August 15, 2022

Navidea Biopharmaceuticals Reports Second Quarter 2022 Financial Results

Conference Call to be Scheduled at a Later Date

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, 2022.

Second Quarter 2022 Highlights and Subsequent Events

- Continued enrollment into the Company's NAV3-33 Phase 3 trial in rheumatoid arthritis ("RA") titled "Evaluation of Tc 99m Tilmanocept Imaging for the Early Prediction of Anti-TNFα Therapy Response in Patients with Moderate to Severe Active Rheumatoid Arthritis." Enrollment is ongoing across the three currently opened sites.
- Announced positive preliminary results from the Company's ongoing NAV3-32 Phase 2b trial comparing Tc99m tilmanocept imaging to histopathology of joints of patients with active RA. Two non-overlapping classes that align with the fibroid and non-fibroid histological pathotypes were identified, supporting the hypothesis that these classes can be identified by Tc99m tilmanocept imaging.
- Received $800,000 from a strategic partner as reimbursement for certain manufacturing and research and development expenses.
- The Company's abstract titled "TAM Targeted Imaging Agents Binding CD206 and Selective Blocking of Off Target Liver Localization" was presented at the Society of Nuclear Medicine and Molecular Imaging Annual Meeting on June 11, 2022 in Vancouver, British Columbia.
- The Company's abstract titled "CD206 Targeted Delivery of Bisphosphonate Payloads Alter Human Macrophage Phenotypes Towards M1-like" was presented at the Tumor Myeloid-Directed Therapies Summit on June 14, 2022 in Boston, MA.
- Announced publication of a manuscript titled "Increased Macrophage Specific Arterial Inflammation Relates Uniquely to Non-calcified Plaque and Specific Immune Activation Pathways in People with HIV: A Targeted Molecular Imaging Approach," based on work performed at the Massachusetts General Hospital ("MGH") and Harvard Medical School, Boston MA, and sponsored by the Company. The research, appearing in *The Journal of Infectious Diseases* (PMID: 35856671), was led by Principal Investigator Steven Grinspoon, MD, Chief of the Metabolism Unit at MGH and Professor of Medicine at Harvard Medical School.
- Announced publication of a manuscript titled "Tilmanocept as a novel tracer for lymphatic mapping and sentinel lymph node biopsy in melanoma and oral cancer," based on work performed at the Crown Princess Mary Cancer Centre ("CPMCC") at the University of Sydney, in Sydney, Australia. The research, appearing in the *ANZ Journal of Surgery* (PMID: 35848587), was led by Principal Investigator Dr. Muzib

Abdul-Razak, MBBS, FRACS, FRCSE, MCh., of the Faculty of Medicine, Department of Surgical Oncology and Head and Neck Surgery in the CPMCC at the University of Sydney.
- Received notification of issuance of patent from the USPTO for the application titled, “Compounds And Compositions For Treating Leishmaniasis And Methods Of Diagnosis And Treating Using Same” (Patent No. US 11,369,680 B2).
- Filed a provisional patent application describing a new degradable linker for dexamethasone and paclitaxel containing Manocept therapeutic constructs. These constructs are being evaluated preclinically for effects on macrophages and in animal models of oncology and inflammatory indications.
- Received a Decision of Grant for patent application in Japan for claims related to targeted delivery of a wide range of therapeutic payloads attached to Manocept platform-based constructs using a degradable hydrazone linker.
- Closed on a $2.5 million bridge loan from the Company’s Vice Chair of the Board of Directors, John K. Scott, Jr.
- Adopted a plan designed to protect the Company’s net operating loss and tax credit carryforwards.

Michael Rosol, Ph.D., Chief Medical Officer for Navidea, said, “The company continues to work diligently to advance the technology in key disease areas, with an emphasis on our RA program. The NAV3-33 Phase 3 and NAV3-32 Phase 2b trials continue to enroll. We are pleased with the preliminary positive results from the NAV3-32 study that thus far support our hypothesis that we can distinguish between fibroid and non-fibroid pathotypes of RA with a single scan.” Dr. Rosol continued, “Concurrent with all of this, we continue to make progress in our therapeutics pipeline, and we expect to keep advancing these towards the clinic.”

Financial Results

- Total net revenues for the second quarter of 2022 were $57,000, compared to $261,000 for the same period in 2021. Total net revenues for the first half of 2022 were $57,000, compared to $385,000 for the same period in 2021. The decrease was primarily due to the 2021 partial recovery of debts previously written off in 2015, the 2021 receipt of reimbursement from Cardinal Health 414, LLC of certain research and development (“R&D”) costs, decreased grant revenue related to Small Business Innovation Research grants from the National Institutes of Health supporting Manocept development, and decreased license revenue from transitional sales of Tc99m tilmanocept in Europe.
- Research and development expenses for the second quarter of 2022 were $1.7 million, compared to $1.5 million for the same period in 2021. R&D expenses for the first half of 2022 were $2.9 million, compared to $2.7 million for the same period in 2021. The increase was primarily due to increased employee compensation including incentive-based awards and increased recruiting fees, offset by decreases in drug project expenses and regulatory consulting expenses.
- Selling, general and administrative (“SG&A”) expenses for the second quarter of 2022 were $1.3 million, compared to $1.4 million for the same period in 2021. SG&A expenses for the first half of 2022 were $3.1 million, compared to $3.7 million for the same period in 2021. Decreases in employee compensation including fringe benefits and incentive-based awards, travel, investor relations, general office expenses,

facilities costs and franchise taxes were offset by increases in insurance, director fees, losses on the abandonment of certain intellectual property and legal and professional services.
- Navidea's net loss attributable to common stockholders for the second quarter of 2022 was $3.0 million, or $0.10 per share, compared to $2.7 million, or $0.09 per share, for the same period in 2021. Navidea's net loss attributable to common stockholders for the first half of 2022 was $6.0 million, or $0.20 per share, compared to $5.6 million, or $0.20 per share, for the same period in 2021.
- Navidea ended the second quarter of 2022 with $328,000 million in cash and cash equivalents.

The Company's registration statement on Form S-1 (Registration No. 333-262691) relative to the Company's current rights offering was declared effective by the Securities and Exchange Commission ("SEC") on August 3, 2022. The prospectus relating to and describing the terms of the rights offering has been filed with the SEC as a part of the registration statement and is available on the SEC's web site at http://www.sec.gov. Copies of the final prospectus for the rights offering may be obtained, when available, from Maxim Group LLC, 300 Park Avenue, New York, NY 10022, Attention Syndicate Department, email: syndicate@maximgrp.com or telephone (212) 895-3745.

This press release does not constitute an offer to sell or the solicitation of an offer to buy these securities, nor will there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

In light of the Company's pending rights offering, the Company will host a second quarter earnings conference call and business update following the conclusion of the rights offering. The Company will issue a press release announcing the date and time of the earnings conference call.

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, 2022 (unaudited)	December 31, 2021
Assets:		
Cash and cash equivalents	$ 328,012	$ 4,230,865
Other current assets	842,728	1,152,420
Non-current assets	1,332,965	1,261,548
Total assets	$ 2,503,705	$ 6,644,833
Liabilities and stockholders' (deficit) equity:		
Current liabilities	$ 5,321,985	$ 5,299,802
Deferred revenue, non-current	700,000	700,000
Note payable to related party, net of discount	720,305	-
Other liabilities	2,062	20,288
Total liabilities	6,744,352	6,020,090
Total stockholders' deficit	(4,533,164)	(106,556)
Noncontrolling interest	292,517	731,299
Total Navidea stockholders' (deficit) equity	(4,240,647)	624,743
Total liabilities and stockholders' (deficit) equity	$ 2,503,705	$ 6,644,833

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Six Months Ended	
	June 30, 2022 (unaudited)	June 30, 2021 (unaudited)	June 30, 2022 (unaudited)	June 30, 2021 (unaudited)
Revenue	$ 57,526	$ 261,046	$ 57,526	$ 384,783
Cost of revenue	473	-	473	-
Gross profit	57,053	261,046	57,053	384,783
Operating expenses:				
Research and development	1,723,988	1,498,056	2,893,242	2,720,810
Selling, general and administrative	1,255,666	1,432,610	3,065,695	3,663,355
Total operating expenses	2,979,654	2,930,666	5,958,937	6,384,165
Loss from operations	(2,922,601)	(2,669,620)	(5,901,884)	(5,999,382)
Other income (expense):				
Interest (expense) income, net	(83,584)	1,266	(87,246)	(1,609)
Gain on extinguishment of debt	-	-	-	366,000
Other, net	6,726	(5,686)	2,427	(5,941)
Net loss	(2,999,459)	(2,674,040)	(5,986,703)	(5,640,932)
Loss attributable to noncontrolling interest	1	1	3	3
Net loss attributable to common stockholders	$ (2,999,458)	$ (2,674,039)	$ (5,986,700)	$ (5,640,929)
Loss attributable to common stockholders per common share (basic and diluted)	$ (0.10)	$ (0.09)	$ (0.20)	$ (0.20)
Weighted average shares outstanding (basic and diluted)	30,268,858	29,117,832	30,238,471	28,531,660

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