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 11, 2021

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 2.02 Results of Operations and Financial Condition.

On August 11, 2021, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release regarding its consolidated financial results for the quarter and year-to-date ended June 30, 2021. A copy of the Company's August 11, 2021 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 August 11, 2021.

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: August 11, 2021

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

Exhibit 99.1

Navidea Biopharmaceuticals Reports Second Quarter 2021 Financial Results

Conference Call to be held Wednesday, August 11, 2021 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 second quarter and year-to-date for the period ended June 30, 2021.

"The Company is prepared and looking forward to our meeting with the U.S. Food and Drug Administration ("FDA") on September 1," said Mr. Jed A. Latkin, Chief Executive Officer of Navidea. "We remain laser focused on a positive meeting and a successful launch to the NAV3-33 trial. Navidea is also extremely excited to now have a full 7-member board with the appointments of Amit Bhalla, Alex Cappello and John K. Scott, Jr. to the board."

Second Quarter 2021 Highlights and Subsequent Events

- Scheduled an End-of-Phase 2 Type B meeting with the FDA to discuss its ongoing program in Rheumatoid Arthritis ("RA") and advancement to the pivotal Phase 3 trial. The meeting will take place on September 1, 2021, via conference call.
- Achieved study closeout in the Company's NAV3-31 Phase 2b study.
- Opened the first U.S. site, Northwestern University, as well as the primary U.K. site, Queen Mary University of London, for enrollment in the Company's NAV3-32 Phase 2b trial comparing Tc99m tilmanocept imaging to histopathology of joints of patients with active RA. A second U.S. site, Attune Health Research, will be opened on August 13, 2021.
- Enrolled over 115 subjects in the Company's NAV3-35 Phase 2b study, "Development of a Normative Database for Rheumatoid Arthritis (RA) Imaging with Tc99m Tilmanocept." Expected total enrollment for this two-arm trial will be 135 participants.
- Completed enrollment in the investigator-initiated Phase 2 trial being run at the Massachusetts General Hospital evaluating Tc99m tilmanocept uptake in atherosclerotic plaques of HIV-infected individuals.
- Announced the granting of a National Institutes of Health ("NIH") award to the University of California San Diego School of Medicine for the proposal entitled, "Renal Molecular Imaging of Mesangial Cell Function with Tc-99m-Tilmanocept." The award (Project Number: 1R01DK127201-01), from the National Institute of Diabetes and Digestive and Kidney Diseases of the NIH, was granted to Co-Principal Investigators UC San Diego faculty Carl Hoh, MD and David Vera, PhD, of the Department of Radiology, and Charles Ginsberg, MD, MAS, of the Department of Medicine, Division of Nephrology.
- Results from the Company's preclinical studies of its targeted cancer immunotherapeutic agent were presented as a poster at the New York Academy of Science's ("NYAS") Frontiers in Cancer Immunotherapy Symposium 2021. The poster is titled, "Targeted Delivery of Doxorubicin (DOX) to Tumor Associated Macrophages (TAMs) Beneficially Alters the Tumor Immune Microenvironment and Synergizes the Activity of Anti-CTLA4."
- Announced that the U.S. Patent and Trademark Office ("USPTO") issued to Navidea U.S. patent 11,007,272, entitled "Compounds and Methods for Diagnosis and Treatment of Viral Infections," with protection to October 7, 2037.

- Converted the provisional patent application “Synthesis of Uniformly Defined Molecular Weight Mannosylated Dextrans and Derivatives Thereof” to an A1 application on July 9, 2021.

- Appointed Amit Bhalla to the Company’s Board of Directors. Mr. Bhalla brings a wealth of financial experience and over 20 years of pharmaceutical experience to the board.

- Appointed John K. Scott, Jr. and Alex Cappello to the Board of Directors. Mr. Scott is the Company’s largest shareholder and Mr. Cappello brings over 30 years of banking and public board experience to the Company.

- Announced that on June 23, 2021, Vice Chancellor Joseph Slights of the Court of Chancery of the State of Delaware (the “Court”) ruled in favor of Navidea’s wholly-owned subsidiary, Macrophage Therapeutics, Inc. (“MT”) and against its former CEO, Dr. Michael Goldberg, finding that Dr. Goldberg breached his fiduciary duties to MT. In addition, the Court denied Dr. Goldberg’s motion to hold MT’s directors and CEO in contempt, denied Dr. Goldberg’s motion to dismiss the lawsuit against him, and granted MT’s motion to dismiss Dr. Goldberg’s petition to remove MT’s board members.

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. We are preparing for our September discussion with the FDA over the results of the completed NAV3-31 Phase 2b trial as well as our proposed plan for the Phase 3 study. We continue to prepare for initiation of the Phase 3 and have opened up key sites for enrollment into the NAV3-32 Phase 2b trial comparing tilmanocept imaging to synovial tissue biopsy samples of RA patients. Concurrent with all of this, we continue to make exciting progress in our therapeutics pipeline, and we expect to continue to advance these towards the clinic.”

Financial Results

- Total net revenues for the second quarter of 2021 were $261,000, compared to $271,000 for the same period in 2020. Total net revenues for the first six months of 2021 were $385,000, compared to $427,000 for the same period in 2020. The decrease was primarily due to decreased grant revenue related to Small Business Innovation Research grants from the National Institutes of Health supporting Manocept™ development, offset by receipt of reimbursement from Cardinal Health 414, LLC of certain research and development (“R&D”) costs and the partial recovery of debts previously written off in 2015.

- R&D expenses for the second quarter of 2021 were $1.5 million, compared to $1.3 million in the same period in 2020. R&D expenses for the first six months of 2021 were $2.7 million, compared to $2.3 million in the same period in 2020. The increase was primarily due to net increases in drug project expenses, including increased Manocept diagnostic and therapeutic development costs. The net increase in research and development expenses also included increased regulatory consulting expenses offset by decreased employee compensation including incentive-based awards.

- Selling, general and administrative (“SG&A”) expenses for the second quarter of 2021 were $1.4 million, compared to $1.3 million in the same period in 2020. SG&A expenses for the first six months of 2021 were $3.7 million, compared to $3.2 million in the same period in 2020. The net increase was primarily due increased consulting services related to preparing for European distribution of Tc99m tilmanocept, increased employee compensation including incentive-based awards, increased insurance cost, increased director fees related to additional board members, increased general office expenses, increased travel costs and increased European license fees, offset by decreased legal and professional services and decreased investor relations costs.

- Navidea's net loss attributable to common stockholders for the second quarter of 2021 was $2.7 million, or $0.09 per share, compared to $2.4 million, or $0.11 per share, for the same period in 2020. Navidea's net loss attributable to common stockholders for the first six months of 2021 was $5.6 million, or $0.20 per share, compared to $5.1 million, or $0.24 per share, for the same period in 2020.

- Navidea ended the second quarter of 2021 with $7.1 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. Participants who would like to ask questions during the question and answer session will be prompted by the moderator, who will provide instructions.

Event: Second Quarter 2021 Earnings Conference Call and Business Update

Date: Wednesday, August 11, 2021

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

U.S. & Canada Dial-in: 877-407-0312

International Dial-in: +1 201-389-0899

Conference ID: 13721827

Webcast Link: https://webcast-eqs.com/navidbioph20210811/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.

Contact

Navidea Biopharmaceuticals, Inc.
Jed Latkin
Chief Executive Officer
614-973-7490
jlatkin@navidea.com

NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2021 (unaudited)	December 31, 2020
Assets:		
Cash and cash equivalents	$ 7,114,103	$ 2,670,495
Other current assets	2,929,307	3,857,833
Non-current assets	1,237,900	1,229,690
Total assets	$ 11,281,310	$ 7,758,018
Liabilities and stockholders' equity:		
Current liabilities	$ 4,024,669	$ 4,715,105
Deferred revenue, non-current	700,000	700,000
Other liabilities	120,471	296,006
Total liabilities	4,845,140	5,711,111
Navidea stockholders' equity	5,704,870	1,315,604
Noncontrolling interest	731,300	731,303
Total stockholders' equity	6,436,170	2,046,907
Total liabilities and stockholders' equity	$ 11,281,310	$ 7,758,018

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Six Months Ended	
	June 30, 2021 (unaudited)	June 30, 2020 (unaudited)	June 30, 2021 (unaudited)	June 30, 2020 (unaudited)
Revenue	$ 261,046	$ 271,101	$ 384,783	$ 427,373
Cost of revenue	-	357	-	966
Gross profit	261,046	270,744	384,783	426,407
Operating expenses:				
Research and development	1,498,056	1,281,779	2,720,810	2,281,048
Selling, general and administrative	1,432,610	1,329,591	3,663,355	3,157,345
Total operating expenses	2,930,666	2,611,370	6,384,165	5,438,393
Loss from operations	(2,669,620)	(2,340,626)	(5,999,382)	(5,011,986)
Other income (expense):				
Interest income (expense), net	1,266	15,343	(1,609)	12,971
Gain on extinguishment of debt	-	-	366,000	-
Other, net	(5,686)	(336)	(5,941)	(212)
Net loss	(2,674,040)	(2,325,619)	(5,640,932)	(4,999,227)
Loss (income) attributable to noncontrolling interest	1	1	3	(1)
Deemed dividend on Series C Preferred Stock beneficial conversion feature	-	(77,778)	-	(77,778)
Net loss attributable to common stockholders	$ (2,674,039)	$ (2,403,396)	$ (5,640,929)	$ (5,077,006)
Loss attributable to common stockholders per common share (basic and diluted)	$ (0.09)	$ (0.11)	$ (0.20)	$ (0.24)
Weighted average shares outstanding (basic and diluted)	29,117,832	22,759,393	28,531,660	21,481,514