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)	August 30, 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 1.02 Termination of a Material Definitive Agreement.

On September 1, 2022, Navidea Biopharmaceuticals, Inc. ("Navidea," the "Company" or "we") issued a press release announcing the termination of the Memorandum of Understanding ("MOU") with Jubilant Radiopharma, originally signed on August 9, 2020. The MOU with Jubilant Radiopharma outlined the terms and framework for an Exclusive License and Distribution Agreement for Navidea's diagnostic imaging agent Tc99m tilmanocept (technetium Tc99m tilmanocept injection) in the United States, Canada, Mexico, and Latin America. In connection with the MOU, Jubilant Radiopharma also made a $1 million equity investment in exchange for a limited exclusivity period. Since the original signing of the MOU, Navidea has advanced Tc99m tilmanocept for indications in rheumatoid arthritis through its Phase 2B proof of concept trial and into the currently enrolling Phase 3 trial as well as the Phase 2B tilmanocept joint localization to joint biopsy study.

A press release announcing, among other things, the transaction described above is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

Item 8.01 Other Events.

As previously disclosed, the Company has been engaged in ongoing litigation with Capital Royalty Partners II L.P. ("CRG") in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement (collectively, the "CRG Lenders"), in the District Court of Harris County, Texas (the "Court"). In April 2018, the plaintiffs asserted claims against Navidea and Macrophage Therapeutics, Inc. for alleged breaches of a Global Settlement Agreement and Loan Agreement entered into by Navidea arising from the Navidea's challenge to the plaintiffs' drawing down on letters of credit in the full amount of $7,153,000. Navidea claimed such draw down resulted in an overpayment of approximately $4.2 million under the Loan Agreement.

On August 30, 2022, the Court made an oral ruling from the bench in open court at the conclusion of the trial in Case No. 2018-24442-151(*Capital Royalty Partners II, L.P. et al. v. Navidea Biopharmaceuticals, Inc. and Macrophage Therapeutics, Inc.*, awarding CRG $2,572,937.61 in attorney's fees on their breach of contract claims against Navidea and Macrophage Therapeutics ("MT"). A formal written final judgment will be entered by the Court in the near future.

The Court's oral ruling did not set out the findings and conclusions made by the Court in support of the ruling; however, on November 21, 2021, the Court entered an Interlocutory Summary Judgment against Navidea and MT, ruling breach of the Global Settlement Agreement in seeking reconsideration and an appeal of the Amended Final Judgment entered by the Court in the prior case among the parties, Case No. 2016-22242-151; *Capital Royalty Partners II, L.P. et al. v. Navidea Biopharmaceuticals, Inc. and Macrophage Therapeutics, Inc.,* and by pursuing a suit against CRG in the State of Ohio.

Once a final written judgment identifying the basis and reasoning in support of the trial court's decision is received, Navidea will reassess the Court's judgment and determine what course of action to pursue, if any, in response to the court's ruling.

A press release announcing the ruling described above is attached hereto as Exhibit 99.2, and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	*Exhibit Description*
99.1	Press Release dated September 1, 2022.
99.2	Press Release dated September 1, 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: September 2, 2022

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

Exhibit 99.1

Navidea Biopharmaceuticals Announces Opening of Nine New Sites in its Pivotal Phase 3 Trial in Rheumatoid Arthritis and Termination of Binding Memorandum of Understanding with Jubilant Radiopharma

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 the opening of nine additional sites for recruitment into its pivotal NAV3-33 Phase 3 clinical trial 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 (RA)." A total of 12 sites open for the NAV3-33 study will enable faster patient enrollment and data gathering.

This Phase 3 trial will establish the ability of Tc99m tilmanocept imaging to serve as an early predictor of treatment response in rheumatoid arthritis ("RA") patients switching to an anti-TNFα therapy. Trial details are posted on clinicaltrials.gov.

RA is a serious and potentially debilitating disease. The standard practice of treating RA is to monitor patients initiating new RA therapies over a course of three to six months and, in those patients for which the new therapies prove to be ineffective, to change their treatments to an alternative therapy with a different mechanism of action. This trial-and-error process of appropriate treatment selection may take several months to more than a year to arrive at an adequate treatment for any RA patient. Imaging with Tc99m tilmanocept, a synthetic molecule with high affinity to CD206 receptors expressed on activated macrophages, offers the potential to provide an early predictor of clinical response by providing an objective, quantifiable readout of changes in macrophage density in the joints of patients undergoing initiation or change of therapy. These macrophage density changes may be observable weeks before disease modification can be detected with standard clinical assessments and are predictive of treatment response.

Tilmanocept imaging could provide rheumatologists and those suffering with RA a noninvasive, quantifiable, early indicator of whether or not an anti-TNFα treatment is working, and this could bring enormous benefit to these patients by assisting physicians in putting them on the right course of treatment earlier than is currently possible.

The Company also announced the termination of the Memorandum of Understanding ("MOU") with Jubilant Radiopharma, originally signed on August 9, 2020. The MOU with Jubilant Radiopharma outlined the terms and framework for an Exclusive License and Distribution Agreement for Navidea's diagnostic imaging agent Tc99m tilmanocept (technetium Tc99m tilmanocept injection) in the United States, Canada, Mexico, and Latin America. In connection with the MOU, Jubilant Radiopharma also made a $1 million equity investment in exchange for a limited exclusivity period. Since the original signing of the MOU, Navidea has advanced Tc99m tilmanocept for indications in RA through its Phase 2B proof of concept trial and into the currently enrolling Phase 3 trial as well as the Phase 2B tilmanocept joint localization to joint biopsy study.

Dr. Michael Rosol, Chief Medical Officer for Navidea, said, "We have generated significant data in support of our hypotheses that Tc99m tilmanocept can provide early prediction of treatment response to anti-TNFα therapy in RA, and we look forward to completion of the RA trials. The additional new sites we have opened will help significantly in this process." Dr. Rosol continued, "Moving forward unencumbered by the exclusivity agreement, we now have the opportunity to discuss partnerships with other companies whose long-term interests align with our global business development strategy as we continue to advance towards U.S. Food and Drug Administration New Drug Application submission and beyond."

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

Exhibit 99.2

Navidea Biopharmaceuticals Announces Oral Ruling in Case Involving Attorney's Fees

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 that on August 30, 2022, the District Court of Harris County, Texas (the "Court") made an oral ruling from the bench in open court at the conclusion of the trial in Case No. 2018-24442-151; *Capital Royalty Partners II, L.P. et al. v. Navidea Biopharmaceuticals, Inc. and Macrophage Therapeutics, Inc*., awarding Capital Royalty Group ("CRG") $2,572,937.61 in attorney's fees on their breach of contract claims against Navidea and Macrophage Therapeutics ("MT").

The Court's oral ruling did not set out the findings and conclusions made by the Court in support of the ruling; however, on November 21, 2021, the Court entered an Interlocutory Summary Judgment against Navidea and MT, ruling breach of the Global Settlement Agreement in seeking reconsideration and an appeal of the Amended Final Judgment entered by the Court in the prior case among the parties, Case No. 2016-22242-151; *Capital Royalty Partners II, L.P. et al. v. Navidea Biopharmaceuticals, Inc. and Macrophage Therapeutics, Inc.,* and by pursuing a suit against CRG in the State of Ohio. A formal written final judgment will be entered by the Court in the case in the near future.

Navidea is disappointed in the Court's ruling and does not believe the law and the facts presented at the trial support the ruling against it. Once a final written judgment identifying the basis and reasoning in support of the trial court's decision is received, Navidea can better assess the Court's judgment and determine what course of action to pursue in response to the court's ruling.

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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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