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 14, 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, par value $.001 per share	NAVB	NYSE American

Item 2.02 Results of Operations and Financial Condition.

On May 14, 2020, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release regarding its consolidated financial results for the quarter ended March 31, 2020. A copy of the Company's May 14, 2020 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 May 14, 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 14, 2020

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

Exhibit 99.1

Navidea Biopharmaceuticals Reports First Quarter 2020 Financial Results

Conference Call to be held Thursday, May 14, 2020 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 first quarter ended March 31, 2020.

"During the first quarter, despite the pandemic and the Work-From-Home quarantine procedures, Navidea has maintained strong business operations. Enrollment in the Company's clinical trials are ongoing and we have enough patients in our NAV3-31 trial to evaluate for the upcoming interim analysis. More importantly, the Company continued its dialogue with several key potential partners and we anticipate providing updates on those initiatives imminently," said Mr. Jed A. Latkin, Chief Executive Officer of Navidea. "Regaining the rights to Lymphoseek in Europe, New Zealand and Australia is a watershed moment for this management team and we are excited about the potential for this asset in Europe based on its successful and broad-based commercial adoption in the United States."

First Quarter 2020 Highlights and Subsequent Events

- Continued with double-digit subject enrollment in the Company's NAV3-31 Phase 2b study in rheumatoid arthritis ("RA") and completed enrollment of subjects in Arms 1 and 2.
- Continued 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 extension by the U.S. Patent and Trademark Office of U.S. patent 6,409,990 pertaining to Lymphoseek® for an additional five years through May 12, 2025.
- Converted two provisional patents, one pertaining to image analysis relevant to the RA program and the other to the therapeutic space, to A1 applications.
- Signed a letter of intent to partner with WorldCare Clinical, LLC for the Company's RA diagnostic clinical imaging workflow.
- Regained the commercialization and distribution rights for Lymphoseek® (Tc99m tilmanocept) injection in Europe through the mutually agreed upon termination of the perpetual license agreement with SpePharm AG, a subsidiary of Norgine B.V.
- Executed agreements with two existing investors to purchase approximately 4.0 million shares of the Company's common stock for aggregate gross proceeds to Navidea of approximately $3.4 million.
- Finalized the previously announced $4.2 million financing related to the judgment by the Ohio Court of Common Pleas (the "Judgment"). Navidea has agreed to issue Keystone Capital Partners, LLC, an existing shareholder, up to $4.2 million of convertible preferred shares, which will be guaranteed by a portion of the proceeds of the Judgment.
- Following execution of the funding transactions described above, the Company regained compliance with the NYSE American's continued listing standards with stockholders' equity of $6.0 million.

Michael Rosol, Ph.D., Chief Medical Officer for Navidea, said, “The clinical research team has been working diligently to continue to advance the technology in key disease areas, with an emphasis on our ongoing RA trials. We are currently analyzing the data from the NAV3-31 Phase 2B trial in RA for our second interim analysis. We also continue to prepare for the start of our second Phase 2B trial comparing tilmanocept imaging to synovial tissue biopsy samples of RA patients as well as the Phase 3 trial.”

Financial Results

Navidea’s consolidated balance sheets, statements of operations, and statements of stockholders’ equity have been restated, as required, for all periods presented to reflect the April 2019 reverse stock split as if it had occurred on January 1, 2018. The consolidated statements of cash flows were not impacted by the reverse stock split.

- Total revenues for the first quarter of 2020 were $156,000, compared to $42,000 in the same period of 2019. The increase was primarily due to an increase in grant revenue related to Small Business Innovation Research grants from the National Institutes of Health supporting Manocept development.

- Research and development expenses for the first quarter of 2020 were $999,000, compared to $741,000 in the same period of 2019. The increase was primarily due to net increases in drug project expenses including Manocept™ diagnostic development costs, offset by decreased Manocept therapeutic development costs.

- Selling, general and administrative expenses for the first quarter of 2020 were $1.8 million, compared to $1.7 million in the same period of 2019. The increase was primarily related to increased legal and professional services, compensation and taxes, offset by decreased depreciation, insurance, travel and investor relations.

- Navidea’s net loss attributable to common stockholders for the first quarter of 2020 was $2.7 million, or $0.13 per share, compared to a net loss attributable to common stockholders of $2.4 million, or $0.24 per share, for the same period in 2019.

- Navidea ended the first quarter of 2020 with $601,000 in cash and cash equivalents. Per Navidea’s recent filings with the SEC, the Company executed funding transactions totaling $7.6 million in proceeds during the first quarter of 2020. The Company’s quarter-ending cash balance reflects the receipt of $850,000 through March 31, 2020. An additional $1.7 million has been received during the second quarter to date, with the remainder of the financing funds expected to come in on a continual basis allowing for the smooth operation of the business.

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:	Q1 2020 Earnings and Business Update Conference Call
Date:	Thursday, May 14, 2020
Time:	5:00 p.m. (EDT)
U.S. & Canada Dial-in:	877-407-0312
International Dial-in:	+1 201-389-0899
Conference ID:	13703112
Webcast Link:	https://webcasts.eqs.com/navidbioph20200514/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.

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NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2020 (unaudited)	December 31, 2019
Assets:		
Cash and cash equivalents	$ 601,355	$ 1,047,159
Other current assets	2,845,404	1,868,624
Non-current assets	1,030,472	1,235,123
Total assets	$ 4,477,231	$ 4,150,906
Liabilities and stockholders' deficit:		
Current liabilities	$ 4,354,569	$ 3,819,551
Deferred revenue, non-current	700,000	700,000
Other liabilities	513,701	512,344
Total liabilities	5,568,270	5,031,895
Navidea stockholders' deficit	(1,822,344)	(1,612,292)
Noncontrolling interest	731,305	731,303
Total stockholders' deficit	(1,091,039)	(880,989)
Total liabilities and stockholders' deficit	$ 4,477,231	$ 4,150,906

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended	
	March 31, 2020 (unaudited)	March 31, 2019 (unaudited)
Revenue:		
Royalty revenue	$ 15,221	$ 3,150
Grant and other revenue	141,051	38,474
Total revenue	156,272	41,624
Cost of revenue	609	6,126
Gross profit	155,663	35,498
Operating expenses:		
Research and development	999,269	740,583
Selling, general and administrative	1,827,754	1,728,516
Total operating expenses	2,827,023	2,469,099
Loss from operations	(2,671,360)	(2,433,601)
Other income (expense):		
Interest (expense) income, net	(2,372)	9,848
Other, net	124	(1,135)
Loss before income taxes	(2,673,608)	(2,424,888)
Provision for income taxes	-	(876)
Net loss from continuing operations	(2,673,608)	(2,425,764)
Loss from discontinued operations, net of tax effect	-	(3,297)
Net loss	(2,673,608)	(2,429,061)
Income (loss) attributable to noncontrolling interest	2	(12)
Net loss attributable to common stockholders	$ (2,673,610)	$ (2,429,049)
Loss per common share (basic and diluted):		
Continuing operations	$ (0.13)	$ (0.24)
Attributable to common stockholders	$ (0.13)	$ (0.24)
Weighted average shares outstanding	20,203,636	10,017,848