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) April 1, 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 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On April 7, 2022, Navidea Biopharmaceuticals, Inc. (the "Company") announced the separation from employment of its Chief Regulatory Officer, Dr. Michel Mikhail, effective April 1, 2022. A copy of the Company's April 7, 2022 press release relating to Dr. Mikhail's separation is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	*Exhibit Description*
99.1	Press Release dated April 7, 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: April 7, 2022

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

Exhibit 99.1

Navidea Biopharmaceuticals Announces New Senior Regulatory Consultant and Return of Former Director of Regulatory Affairs

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 welcomed Kenneth Berger, Ph.D., as Senior Regulatory Consultant, and the return of the Company's former Director of Regulatory Affairs, Richard McFerron. Navidea's former Chief Regulatory Officer, Dr. Michel Mikhail, is no longer with the Company.

Dr. Berger brings decades of experience in regulatory, clinical, and quality management in biologics, pharmaceuticals, and medical devices to Navidea's regulatory team. He has an extensive background involving Investigational New Drug submission for novel therapeutics, FDA regulatory package submissions including successful Special Protocol Assessment and Orphan Drug Status filings, and clinical Good Manufacturing Practice. He holds a Ph.D. from the University of Southern California. He will be actively engaged with the clinical team as well as the Company's network of consultants in pharmacovigilance and drug product development.

Mr. McFerron has a long track record with Navidea and was involved in the successful submission of regulatory approval packages to the FDA as well as the European Medicines Agency for approval of Lymphoseek. He will work closely with Dr. Berger as well as the clinical team on advancing the Company's Rheumatoid Arthritis ("RA") radiopharmaceutical diagnostic through Phase 3 as well as on advancing other Manocept platform diagnostic and therapeutic agents.

Dr. Michael Rosol, Chief Medical Officer for Navidea, said, "We are delighted to welcome Ken to the Company in a senior advisory role. Ken brings a wealth of experience in the critical areas of FDA submissions and drug product manufacturing." Dr. Rosol continued, "We are also happy that our former Director of Regulatory Affairs is returning. Rich was a key player at Navidea for many years, including during the approval processes of Lymphoseek and more recently in our Phase 1 and 2 trials in RA. We are excited to move forward with this strong regulatory group."

The Company also advises that its audited consolidated financial statements for the fiscal year ended December 31, 2021, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 28, 2022, contains an audit opinion from its independent registered public accounting firm that includes an explanatory paragraph related to the Company's ability to continue as a going concern. Release of this information is required by Sections 401(h) and 610(b) of the NYSE American Company Guide. This announcement does not represent any change or amendment to the Company's financial statements or to its Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

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.
Jeffrey Smith
Vice President of Operations
614-822-2365
jsmith@navidea.com