA were included in this interim analysis, each of which was set to begin a new or first-time treatment regimen with an anti-TNF alpha therapy. Whole body and hand/wrist planar gamma camera images were obtained at baseline prior to initiation of new treatment, again at 5 weeks post therapy initiation, and then again at 12 weeks on 8 of the 15 subjects. The remaining 7 subjects had received baseline and 5-week scans only at the time of this analysis. A panel of established clinical assessments was performed at each time point as well, in order to compare imaging results with clinical standards over the 12-week time course. Results of the preliminary analysis demonstrate:

- Tc99m tilmanocept imaging from baseline to week 5 was predictive of clinical outcome at 12 weeks in 7 out of 8 subjects with 12-week clinical assessment available at the time of the interim analysis. The one subject who did not demonstrate concordance of signal quantification and clinical assessment had undergone a change in treatment regime while enrolled in the trial that may have impacted the trajectory of the clinical response.
- Combined data from all 15 subjects in Arm 3 suggest a wide dynamic range of more than one order of magnitude (>10-fold) for calculated global Tc99m tilmanocept uptake values in joints with RA-involved inflammation.

- In the subjects with 12-week follow up data available, global Tc99m tilmanocept signals declined by an average of 58% from baseline to week 5 in those who responded significantly to anti-TNF alpha treatment by week 12. In those subjects who did not have a significant clinical response to anti-TNF alpha treatment by week 12, Tc99m tilmanocept signals increased by an average of 79% from baseline to 5 weeks. These preliminary results indicate that marked changes in Tc99m tilmanocept global uptake values by week 5 are in agreement with clinical efficacy evaluations made at week 12 of treatment.
- The wide dynamic range of global Tc99m tilmanocept signal readout combined with the low variability of imaging signal quantification established in Arms 1 and 2 of this trial are supportive of the idea that clinically meaningful changes in signal localization can be detected.

These interim data are supportive of Navidea's hypotheses that Tc99m tilmanocept imaging can provide quantifiable imaging assessment of RA-involved joints that enables early prediction of clinical response as well as longitudinal monitoring of clinical status.

Michael Rosol, Chief Medical Officer for Navidea, said, "We are encouraged by these interim results, which are in line with our hypotheses, support the continuation of the current Phase 2B study, and will be fundamental to speaking with the FDA about moving forward into the Phase 3 trial later this year." Dr. Rosol continued, "We are excited that we are on track to possibly providing rheumatologists and those suffering with RA a noninvasive, quantifiable, early indicator of whether or not an anti-TNF alpha treatment is working. This could bring enormous benefit to these patients by assisting physicians in putting them on the right course of treatment earlier than would otherwise be possible today."

Jed Latkin, Navidea's Chief Executive Officer, said, "I am once again very pleased that the interim results of our ongoing Phase 2B study are so encouraging. These data support our belief that Tc99m tilmanocept imaging has the potential to provide an early and accurate indication of treatment effectiveness to rheumatologists, allowing them to tailor effective treatment regimens for RA patients. We are looking forward to continuing our progress into a Phase 3 study."

RA is a chronic disease affecting over 1.3 million Americans and as much as 1% of the worldwide population[1]. If the product is successfully developed, Navidea would expect to play a major role in the management of RA patients worldwide.

Conference Call Details

Investors and the public are invited to dial into the conference call through the information listed below, or participate via the audio webcast on the company website, www.navidea.com. Participants who would like to ask questions during the question and answer session will be prompted by the moderator, who will provide instructions.

Event:	Results of Interim Analysis of Phase 2B Study in Rheumatoid Arthritis
Date:	Thursday, May 21, 2020
Time:	5:30 p.m. (EDT)
U.S. & Canada Dial-in:	877-407-0312
International Dial-in:	+1-201-389-0899
Conference ID:	13704352
Webcast Link:	https://78449.themediaframe.com/dataconf/productusers/navidea/mediaframe/38396/indexl.html

Reference
1. https://www.rheumatoidarthritis.org/ra/facts-and-statistics/

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 our current studies and potential results, FDA approval process, ability to provide rheumatologists and those suffering from RA with expected benefits, the accuracy and timing of our imaging as an indication of treatment effectiveness, the use of our imaging as part of treatment for RA patients, our ability to progress into a Phase 3 study, our ability to successfully develop products, and the role of Navidea in the management of RA worldwide. 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.

References and links to websites have been provided as a convenience, and the information contained on such websites is not incorporated by reference into this press release. Navidea is not responsible for the contents of third-party websites.

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