

Navidea Biopharmaceuticals Reports First Quarter 2019 Financial Results

Conference Call to be held Wednesday, May 8, 2019 at 5:00 pm ET

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 of 2019. Navidea reported total revenues for the quarter of \$136,000. Net loss attributable to common stockholders was \$2.4 million.

"During the first quarter, Navidea received clearance from the FDA to commence the Phase 2b trials and solid guidance on the final pivotal trial for our rheumatoid arthritis diagnostic program," said Mr. Jed A. Latkin, Chief Executive Officer of Navidea. "The Company remains fully focused on completing these trials and bringing this ground-breaking diagnostic to the market."

First Quarter 2019 Highlights and Subsequent Events

- Executed a Stock Purchase Agreement for up to \$3.0 million with an existing investor
- Received feedback from the U.S. Food and Drug Administration ("FDA") regarding the Company's planned clinical studies that will evaluate joint disease in patients with rheumatoid arthritis ("RA") and monitor patient response to therapy
- Began enrolling patients in a Phase 2b trial entitled, "Evaluation of the Precision and Sensitivity of Tilmanocept Uptake Value ("TUV") on Tc99m Tilmanocept Planar Imaging" (ClinicalTrials.gov Identifier: NCT03938636)
- Announced that Professor Mike Sathekge, MBChB, M. Med (Nuclear Medicine), PhD, Professor and Head of the Department of Nuclear Medicine in the Faculty of Health Sciences at the University of Pretoria/Steve Biko Academic Hospital, plans to initiate a comparative study to explore using 68Ga tilmanocept as an aid in tuberculosis ("TB") patient management while contributing to the better understanding of the biology of TB granulomas
- Effected a one-for-twenty reverse stock split and received notification of stock price compliance from the NYSE American

Financial Results

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

- Total revenues for the first quarter of 2019 were \$136,000, compared to \$276,000 in the same period of 2018. The decrease was primarily due to a reduction in grant revenue related to SBIR grants from the NIH supporting Manocept development, offset by sublicense revenue related to the adoption of new lease accounting standards effective January 1, 2019.
- Research and development ("R&D") expenses for the first quarter of 2019 were \$741,000, compared to \$999,000 in the same period of 2018. The decrease was primarily due to net decreases in drug project expenses including therapeutics and Tc99m tilmanocept development costs, coupled with decreased compensation costs resulting from net decreased salaries and headcount.
- Selling, general and administrative ("SG&A") expenses were approximately \$1.8 million in each of the first quarters of 2019 and 2018. Increased legal and professional services and increased lease expenses due to the new lease accounting standards which were effective January 1, 2019 were offset by decreased compensation and decreased investor relations costs.
- Navidea's net loss attributable to common stockholders for the first quarter of 2019 was \$2.4 million, or \$0.24 per share, compared to a net loss attributable to common stockholders of \$6.7 million, or \$0.83 per share, for the same period in 2018.
- Navidea ended the first quarter of 2019 with \$2.1 million in cash and investments.

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 2019 Earnings and Business Update Conference Call

Date: Wednesday, May 8, 2019

Time: 5:00 p.m. (EDT) U.S. & Canada Dial- 877-407-0312

in:

International Dial-in: +1 201-389-0899 Conference ID: 13690285

The recorded conference call can be replayed and will be available for 90 days following the call, available on the investor relations page of Navidea's corporate website at www.navidea.com.

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. The development activities of the Manocept immunotherapeutic platform are being conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics, Inc. 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 <u>www.navidea.com</u>.

Forward-Looking Statements

This release and any oral statements made with respect to the information contained in this 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. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: any future actions by Platinum-Montaur; general economic and business conditions, both nationally and in our markets; our history of 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; our expectations and estimates concerning future financial performance, financing plans and the impact of competition; our ability to raise capital sufficient to fund our development and commercialization programs; our ability to implement our growth strategy; anticipated trends in our business; advances in technologies; our ability to comply with the NYSE American continued listing standards; our ability to maintain effective internal control over financial reporting; 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 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. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

March 31,	December 31,
2019	2018
(unaudited)	

Assets:

Cash and available-for-sale securities Other current assets Non-current assets Total assets	\$ 2,070,670 \$ 4,275,151 1,159,661 1,320,605 1,729,429 1,425,771 \$ 4,959,760 \$ 7,021,527
Liabilities and stockholders' equity:	
Current liabilities	\$ 3,416,140 \$ 3,378,518
Deferred revenue	700,000 700,000
Other liabilities	748,985 532,549
Total liabilities	4,865,125 4,611,067
Navidea stockholders' (deficit) equity	(573,674) 1,742,139
Noncontrolling interest	668,309 668,321
Total stockholders' equity	94,635 2,410,460
Total liabilities and stockholders' equity	\$ 4,959,760 \$ 7,021,527

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

CONDENSED CONSOCIDATED STATEMENTS OF	OI LIVATIONS				
	Three Months Ended				
	March 31,		March 31,		
	2019			2018	
	(u	naudited)	(unaudited)	
Revenue:					
Royalty revenue	\$	3,150	\$	795	
Sublease revenue		94,408		-	
Grant and other revenue		38,474		275,650	
Total revenue	136,032		276,445		
Cost of revenue		6,126		318	
Gross profit		129,906		276,127	
Operating expenses:					
Research and development		740,583		998,956	
Selling, general and administrative	1,822,924		1,776,372		
Total operating expenses	2	2,563,507		2,775,328	
Loss from operations	(2	2,433,601)		(2,499,201)	
Other income (expense):					
Interest income, net		9,848		31,387	
Loss on extinguishment of debt		_		(4,265,434)	
Other, net		(1,135)		(4,714)	
Loss before income taxes		2,424,888)		(6,737,962)	
Provision for income taxes	•	(876)		_	
Loss from continuing operations	(2	2,425,764)		(6,737,962)	
Loss from discontinued operations, net of tax effect		(3,297)		-	
Net loss	(2	2,429,061)		(6,737,962)	
Less loss attributable to noncontrolling interest		(12)		(9)	
Net loss attributable to common stockholders	\$ (2	2,429,049)	\$	(6,737,953)	
Loss per common share (basic and diluted):					
Continuing operations	\$	(0.24)	\$	(0.83)	
Discontinued operations	\$	-	\$	-	
Attributable to common stockholders	\$	(0.24)	\$	(0.83)	
Weighted average shares outstanding	10	0,017,848		8,113,451	

View source version on businesswire.com:

https://www.businesswire.com/news/home/20190508005869/en/

Navidea Biopharmaceuticals, Inc. Jed Latkin, CEO, 614-973-7490 <u>jlatkin@navidea.com</u>

Source: Navidea Biopharmaceuticals, Inc.