November 12, 2020

Navidea Biopharmaceuticals Reports Third Quarter and Year-to-Date 2020 Financial Results

Conference Call to be held Thursday, November 12, 2020 at 5:00 pm EST

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 and year-to-date for the period ended September 30, 2020.

"Navidea continues to build on its clinical momentum and this quarter fully shows our ability to execute during a very trying time globally," said Mr. Jed A. Latkin, Chief Executive Officer of Navidea. "The due diligence continues with Jubilant and the Phase 2b is nearing its conclusion. We are very excited to move forward and present to the FDA in the near future."

Third Quarter 2020 Highlights and Subsequent Events

- Executed a binding memorandum of understanding ("MOU") on August 9, 2020 with Jubilant Draximage Inc. dba Jubilant Radiopharma, Radiopharmaceuticals Division ("Jubilant"). The MOU outlines the terms and framework for an Exclusive License and Distribution Agreement for Navidea's Rheumatoid Arthritis Diagnostic in the United States, Canada, Mexico, and Latin America. In connection with the MOU, Jubilant made a $1 million equity investment in exchange for a limited exclusivity period while final due diligence efforts are completed.
- Entered into a Stock Purchase Agreement with investors, pursuant to which the investors agreed to purchase up to $25.0 million in shares of the Company's Common Stock.
- Entered into a Stock Purchase Agreement and Letter of Investment Intent with an existing investor, pursuant to which the Company agreed to issue to the investor 150,000 shares of newly-designated Series D Redeemable Convertible Preferred Stock (the "Series D Preferred Stock") for an aggregate purchase price of $15.0 million. Pursuant to the Series D Preferred Stock Purchase Agreement, Keystone will purchase Series D Preferred Stock in amounts to be determined by Keystone in one or more closings during the nine-month period following the date on which the prospectus supplement to register the underlying Common Stock was filed with the SEC, provided that all of the Series D Preferred Stock must be purchased by such date. The Series D Preferred Stock will be convertible into a maximum of 5,147,000 shares of Common Stock.
- Announced acceptance by the American College of Rheumatology ("ACR") of the results from the Company's second interim analysis of its ongoing NAV3-31 Phase 2b clinical study for presentation at the ACR Annual Meeting ("ACR Convergence 2020")

under the title, “Tc99m Tilmanocept Imaging Is an Early Predictor of Clinical Response in Rheumatoid Arthritis Patients Beginning New Anti-TNFα Therapy.”
- Continued longitudinal imaging and clinical assessments of Arm 3 subjects, who are beginning new anti-TNFα therapy, in the NAV3-31 trial.
- 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.
- Converted a provisional patent on blocking off-target organ uptake of Tilmanocept to improve on-target localization.
- Received a one-year extension on its NIH phase 1 Small Business Technology Transfer grant (1R41HL147640-01A1) entitled *Gallium 68 Tilmanocept for PET Imaging of Atherosclerosis Plaques*, due to COVID-19 related shutdown of the research facility at the University of Alabama Birmingham. The site has reopened and these preclinical studies are ongoing.
- Won dismissal of Platinum-Montaur Life Sciences LLC’s lawsuit against the Company.

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. The currently running Phase 2b trial in RA is proceeding well, with Arm 3 subjects having their later imaging and clinical assessments. Preparation of the package to discuss with the FDA in planning for the upcoming Phase 3 is nearing completion. We are also preparing for the start of our second Phase 2b trial comparing tilmanocept imaging to synovial tissue biopsy samples of RA patients.”

Financial Results

- Total revenues for the third quarter 2020 were $268,000, compared to $237,000 for the same period in 2019. Total revenues for the first nine months of 2020 were $696,000, compared to $539,000 for the same period in 2019. The increases were primarily due to increased 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 2020 were $1.4 million, compared to $1.8 million in the same period in 2019. The third quarter decrease was primarily due to net decreases in drug project expenses, including decreased Manocept diagnostic and Tc99m tilmanocept development costs, coupled with decreased employee compensation. R&D expenses for the first nine months of 2020 were $3.7 million, compared to $3.6 million in the same period in 2019. The year-to-date increase was primarily due to net increases in drug project expenses, including increased Manocept diagnostic development costs offset by decreased Manocept therapeutic and Tc99m tilmanocept development costs, coupled with increased employee compensation.
- Selling, general and administrative (“SG&A”) expenses for the third quarter of 2020 were $1.8 million, compared to $1.5 million in the same period in 2019. The third quarter increase was primarily due to increased legal and professional services and employee compensation, offset by decreased travel, insurance, and depreciation costs. SG&A expenses for the first nine months of 2020 were $4.9 million, compared to $5.1 million in the same period in 2019. The year-to-date decrease was primarily due to decreased travel, legal and professional services, insurance, depreciation, and investor

relations costs, offset by increased employee compensation and franchise taxes.

- Navidea's net loss attributable to common stockholders for the third quarter of 2020 was $3.3 million, or $0.13 per share, compared to $3.1 million, or $0.17 per share, for the same period in 2019. Navidea's net loss attributable to common stockholders for the first nine months of 2020 was $8.4 million, or $0.37 per share, compared to $8.2 million, or $0.62 per share, for the same period in 2019.
- Navidea ended the third quarter of 2020 with $3.7 million in cash and cash equivalents. Since September 30, 2020, the Company has received $700,000 of cash related to the August 2020 funding transactions.

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 2020 Earnings and Business Update Conference Call
Date:	Thursday, November 12, 2020
Time:	5:00 p.m. (EST)
U.S. & Canada Dial-in:	800-754-1336
International Dial-in:	+1 415-226-5358
Conference ID:	21971993
Webcast Link:	https://webcasts.eqs.com/navidbioph20201112/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

	September 30, 2020 (unaudited)	December 31, 2019
Assets:		
Cash and cash equivalents	$ 3,722,852	$ 1,047,159
Other current assets	1,070,099	1,868,624
Non-current assets	1,202,884	1,235,123
Total assets	$ 5,995,835	$ 4,150,906
Liabilities and stockholders' equity (deficit):		
Current liabilities	$ 4,014,418	$ 3,819,551

Deferred revenue, non-current	700,000	700,000
Other liabilities	380,236	512,344
Total liabilities	5,094,654	5,031,895
Navidea stockholders' equity (deficit)	169,877	(1,612,292)
Noncontrolling interest	731,304	731,303
Total stockholders' equity (deficit)	901,181	(880,989)
Total liabilities and stockholders' equity (deficit)	$ 5,995,835	$ 4,150,906

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Nine
	September 30, 2020 (unaudited)	September 30, 2019 (unaudited)	Septembe 2020 (unaudite
Revenue:			
Royalty revenue	$ 2,047	$ 4,895	$ 26,
License revenue	4,726	-	4,
Grant and other revenue	261,616	231,916	664,
Total revenue	268,389	236,811	695,
Cost of revenue	82	195	1,
Gross profit	268,307	236,616	694,
Operating expenses:			
Research and development	1,377,998	1,801,558	3,659,
Selling, general and administrative	1,788,934	1,519,496	4,946,
Total operating expenses	3,166,932	3,321,054	8,605,
Loss from operations	(2,898,625)	(3,084,438)	(7,910,
Other income (expense):			
Interest income (expense), net	(149)	11,858	12,
Other, net	(564)	(1,524)	(
Loss before income taxes	(2,899,338)	(3,074,104)	(7,898,
Provision for income taxes	-	-	
Loss from continuing operations	(2,899,338)	(3,074,104)	(7,898,
Loss from discontinued operations, net of tax effect	-	-	
Net loss	(2,899,338)	(3,074,104)	(7,898,
Loss (income) attributable to noncontrolling interest	-	2	
Deemed dividend on Series C and Series D preferred stock beneficial conversion feature	(405,555)	-	(483,
Net loss attributable to common stockholders	$ (3,304,893)	$ (3,074,102)	$ (8,381,
Loss per common share (basic and diluted):			
Continuing operations	$ (0.13)	$ (0.17)	$ (
Attributable to common stockholders	$ (0.13)	$ (0.17)	$ (

Weighted average shares outstanding (basic)	25,843,732	18,044,406	22,946,:

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