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)	October 29, 2019

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 October 29, 2019, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release announcing the results of its first interim analysis of its Phase 2B Study in rheumatoid arthritis. A copy of the Company's October 29, 2019 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 October 29, 2019.

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: October 29, 2019

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 of First Interim Analysis of Ongoing Phase 2B Study in Rheumatoid Arthritis

Data Demonstrated Quantitative Repeatability and Stability of Signal

Company Continues to Enroll Subjects as Planned to Complete the Phase 2B and Prepare for the Upcoming Phase 3 Trial

DUBLIN, Ohio — (BUSINESS WIRE) —October 29, 2019 — 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 results from the Company's first interim analysis of its ongoing NAV3-31 Phase 2B study. Analysis demonstrates that these interim data support Navidea's hypotheses that Tc 99m Tilmanocept imaging can provide robust, quantitative imaging in healthy controls and in patients with active rheumatoid arthritis ("RA") and that this imaging is stable, reproducible, and can define joints with and without RA-involved inflammation.

Navidea's NAV3-31 Phase 2B trial titled "Evaluation of the Precision and Sensitivity of Tilmanocept Uptake Value (TUV) on Tc 99m Tilmanocept Planar Imaging" has three arms: Arm 1 consists of healthy subjects, Arm 2 is comprised of patients with active, moderate-to-severe rheumatoid arthritis (RA) who are on stable therapy, and Arm 3 is a pilot arm of the upcoming Phase 3 trial assessing the ability of Tc 99m tilmanocept to provide an early indicator of efficacy of anti-TNF alpha treatment in RA patients.

This interim analysis was designed to examine data from Arms 1 and 2 of the study in order to confirm the repeatability, reproducibility, and stability of Tc 99m tilmanocept imaging and further establish the quantitative determinants of healthy joints vs. those with RA-involved inflammation. A total of 30 subjects were included — 18 healthy controls and 12 patients with RA. Whole body and hand/wrist planar gamma camera images were obtained at multiple time points within the same day (both Arms 1 and 2) and on an additional day (Arm 2) to assess imaging stability and variability, which are measures of any change from one image set to the next and from one day to another.

Image sets (whole body and hand/wrist) acquired on the same day at multiple time points demonstrated quantitative repeatability and stability of signal. Importantly, images from patients with active RA show the same localization patterns on images taken a week apart. There was notable agreement between qualitative and quantitative assessment of joint-specific localization across all time points. Data gathered from this interim analysis along with the remainder of NAV3-31 Arms 1 and 2 provide the necessary input to establish quantitative "cut points" to differentiate between joints with and without the inflammation typically seen in RA. These data will also serve to establish the quantitative metrics to enable the detection of change in disease status in patients with RA, in order to determine whether or not a prescribed therapy is having an effect.

Michael Rosol, Chief Medical Officer for Navidea, said, "These results support our hypotheses for Arms 1 and 2 of this trial and are key for the path forward to the Phase 3. The demonstration that Tc 99m tilmanocept imaging is stable and has low variability enables us to proceed with confidence in testing our hypothesis that this can be an early indicator of therapeutic efficacy in these patients." Dr. Rosol continued, "With these exciting results in hand, we continue to enroll subjects as planned to complete this Phase 2B and prepare for the upcoming Phase 3."

Jed Latkin, Navidea's Chief Executive Officer, said, "I am very pleased that the results of this interim analysis are so encouraging. It reaffirms that we are heading in the right direction with our clinical trial pipeline in rheumatoid arthritis. I look forward to continuing this momentum into the Phase 3."

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 a conference call through the information listed below, or participate via the audio webcast on the company website. 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 Conference Call
Date:	Tuesday, October 29, 2019
Time:	5:00 p.m. (EDT)
U.S. & Canada Dial-in:	877-407-0312
International Dial-in:	+1 201-389-0899
Conference ID:	13696293

Webcast Link: https://webcasts.eqs.com/navidbioph20191029/en

The recorded conference call can be replayed and will be available for 90 days following the call, available on the investor relations page of Navidea's corporate website at www.navidea.com.

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 relating to our clinical trials, plans for product development and commercialization, and role in the management of RA patients worldwide. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things:

our history of 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; our dependence on royalties and grant revenue; our ability to raise capital sufficient to fund our development and commercialization programs; 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; 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.

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