August 13, 2020

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

Conference Call to be held Thursday, August 13, 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 second quarter and year-to-date for the period ended June 30, 2020.

"The past four months have been truly momentous for the company. The successful second interim look showed how valuable our diagnostic agent will be for the effective management of Rheumatoid Arthritis," said Mr. Jed A. Latkin, Chief Executive Officer of Navidea. "The signing of the binding MOU with Jubilant is a transformational event for the future of Navidea. Partnering with the second largest radiopharmaceutical company in the United States and a global leader in pharmaceuticals is something we have worked hard to achieve for many years. Furthermore, the $25 million in growth capital pledged by a top-notch syndicate of investors has assured the company's non-RA related growth funding for years to come."

Second 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.
- Signed a binding commitment letter on August 9, 2020 with Mastiff Group LLC, for a private placement financing of up to $25 million in aggregate gross proceeds of shares of Navidea's common stock, to be priced either "at the market" or at a premium to Navidea's closing price on the date of execution. Navidea expects to sign definitive documents for a common stock only transaction, with an investor syndicate comprised of Mastiff Group LLC, John Kim Scott, Jr. and other fundamental biotech focused investors no later than August 18, 2020, with the closing to take place within 15 business days thereafter.
- 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.
- Finalized the previously announced $4.2 million financing related to the judgment by

the Ohio Court of Common Pleas (the "Judgment"). Navidea agreed to issue Keystone Capital Partners, LLC, up to $4.2 million of convertible preferred shares, which will be guaranteed by a portion of the proceeds of the Judgment.

- Announced positive preliminary results from the Company's second interim analysis of its ongoing NAV3-31 Phase 2b study. Analysis demonstrated that these interim data further corroborate Navidea's hypotheses that Tc99m tilmanocept imaging can provide robust, quantitative imaging in healthy controls and in patients with active rheumatoid arthritis ("RA"), and that this imaging can provide an early indicator of treatment efficacy in patients with active RA.
- Achieved full enrollment in its ongoing NAV3-31 Phase 2b study titled "Evaluation of the Precision and Sensitivity of Tilmanocept Uptake Value (TUV) on Tc99m Tilmanocept Planar Imaging." All of the subjects have been enrolled in the three-arm trial, with the protocol-specified longitudinal imaging events on track.
- Presented results from the Company's first interim analysis of its ongoing NAV3-31 phase 2b clinical study, titled, *A Phase 2b Study of Intravenously Administered Tc 99m Tilmanocept to Determine Differential Uptake, Reproducibility Over Time and Image Stability in Healthy Subjects and in Patients with Rheumatoid Arthritis ("RA") on Stable Treatment*, at the European League Against Rheumatism ("EULAR") Congress 2020.
- 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.
- Filed a provisional patent on improved synthesis of Tilmanocept.
- 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.

Michael Rosol, Ph.D., Chief Medical Officer for Navidea, said, "The clinical research team continues to work diligently to advance the technology in key disease areas, with an emphasis on our RA program. Our currently running Phase 2b trial in RA is proceeding well and, building upon the interim analysis results, we are preparing to discuss the upcoming Phase 3 with the FDA. 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 second quarter 2020 were $271,000, compared to $260,000 for the same period in 2019. Total revenues for the first half of 2020 were $427,000, compared to $302,000 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 second quarter of 2020 were $1.3 million, compared to $1.1 million in the same period in 2019. R&D expenses for the first half of 2020 were $2.3 million, compared to $1.8 million in the same period in 2019. The increases were primarily due to net increases in drug project expenses, including increased Manocept™ diagnostic development costs offset by decreased Manocept therapeutic development costs, coupled with increased employee compensation.

- Selling, general and administrative ("SG&A") expenses for the second quarter of 2020 were $1.3 million, compared to $1.9 million in the same period in 2019. SG&A expenses for the first half of 2020 were $3.2 million, compared to $3.6 million in the same period in 2019. The decrease was primarily due to decreased legal and professional services, travel, insurance, depreciation, and investor relations costs, offset by increased employee compensation and franchise taxes.
- Navidea's net loss attributable to common stockholders for the second quarter of 2020 was $2.4 million, or $0.11 per share, compared to $2.7 million, or $0.24 per share, for the same period in 2019. Navidea's net loss attributable to common stockholders for the first half of 2020 was $5.1 million, or $0.24 per share, compared to $5.1 million, or $0.48 per share, for the same period in 2019.
- Navidea ended the second quarter of 2020 with $1.6 million in cash and investments. Since June 30, 2020, the Company has received the final $3.9 million of cash related to the February 2020 funding transactions. In addition, the Company received $1.0 million related to execution of the Jubilant MOU in August 2020.

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:	Q2 2020 Earnings and Business Update Conference Call
Date:	Thursday, August 13, 2020
Time:	5:00 p.m. (EDT)
U.S. & Canada Dial-in:	877-407-0312
International Dial-in:	+1 201-389-0899
Conference ID:	13708190
Webcast Link:	https://webcasts.eqs.com/navidbioph20200813/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

	June 30, 2020 (unaudited)	December 31, 2019
Assets:		
Cash and cash equivalents	$ 1,617,001	$ 1,047,159
Other current assets	4,449,021	1,868,624
Non-current assets	1,040,661	1,235,123
Total assets	$ 7,106,683	$ 4,150,906
Liabilities, mezzanine equity and stockholders' deficit:		
Current liabilities	$ 4,145,074	$ 3,819,551
Lease liabilities, non-current	434,324	512,344
Deferred revenue, non-current	700,000	700,000
Total liabilities	5,279,398	5,031,895
Mezzanine equity	3,450,000	-
Navidea stockholders' deficit	(2,354,019)	(1,612,292)

Noncontrolling interest	731,304	731,303
Total stockholders' deficit	(1,622,715)	(880,989)
Total liabilities, mezzanine equity and stockholders' deficit	$ 7,106,683	$ 4,150,906

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Six Months Ended	
	June 30, 2020 (unaudited)	June 30, 2019 (unaudited)	June 30, 2020 (unaudited)	June 30, 2019 (unaudited)
Revenue:				
Royalty revenue	$ 8,920	$ 5,940	$ 24,141	$ 9,090
License revenue	-	9,953	-	9,953
Grant and other revenue	262,181	244,199	403,232	282,673
Total revenue	271,101	260,092	427,373	301,716
Cost of revenue	357	238	966	6,364
Gross profit	270,744	259,854	426,407	295,352
Operating expenses:				
Research and development	1,281,779	1,070,642	2,281,048	1,811,225
Selling, general and administrative	1,329,591	1,861,600	3,157,345	3,590,116
Total operating expenses	2,611,370	2,932,242	5,438,393	5,401,341
Loss from operations	(2,340,626)	(2,672,388)	(5,011,986)	(5,105,989)
Other income (expense):				
Interest income (expense), net	15,343	1,630	12,971	11,478
Other, net	(336)	(3,220)	(212)	(4,356)
Loss before income taxes	(2,325,619)	(2,673,978)	(4,999,227)	(5,098,867)
Benefit from (provision for) income taxes	-	168	-	(708)
Loss from continuing operations	(2,325,619)	(2,673,810)	(4,999,227)	(5,099,575)
Income (loss) from discontinued operations, net of tax effect	-	632	-	(2,665)
Net loss	(2,325,619)	(2,673,178)	(4,999,227)	(5,102,240)
Less loss attributable to noncontrolling interest	(1)	(3)	1	(15)
Deemed dividend on Series C Preferred Stock beneficial conversion feature	(77,778)	-	(77,778)	-
Net loss attributable to common stockholders	$ (2,403,396)	$ (2,673,175)	$ (5,077,006)	$ (5,102,225)
Loss per common share (basic and diluted):				
Continuing operations	$ (0.11)	$ (0.24)	$ (0.24)	$ (0.48)
Attributable to common stockholders	$ (0.11)	$ (0.24)	$ (0.24)	$ (0.48)
Weighted average shares outstanding	22,759,393	11,096,834	21,481,514	10,560,265

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