Navidea Provides Corporate Update and Reports Full Year 2016 Results

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DUBLIN, Ohio--(BUSINESS WIRE)--Mar. 29, 2017-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAVB) today reported business and financial highlights for the fourth quarter and year ended December 31, 2016.

2016 Top Highlights

- Achieved $1 million in Lymphoseek® (technetium Tc 99m tilmanocept) injection commercial milestones upon sale of 100,000th patient dose and receipt of European approval to manufacture a reduced-mass vial
- Completed sale of Lymphoseek to Cardinal Health 414, LLC ("Cardinal Health 414") and received approximately $83 million in upfront payments including an advance of $3 million of future earnout payments, with up to $227 million in potential additional earnout payments through 2026
- Initiated intravenous ("IV") dose escalation Phase 1 imaging/disease-finding study in rheumatoid arthritis ("RA") of ten cohorts with three dose cohorts completed with major escalations and imaging of active RA
- Completed nine-subject cardiovascular imaging disease-finding study in HIV/CV patients and published clinical results in *The Journal of Infectious Diseases*
- Awarded $1.8 million Fast-track Small Business Innovation Research ("SBIR") Grant for Manocept™-based treatment for Kaposi's Sarcoma ("KS")
- Appointed Michael M. Goldberg, M.D., as President and Chief Executive Officer and Eric K. Rowinsky, M.D., as Chairman of the Board of Directors

Business and Product Development Update

This past year and first quarter of 2017 were positively transformative for us. We refocused Navidea from investing in developing the commercial infrastructure to sell its sole commercial imaging product to a late-stage development company focused on several very large imaging market opportunities, and through its Macrophage Therapeutics, Inc. ("MT") subsidiary successfully advanced a number of novel immunotherapy products through proof of concept studies in animals. In the process, we transformed our capital structure by paying down our high interest and very covenant restrictive debt. The Company has gone from losing close to $28 million in 2015 to a net loss of $14 million in 2016 to operating at cash flow positive projected for 2017 not including discretionary research projects. Furthermore the Company, which had no excess cash flow for discretionary, non grant related research, now has sufficient cash to advance all of our existing imaging and MT ongoing initiatives.

While transforming our business model, balance sheet and income statements, we made significant progress with our technology and pipeline. We are fortunate that both our imaging and therapeutic product candidates are based on the same drug delivery system that targets activated macrophages, even when an additional agent is chemically attached. In humans, we advanced two new delivery approaches and confirmed their utility when dosed subcutaneously or intravenously. In animals, we initiated development of an oral delivery formulation for our therapeutic product candidates.

Additionally, we confirmed that in humans we can target the classically-activated or M1 macrophage in patients with RA and atherosclerosis. This is a major advance, as the alternative activation state, or M2 macrophage, is well known to have significantly higher cell surface expression of the mannose receptor (CD206) than the M1 macrophage in the activated state. Clinical results clearly demonstrate sufficient CD206 expression on M1 activated macrophages to target this receptor with our technology. Our animal studies confirmed as well that targeting either M1 or M2 macrophages implicated in disease is feasible with the appropriate therapeutic linked to our delivery system. In animal models we verified the activity of our product candidates in both M1-based diseases as well as M2-based diseases. Finally, working with various academic groups we demonstrated that by targeting the host macrophage that acts as an incubator we can eliminate viral reservoirs containing Zika, dengue, human immunodeficiency virus ("HIV"), human herpesvirus 8 ("HHV8"), and other infectious agents such as leishmaniosis. We are also currently working with National Institutes of

Health (“NIH”)-funded labs, at no cost to Navidea, to explore our antiviral and anti-infective performance in appropriate animal models.

Financial Results

Revenues for the year ended December 31, 2016 were $22.0 million compared to $13.2 million for 2015. Navidea’s revenues for 2016 consisted of $17.0 million in sales of Lymphoseek, $3.1 million from various federal grants and other revenue, and $1.8 million related to license agreements, compared to $10.3 million, $1.9 million and $1.1 million, respectively, for 2015.

Operating expenses for the year ended December 31, 2016 were approximately $21.9 million compared to $30.0 million for 2015. Research and development expenses were $8.9 million during 2016 compared to $12.8 million during 2015. The net decrease was primarily a result of reductions in NAV4694, Lymphoseek and NAV5001 product development costs coupled with reduced headcount and related support costs, offset by increased Manocept diagnostic and therapeutic product development costs. Selling, general and administrative expenses were approximately $13.0 million for 2016 compared to $17.3 million for 2015. The net decrease was primarily due to reduced headcount and related support costs, contracted medical science liaisons, business development consulting services, market development expenses related to Lymphoseek, and investor relations, offset by increased legal and professional services.

Navidea’s loss from operations for the year ended December 31, 2016 was $2.2 million compared to $18.6 million for 2015. For the year ended December 31, 2016, Navidea reported a loss attributable to common stockholders of $14.3 million, or $0.09 per share, compared to a loss attributable to common stockholders of $27.6 million, or $0.18 per share, for the same period in 2015.

Revenues for the fourth quarter of 2016 were $3.4 million compared to $4.3 million for the same period in 2015. Navidea’s revenues for the fourth quarter of 2016 consisted of $2.3 million in sales of Lymphoseek and $1.0 million from various federal grants and other revenue, compared to $3.5 million and $541,000, respectively, coupled with $250,000 related to license agreements, for the same period in 2015. Additionally, approximately $2 million in sales of Lymphoseek to Cardinal Health 414 recorded in the third quarter of 2016 was accelerated to help facilitate the transaction that was ultimately closed in March 2017. Without acceleration of such, the related sales would have occurred in the fourth quarter of 2016.

Fourth quarter 2016 operating expenses were $5.5 million compared to $6.4 million for the fourth quarter of 2015. Research and development expenses were $2.4 million during the fourth quarter of 2016 compared to $2.6 million during the fourth quarter of 2015. The net decrease from 2015 to 2016 was primarily a result of reduced headcount and related support costs coupled with decreased NAV4694 product development costs, offset by increased Manocept diagnostic and Lymphoseek product development costs. Selling, general and administrative expenses were $3.1 million for the fourth quarter of 2016 compared to $3.8 million for the same period in 2015. The net decrease was primarily due to reduced headcount and related support costs, market development expenses related to Lymphoseek and investor relations, offset by increased legal and professional services.

Navidea’s loss from operations for the fourth quarter of 2016 was $2.4 million compared to $2.6 million for the fourth quarter of 2015. For the fourth quarter of 2016, Navidea reported a loss attributable to common stockholders of $3.9 million, or $0.02 per share, compared to a loss attributable to common stockholders of $2.5 million, or $0.02 per share, for the fourth quarter of 2015.

Detailed Highlights

- **Navidea and Cardinal Health 414**
  - Completed sale of Lymphoseek to Cardinal Health 414 for lymphatic mapping, lymph node biopsy and the diagnosis of metastatic spread to lymph nodes for the staging of cancer in North America
  - Received approximately $83 million in upfront payments including an advance of $3 million of future earnout

payments, with up to $227 million in potential additional earnout payments through 2026, $17.1 million of which is guaranteed over the next three years

- **CRG et al**
  - Entered into a Global Settlement Agreement between the Company, MT, Capital Royalty Partners II L.P. and its affiliates ("CRG"), and Cardinal Health 414 in which Navidea repaid $59 million (the "Deposit Amount") of its indebtedness and other obligations outstanding under the CRG Term Loan.
- **Platinum et al**
  - Concurrently with payment of the Deposit Amount to CRG, the Company also paid to Platinum Partners Credit Opportunities Master Fund, LP ("PPCO") an aggregate of $7.7 million in partial satisfaction of the Company's liabilities, obligations and indebtedness under that certain Loan Agreement, dated July 25, 2012 (as amended) by and between the Company and Platinum-Montaur Life Sciences, LLC, which, to the extent of such payment, were transferred by Platinum-Montaur to PPCO. Approximately $1.9 million remains outstanding under the Platinum Loan Agreement.
- **U.S. Food and Drug Administration ("FDA")**
  - Held several discussions/meetings with the FDA significantly expediting development and approval timelines for Manocept-RA disease-finding approaches to rheumatoid arthritis
- **Cardiovascular ("CV") Initiative**
  - Completed nine-subject cardiovascular imaging disease-finding study in HIV/CV patients
  - Presented clinical results at CROI-2017 and published in the *Journal of Infectious Disease*
  - Additional planned studies include a large potential partner evaluating product in their proprietary animal models
- **Rheumatoid Arthritis**
  - Completed 18-subject subcutaneous ("SC") Manocept RA study
  - Initiated RA intravenous ("IV") dose escalation Phase 1 imaging/disease-finding study of 10 cohorts with three dose cohorts completed with major escalations and imaging of active RA
  - Appointed strategic clinical and regulatory consulting firm to optimize clinical development plan for RA imaging candidate
- **Non-Alcoholic Steatohepatitis (NASH) Therapy**
  - Completed three *in vivo* studies employing two Manocept conjugate agents and three different dosing regimens demonstrating effectiveness at preventing non-alcoholic fatty liver disease ("NAFLD") progression to NASH and NASH's progression to liver cirrhosis
  - A poster presentation on certain of our NASH results will be presented at a meeting next week and will be posted on the MT website
- **Cancer Therapy**
  - Completed three preclinical studies, two single agent and one in combination with a well-established therapeutic antibody (two confirmatory *in vivo* studies – murine human tumor model). All three studies confirmed a positive impact on the tumor progression and inhibition/tumor kill.
- **Cancer Imaging to Treatment**
  - *Colorectal Cancer and Liver Cancer* – completed preclinical testing for the requirements to administer the Manocept imaging agent for colorectal cancer and colorectal cancer with synchronous liver metastases.
  - *Cervical Cancer* – completed a significant portion of the clinical testing for a new indication for imaging of metastatic disease (lymph node metastasis) in cervical cancer. Navidea's portion of the study will be completed in Q1 2017.
- **Lipid Storage Disease (Neuro)**
  - Initiated *in vitro* cell culture study in which Manocept conjugates demonstrated substantial protective effect of glial cells exposed to toxic metabolite
- **Anti-Infectives**
  - Zika Virus – Initiated and completed four *in vitro* studies in human tissue demonstrating a highly effective reduction in Zika infectivity and antiviral activity by multiple Manocept conjugates
  - Dengue Virus – Initiated and completed four *in vitro* studies in human tissue demonstrating a highly effective

reduction in dengue infectivity and antiviral activity by multiple Manocept conjugates
    - Leishmaniosis – Initiated and completed two *in vivo* studies demonstrating a highly effective targeting in Leishmaniosis infectivity and parasite activity by multiple Manocept conjugates
    - Cytomegalovirus ("CMV") – Held discussions with NIH/NIAID on testing of key Manocept conjugates in CMV infection and disease progression with preclinical studies to be initiated in H2 2017
- **Kaposi's Sarcoma**
    - Received NIH/NCI funding to support the therapeutic development of anticancer (Anti-KS) Manocept conjugates
    - Phase 1 of the grant completed and Phase 2 clinical protocols are IRB-approved with study initiation anticipated shortly
    - Human Herpes Virus 8 – The testing of Manocept agents against HHV8 are an integral part of the Kaposi's Sarcoma therapy initiatives
    - Human Immunodeficiency Virus – The testing of Manocept agents against HIV is an integral part of the KS therapy initiatives
- **Completed Preclinical FDA requirements** for IV administration of tilmanocept for all radio-diagnostic applications
- **Inflammatory Bowel Disease and Crohn's Disease ("BD/C")**
    - Initiated partnership with major pharma group to assess the efficacy of Manocept conjugates in appropriate *in vivo* models with results anticipated in the coming months.

About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products and platforms including Manocept™ and NAV4694 to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making, targeted treatment and, ultimately, patient care. Lymphoseek® (technetium Tc 99m tilmanocept) injection, Navidea's first commercial product from the Manocept platform, was approved by the FDA in March 2013 and in Europe in November 2014. The development activities of the Manocept immunotherapeutic platform will be conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics. 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.

NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2016 (unaudited)	December 31, 2015
Assets:		
Cash	$1,539,325	$7,166,260
Restricted cash	5,001,253	-
Other current assets	4,285,691	5,410,914
Non-current assets	1,635,407	2,387,339
Total assets	$12,461,676	$14,964,513
Liabilities and stockholders' deficit:		
Deferred revenue, current	$2,315,037	$1,044,281

Notes payable, current	51,957,913	333,333
Other current liabilities	15,588,838	4,806,236
Notes payable, net of discount	9,641,179	60,746,002
Other liabilities	624,922	1,870,361
Total liabilities	80,127,889	68,800,213
Navidea stockholders' deficit	(68,135,123)	(54,305,258)
Noncontrolling interest	468,910	469,558
Total stockholders' deficit	(67,666,213)	(53,835,700)
Total liabilities and stockholders' deficit	$12,461,676	$14,964,513

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Twelve Months Ended	
	December 31, 2016 (unaudited)	December 31, 2015 (unaudited)	December 31, 2016 (unaudited)	December 31, 2015
Revenue:				
Lymphoseek sales revenue	$2,332,609	$3,502,860	$17,037,098	$10,254,352
Lymphoseek license revenue	-	250,000	1,795,625	1,133,333
Grant and other revenue	1,022,988	540,806	3,136,983	1,861,622
Total revenue	3,355,597	4,293,666	21,969,706	13,249,307
Cost of good sold	279,554	515,386	2,297,040	1,754,763
Gross profit	3,076,043	3,778,280	19,672,666	11,494,544
Operating expenses:				
Research and development	2,421,422	2,607,216	8,882,576	12,787,733
Selling, general and administrative	3,087,991	3,771,753	13,013,565	17,257,329
Total operating expenses	5,509,413	6,378,969	21,896,141	30,045,062
Loss from operations	(2,433,370)	(2,600,689)	(2,223,475)	(18,550,518)
Other income (expense):				
Interest expense, net	(2,573,101)	(2,183,050)	(14,861,270)	(6,873,736)
Equity in the loss of joint venture	-	(10,036)	(15,159)	(305,253)
Loss on disposal of joint venture	-	-	(39,732)	-
Change in fair value of financial instruments	1,102,535	1,088,120	2,858,524	(614,782)
Loss on extinguishment of debt	-	-	-	(2,440,714)
Other income (expense), net	21,997	708	(27,919)	26,808
Net loss	(3,881,939)	(3,704,947)	(14,309,031)	(28,758,195)
Benefit from income taxes	-	436,051	-	436,051
Loss from continuing operations	(3,881,939)	(3,268,896)	(14,309,031)	(28,322,144)
Income from discontinued operations, net of tax	-	758,609	-	758,609
Net loss	(3,881,939)	(2,510,287)	(14,309,031)	(27,563,535)
Less loss attributable to noncontrolling interest	(132)	(174)	(648)	(855)
Deemed dividend on beneficial conversion feature	-	-	-	(46,000)
Net loss attributable to common stockholders	$(3,881,807)	$(2,510,113)	$(14,308,383)	$(27,608,680)

Loss per common share (basic and diluted):				
Continuing operations	$(0.02)	$(0.02)	$(0.09)	$(0.19)
Discontinued operations	$-	$0.00	$-	$0.01
Attributable to common stockholders	$(0.02)	$(0.02)	$(0.09)	$(0.18)
Weighted average shares outstanding (basic and diluted)	155,516,120	154,591,487	155,422,384	151,180,222

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