May 11, 2021

Navidea Biopharmaceuticals Reports First Quarter 2021 Financial Results

Conference Call to be held Tuesday, May 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 first quarter for the period ended March 31, 2021.

"We are continuing a positive dialogue with the FDA and are moving as quickly as we can to fully document all the data from Arm 3 of NAV3-31," said Mr. Jed A. Latkin, Chief Executive Officer of Navidea. "We are also excited to begin patient enrollment for NAV3-32 both here in the U.S. and in the UK."

First Quarter 2021 Highlights and Subsequent Events

- Submitted a formal Type B Meeting Request to the U.S. Food and Drug Administration ("FDA"). The FDA granted the Type B Meeting and reviewed the formal briefing documents Navidea submitted containing results from the NAV3-31 Phase 2B study and the proposed Phase 3 design and protocol. Following the feedback received from the FDA at the end of March 2021, the Company continues to work toward completing the analysis of the full trial dataset in preparation for the standard End of Phase 2 Type B meeting and in preparation for the Phase 3 study.
- Achieved last patient, last visit in the Company's NAV3-31 Phase 2B study. Study closeout and data analysis are ongoing.
- Opened the first US site, Northwestern University, as well as the primary UK 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 rheumatoid arthritis ("RA").
- Opened the NAV3-35 trial to establish a normative database of healthy controls for Tc99m tilmanocept imaging in rheumatoid arthritis.
- 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.
- Received a notice of allowance from the United States Patent and Trademark Office for the patent application: "Compounds and methods for diagnosis and treatment of viral infections" (U.S. Patent Application 15/729,635).
- Announced that the results from the Company's preclinical studies of its targeted cancer immunotherapeutic agent will be 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."
- Entered into a Stock Purchase Agreement and Letter of Investment Intent with an existing investor, pursuant to which the Company issued to the investor 50,000 shares of newly-designated Series E Redeemable Convertible Preferred Stock (the "Series E Preferred Stock") for an aggregate purchase price of $5.0 million. The Series E Preferred Stock is convertible into a maximum of 2,173,913 shares of Common Stock.
- Appointed Amit Bhalla to the Company's Board of Directors. Mr. Bhalla brings a wealth of financial experience to the board.

Michael Rosol, Ph.D., Chief Medical Officer for Navidea, said, "The clinical research team is working diligently to advance the technology in key disease areas, with an emphasis on our RA program. We are completing the analysis of the full dataset from the NAV3-31 Phase 2B trial as well as planning for the Phase 3 trial. We continue to prepare for initiation of this trial 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, some of which will be presented this month at the NYAS conference, and we expect to continue to advance these towards the clinic."

Financial Results

- Total net revenues for the first quarter of 2021 were $124,000, compared to $156,000 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 the partial recovery in the first quarter of 2021 of debts previously written off in 2015.
- Research and development expenses for the first quarter of 2021 were $1.2 million, compared to $999,000 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 and increased Tc99m development costs, offset by decreased employee compensation.
- Selling, general and administrative expenses for the first quarter of 2021 were $2.2 million, compared to $1.8 million in the same period in 2020. The net increase was primarily due to increased legal and professional services, insurance, investor relations services, and employee compensation, offset by decreased franchise taxes.
- Navidea's net loss attributable to common stockholders for the first quarter of 2021 was $3.0 million, or $0.11 per share, compared to $2.7 million, or $0.13 per share, for the same period in 2020.
- Navidea ended the first quarter of 2021 with $7.5 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:	Q1 2021 Earnings and Business Update Conference Call
Date:	Tuesday, May 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:	13718969
Webcast Link:	https://webcasts.eqs.com/navidbioph20210511/en

A live audio webcast of the conference call will also be available on the investor relations page of Navidea's corporate website at www.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.

NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2021 (unaudited)	December 31, 2020
Assets:		
Cash and cash equivalents	$ 7,507,319	$ 2,670,495
Other current assets	1,320,720	3,857,833
Non-current assets	1,249,036	1,229,690
Total assets	$10,077,075	$ 7,758,018
Liabilities and stockholders' equity:		
Current liabilities	$ 4,158,754	$ 4,715,105
Deferred revenue, non-current	700,000	700,000
Other liabilities	209,439	296,006
Total liabilities	5,068,193	5,711,111
Navidea stockholders' equity	4,277,581	1,315,604
Noncontrolling interest	731,301	731,303
Total stockholders' equity	5,008,882	2,046,907
Total liabilities and stockholders' equity	$10,077,075	$ 7,758,018

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended	
	March 31, 2021 (unaudited)	March 31, 2020 (unaudited)
Revenue	$ 123,737	$ 156,272
Cost of revenue	-	609
Gross profit	123,737	155,663

Operating expenses:		
Research and development	1,222,754	999,269
Selling, general and administrative	2,230,745	1,827,754
Total operating expenses	3,453,499	2,827,023
Loss from operations	(3,329,762)	(2,671,360)
Other income (expense):		
Interest expense, net	(2,875)	(2,372)
Gain on extinguishment of debt	366,000	-
Other, net	(255)	124
Net loss	(2,966,892)	(2,673,608)
Less (loss) income attributable to noncontrolling interest	(2)	2
Net loss attributable to common stockholders	$ (2,966,890)	$ (2,673,610)
Loss attributable to common stockholders per common share (basic and diluted)	$ (0.11)	$ (0.13)
Weighted average shares outstanding (basic and diluted)	28,066,296	20,203,636

View source version on businesswire.com:
https://www.businesswire.com/news/home/20210511006055/en/

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