

# Navidea Biopharmaceuticals Reports Second Quarter 2019 Financial Results

Conference Call to be held Thursday, August 8, 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 second quarter of 2019. Navidea reported total revenues for the quarter of \$260,000. Net loss attributable to common stockholders was \$2.7 million.

"During the second quarter, Navidea continued to deliver on its renewed focus to complete its NAV 3-31 trial and raise the funding to cover it," said Mr. Jed A. Latkin, Chief Executive Officer of Navidea. "The Company furthered its partnership discussions around the globe but most importantly Navidea met its internal recruiting and enrollment goals for its ongoing RA trials. The Company remains focused on bringing its RA diagnostic to market."

# **Second Quarter 2019 Highlights and Subsequent Events**

- Effected a one-for-twenty reverse stock split and received notification of stock price compliance from the NYSE American
- Announced that results of the Company's NAV3-21 clinical study for diagnosis of rheumatoid arthritis were presented at the Society of Nuclear Medicine and Molecular Imaging ("SNMMI") Annual Meeting by Arash Kardan, M.D.
- Completed an underwritten public offering with gross proceeds of \$6.0 million
- Achieved double-digit subject enrollment in our NAV3-31 Phase 2b study and are on track with recruitment projections to date
- Received an Intent to Fund notification from the National Heart, Lung and Blood Institute for its 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"

"We were extremely pleased with the recognition received at the annual SNMMI meeting following our Phase 1 and 2 study results, and we are pressing forward with recruitment in the ongoing Phase 2B," said Dr. Michael Rosol, Chief Medical Officer of Navidea. "This Phase 2b study will provide the fundamental test-retest and longitudinal data to validate our power calculations for the upcoming Phase 3 trial."

## **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 second quarter of 2019 were \$260,000, compared to \$542,000 in the same period of 2018. Total revenues for the first six months of 2019 were \$302,000, compared to \$819,000 in the same period of 2018. The decrease was primarily due to a decrease in license revenue related to the sublicense of our NAV4694 technology which included a non-refundable upfront payment in 2018, coupled with a reduction in grant revenue related to SBIR grants from the NIH supporting Manocept development.
- Research and development ("R&D") expenses were approximately \$1.1 million in each
  of the second quarters of 2019 and 2018. R&D expenses for the first six months of
  2019 were \$1.8 million, compared to \$2.1 million in the same period of 2018. The
  year-to-date decrease was primarily due to net decreases in drug project expenses
  including therapeutics, Tc99m tilmanocept, and NAV4694 development costs, offset by
  increased Manocept diagnostic development costs. The net decrease 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 second quarter of 2019 were \$1.9 million, compared to \$1.8 million in the same period of 2018. SG&A expenses were approximately \$3.6 million in each of the first six months of 2019 and 2018. Increased legal and professional services were offset by decreased compensation costs.
- Navidea's net loss attributable to common stockholders for the second quarter of 2019 was \$2.7 million, or \$0.24 per share, compared to a net loss attributable to common stockholders of \$2.4 million, or \$0.29 per share, for the same period in 2018.
   Navidea's net loss attributable to common stockholders for the first six months of 2019 was \$5.1 million, or \$0.48 per share, compared to a net loss attributable to common stockholders of \$9.1 million, or \$1.12 per share, for the same period in 2018.
- Navidea ended the second quarter of 2019 with \$5.3 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: Q2 2019 Earnings and Business Update Conference Call

Date: Thursday, August 8, 2019

 Time:
 5:00 p.m. (EDT)

 U.S. & Canada Dial-in:
 877-407-0312

 International Dial-in:
 +1 201-389-0899

 Conference ID:
 13693119

Webcast Link: https://webcasts.egs.com/navidbioph20190808/en

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 <a href="https://www.navidea.com">www.navidea.com</a>.

#### **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 <u>www.navidea.com</u>.

# **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 for the use of proceeds received from the offering. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: market and other conditions, the satisfaction of customary closing conditions related to the public offering and the impact of general economic, industry or political conditions in the United States or internationally, 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 <a href="http://www.sec.gov">http://www.sec.gov</a> or at <a href="http://ir.navidea.com">http://ir.navidea.com</a>.

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,	December 31,		
	2019	2018		
	(unaudited)			
Assets:				
Cash and available-for-sale securities	\$5,263,045	\$	4,275,151	
Other current assets	1,211,753		1,320,605	
Non-current assets	1,655,597		1,425,771	
Total assets	\$8,130,395	\$	7,021,527	
Liabilities and stockholders' equity:				
Current liabilities	\$3,822,135	\$	3,378,518	
Deferred revenue, non-current	700,000		700,000	
Other liabilities	676,753		532,549	
Total liabilities	5,198,888		4,611,067	
Navidea stockholders' equity	2,263,201		1,742,139	
Noncontrolling interest	668,306		668,321	
Total stockholders' equity	2,931,507		2,410,460	
Total liabilities and stockholders' equity	\$8,130,395	\$	7,021,527	

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Т	Three Months Ended		Six Months Ended			
	Jι	June 30, June 30,		June 30,		June 30,	
		2019	2018	2019		2018	
	(un	audited)	(unaudited)	(unaudited)		(unaudited)	
Revenue:							
Royalty revenue	\$	5,940	\$ 6,665	\$	9,090	\$	7,460
License revenue		9,953	257,709		9,953		257,709
Grant and other revenue		244,199	277,753		282,673		553,403
Total revenue		260,092	542,127		301,716		818,572
Cost of revenue		238	35,392		6,364		35,710
Gross profit		259,854	506,735		295,352		782,862
Operating expenses:							
Research and development	1,	070,642	1,142,718	1,	811,225	2	,141,674
Selling, general and administrative	1,	,861,600	1,789,399	3,	590,116	3	,565,771
Total operating expenses	2,	932,242	2,932,117	5,	401,341	5	,707,445
Loss from operations	(2,	672,388)	(2,425,382)	(5,	105,989)	(4	,924,583)
Other (expense) income:							
Interest income (expense), net		1,630	(23,547)		11,478		7,840
Loss on extinguishment of debt		-	-		-	(4	,265,434)
Other, net		(3,220)	2,828		(4,356)		(1,886)
Loss before income taxes	(2,	673,978)	(2,446,101)	(5,	098,867)	(9	,184,063)
Benefit from (provision for) income taxes		168	10,929		(708)		10,929
Loss from continuing operations	(2,	673,810)	(2,435,172)	(5,	099,575)	(9	,173,134)
Discontinued operations, net of tax effect:							
Gain (loss) from operations		632	(1,938)		(2,665)		(1,938)
Gain on sale		-	43,053		-		43,053
Net loss	(2,	673,178)	(2,394,057)	(5,	102,240)	(9	,132,019)
Less loss attributable to noncontrolling interest	t	(3)	(16)		(15)		(25)
Net loss attributable to common stockholders	\$ (2,	673,175)	\$(2,394,041)	\$ (5,	102,225)	\$(9	,131,994)
Loss per common share (basic and diluted):				-			
Continuing operations	\$	(0.24)	\$ (0.30)	\$	(0.48)	\$	(1.13)
Discontinued operations	\$	0.00	\$ 0.01	\$	(0.00)	\$	0.01
Attributable to common stockholders	\$	(0.24)	\$ (0.29)	\$	(0.48)	\$	(1.12)
Weighted average shares outstanding	11,	,096,834	8,135,849	10,	,560,265	8	,124,711

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Source: Navidea Biopharmaceuticals, Inc.