November 7, 2019

Navidea Biopharmaceuticals Reports Third Quarter 2019 Financial Results

Conference Call to be held Thursday, November 7, 2019 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 third quarter ended September 30, 2019.

"During the third quarter, Navidea continued to deliver on the Company's initiatives to complete the NAV 3-31 Phase 2B trial in patients with Rheumatoid Arthritis ("RA")," said Mr. Jed A. Latkin, Chief Executive Officer of Navidea. "The Company furthered its partnership discussions around the globe, and most importantly, met its internal enrollment goals for the ongoing RA trials. We also achieved several key milestones in Navidea's clinical pipeline, and continue to advance programs in the therapeutics division. Navidea remains focused on potentially bringing its RA diagnostic to market within the next 18 to 24 months."

Third Quarter 2019 Highlights and Subsequent Events

- Continued with double-digit subject enrollment in the Company's NAV3-31 Phase 2b study in rheumatoid arthritis ("RA").
- Announced positive results of the first interim analysis of the NAV3-31 Phase 2b study, demonstrating that Tc99m tilmanocept imaging can provide robust, quantitative imaging in healthy controls and in patients with active RA, and that this imaging is stable, reproducible, and can define joints with and without RA-involved inflammation.
- Entered into a collaboration agreement with IMV Inc., a clinical-stage immuno-oncology company, to explore the combinatory effect of Navidea's and IMV's proprietary immuno-oncology platforms.
- Received the Notice of Award from the National Heart, Lung and Blood Institute for the Small Business Technology Transfer Phase 1 grant application that will support a collaboration with the University of Alabama at Birmingham titled "Gallium 68 Tilmanocept for PET Imaging of Atherosclerosis Plaques", with studies set to begin shortly.
- Completed patient enrollment in NAV3-24, the NIH-funded imaging trial in Kaposi Sarcoma patients titled, "An Evaluation of the Safety of Escalating Doses of Tc 99m Tilmanocept by Intravenous (IV) Injection and a Comparison to Subcutaneous (SC) Injection in Human Immunodeficiency Virus (HIV) Subjects Diagnosed with Kaposi Sarcoma (KS)".
- Continued enrollment in the Investigator Initiated Phase 2 trial being run at the Massachusetts General Hospital evaluating Tc 99m tilmanocept uptake in atherosclerotic plaques of HIV-infected individuals.

Michael Rosol, Chief Medical Officer for Navidea, said, “The clinical research team has been working diligently to advance the technology in key disease areas, with an emphasis on our ongoing RA trials. We continue to advance our Phase 2B trial in RA, building upon the recently announced interim analysis results, and are planning ahead for 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 third quarter of 2019 were $237,000, compared to $231,000 in the same period of 2018. Total revenues for the first nine months of 2019 were $539,000, compared to $1.1 million in the same period of 2018. The year-to-date decrease was primarily due to a decrease in license revenue related to the sublicense of the Company’s NAV4694 technology, which included a non-refundable upfront payment in 2018, coupled with a reduction in grant revenue related to Small Business Innovation Research grants from the National Institutes of Health supporting Manocept development.
- Research and development (“R&D”) expenses for the third quarter of 2019 were $1.8 million, compared to $1.2 million in the same period of 2018. R&D expenses for the first nine months of 2019 were $3.6 million, compared to $3.4 million in the same period of 2018. The year-to-date increase was primarily due to net increases in drug project expenses, which includes Manocept™ diagnostic and Tc99m tilmanocept development costs, offset by decreased Manocept therapeutic and NAV4694 development costs. The net increase in R&D expenses also included decreased compensation costs resulting from net decreased salaries and headcount.
- Selling, general and administrative (“SG&A”) expenses for the third quarter of 2019 were $1.5 million, compared to $2.7 million in the same period of 2018. SG&A expenses for the first nine months of 2019 were $5.1 million, compared to $6.2 million in the same period of 2018. Decreased compensation, primarily related to the resignation of the former CEO in 2018, coupled with net decreased related support costs such as director compensation, general office expenses and taxes, were offset by increased legal and professional services, primarily related to the Goldberg litigation.
- Navidea’s net loss attributable to common stockholders for the third quarter of 2019 was $3.1 million, or $0.17 per share, compared to a net loss attributable to common stockholders of $3.8 million, or $0.46 per share, for the same period in 2018. Navidea’s net loss attributable to common stockholders for the first nine months of 2019 was $8.2 million, or $0.62 per share, compared to a net loss attributable to common stockholders of $13.0 million, or $1.58 per share, for the same period in 2018.
- Navidea ended the third quarter of 2019 with $2.8 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:	Q3 2019 Earnings and Business Update Conference Call
Date:	Thursday, November 7, 2019
Time:	5:00 p.m. (EST)
U.S. & Canada Dial-in:	877-407-0312
International Dial-in:	+1 201-389-0899
Conference ID:	13696379

Webcast Link: https://webcasts.eqs.com/navidbioph20191107/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 relating to our clinical trials, plans for product development and commercialization, and role in the management of RA patients worldwide. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: 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 dependence on royalties and grant revenue; 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; 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; 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

	September 30, 2019 (unaudited)	December 31, 2018
Assets:		
Cash and available-for-sale securities	$ 2,841,498	$ 4,275,151
Other current assets	392,817	1,320,605
Non-current assets	1,587,341	1,425,771
Total assets	$ 4,821,656	$ 7,021,527
Liabilities and stockholders' (deficit) equity:		
Current liabilities	$ 3,576,335	$ 3,378,518
Deferred revenue, non-current	700,000	700,000
Other liabilities	638,064	532,549
Total liabilities	4,914,399	4,611,067
Navidea stockholders'(deficit) equity	(761,047)	1,742,139
Noncontrolling interest	668,304	668,321
Total stockholders' (deficit) equity	(92,743)	2,410,460
Total liabilities and stockholders' (deficit) equity	$ 4,821,656	$ 7,021,527

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Nine Months Ended	
	September 30, 2019 (unaudited)	September 30, 2018 (unaudited)	September 30, 2019 (unaudited)	September 30, 2018 (unaudited)
Revenue:				
Royalty revenue	$ 4,895	$ 2,382	$ 13,985	$ 9,842
License revenue	-	19,930	9,953	277,639
Grant and other revenue	231,916	209,146	514,589	762,549
Total revenue	236,811	231,458	538,527	1,050,030
Cost of revenue	195	38,101	6,559	73,811
Gross profit	236,616	193,357	531,968	976,219
Operating expenses:				
Research and development	1,801,558	1,225,770	3,612,783	3,367,444
Selling, general and administrative	1,519,496	2,688,703	5,109,612	6,254,474
Total operating expenses	3,321,054	3,914,473	8,722,395	9,621,918
Loss from operations	(3,084,438)	(3,721,116)	(8,190,427)	(8,645,699)

Other income (expense):				
Interest income (expense), net	11,858	(28,074)	23,336	(20,234)
Loss on extinguishment of debt	-	-	-	(4,265,434)
Other, net	(1,524)	3,540	(5,880)	1,654
Loss before income taxes	(3,074,104)	(3,745,650)	(8,172,971)	(12,929,713)
Provision for income taxes	-	(76,259)	(707)	(65,330)
Loss from continuing operations	(3,074,104)	(3,821,909)	(8,173,678)	(12,995,043)
Discontinued operations, net of tax effect:				
Loss from operations	-	-	(2,665)	(1,938)
Gain on sale	-	-	-	43,053
Net loss	(3,074,104)	(3,821,909)	(8,176,343)	(12,953,928)
Less loss attributable to noncontrolling interest	(2)	(308)	(16)	(333)
Net loss attributable to common stockholders	$ (3,074,102)	$ (3,821,601)	$ (8,176,327)	$ (12,953,595)
Loss per common share (basic and diluted):				
Continuing operations	$ (0.17)	$ (0.46)	$ (0.62)	$ (1.59)
Discontinued operations	$ -	$ -	$ (0.00)	$ 0.01
Attributable to common stockholders	$ (0.17)	$ (0.46)	$ (0.62)	$ (1.58)
Weighted average shares outstanding (basic)	18,044,406	8,342,771	13,082,393	8,198,197

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