

March 6, 2014



Navidea Announces Fourth Quarter and Full Year 2013 Results

– *Management hosting webcast and conference call on March 6, 2014 at 8:30 a.m. ET*

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DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAV), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced results for the fourth quarter and year ended December 31, 2013.

Business Update

Key commercial and development milestones achieved by Navidea in 2013 and to date in 2014 include:

- Lymphoseek® (technetium Tc 99m tilmanocept) Injection
 - Received U.S. approval in March 2013 for use in lymphatic mapping procedures that are performed to aid in the diagnostic evaluation of potential cancer spread for patients with breast cancer and melanoma and initiated sales activities with U.S. distribution partner in May 2013.
 - Maintained solid Lymphoseek growth trajectory measured by increasing number of units and growth in key sales metrics.
 - Received Centers for Medicare & Medicaid Services (CMS) codes for reimbursement (pass-through C-Code and A-Code).
 - Received Fast Track and Priority Review of a Lymphoseek supplemental New Drug Application (sNDA) for expanded indication in sentinel lymph node (SLN) detection in patients with head and neck cancer with Prescription Drug User Fee Act (PDUFA) review date targeted for June 16, 2014. Also received notification of acceptance for review of another Lymphoseek sNDA for a proposed expanded label to support broader and more flexible use in imaging and lymphatic mapping procedures, including lymphoscintigraphy and other optimization capabilities with a PDUFA review date targeted for October 16, 2014.
 - Notified that the European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) consideration of Lymphoseek Marketing Authorization Application (MAA) expected in March 2014.
- NAV4694
 - Initiated enrollment in a global Phase 3 pivotal registration trial in Alzheimer's disease (AD).
 - Selected by the Australian Imaging, Biomarker & Lifestyle (AIBL) study as the sole amyloid tracer for use in their flagship work on AD.
 - Enrolled first subjects in a Phase 2b trial in subjects with mild cognitive impairment (MCI).
- NAV5001

- Initiated a Phase 3 program for Parkinson's disease (PD).
 - Received two Special Protocol Assessments (SPAs) from FDA for Phase 3 pivotal registration program.
- Manocept™
 - Published data from collaborative, proof-of-principle studies for multiple disorders, including Kaposi's Sarcoma, tuberculosis and rheumatoid arthritis (RA), using the Manocept platform in *Nature Outlook – Medical Imaging*.
 - Began a physician-initiated study in Kaposi's Sarcoma patients at the University of California at San Francisco.

Financial Results

Full Year Financial Results: Revenues for the year ended December 31, 2013 were \$1.1 million compared to \$79,000 for 2012. Navidea's revenues for 2013 consisted of \$614,000 in sales of Lymphoseek following its approval in the first quarter of 2013 and initial launch in the second quarter of 2013, and \$516,000 from various federal and state grants. Revenues for 2012 related primarily to payments received from our U.S. distribution partner related to the reimbursement of certain Lymphoseek commercialization activities.

Operating expenses for the year ended December 31, 2013 were \$39.2 million compared to \$28.1 million for 2012. Research and development expenses were \$23.7 million during 2013 compared to \$16.9 million during 2012. The net increase from 2012 to 2013 was primarily a result of net increases in NAV4694, NAV5001 and Manocept platform product development costs and compensation and other support costs related to increased headcount offset by decreases in Lymphoseek development costs and potential pipeline expansion activities. Selling, general and administrative expenses were \$15.5 million for 2013 compared \$11.2 million for 2012. The net increase from 2012 to 2013 was primarily a result of increased medical education costs, compensation and other support costs related to increased headcount, and legal and professional services costs, offset by decreased out-of-pocket marketing costs to support the commercial launch of Lymphoseek.

Navidea's loss from operations for the year ended December 31, 2013 was \$38.4 million compared to \$28.0 million for the same period of 2012. For the year ended December 31, 2013, Navidea reported a loss attributable to common stockholders of \$42.7 million, or \$0.35 per share, compared to a loss attributable to common stockholders of \$29.2 million, or \$0.29 per share, for the same period in 2012.

Fourth Quarter Financial Results: Revenues for the fourth quarter of 2013 were \$535,000 compared to \$7,000 for the same period in 2012. Revenues from sales of Lymphoseek for the fourth quarter of 2013 were \$343,000 compared to \$144,000 in the third quarter of 2013. The fourth quarter of 2013 represented the first quarter of Lymphoseek sales under CMS reimbursement. There were no sales of Lymphoseek in 2012.

Fourth quarter 2013 operating expenses were \$13.4 million compared to \$7.0 million for the fourth quarter of 2012. Research and development expenses were \$9.4 million during the fourth quarter of 2013 compared to \$4.3 million during fourth quarter of 2012. The net increase from 2012 to 2013 was primarily a result of net increases in NAV4694, NAV5001, Lymphoseek and Manocept platform product development costs, and compensation and other support costs related to increased headcount. Selling, general and administrative

expenses were \$4.0 million for 2013 compared \$2.7 million for 2012. The net increase from 2012 to 2013 was attributable to the same primary factors noted for the full year comparison.

Navidea's loss from operations for the fourth quarter of 2013 was \$13.1 million compared to \$7.0 million for the fourth quarter of 2012. For the fourth quarter of 2013, Navidea reported a loss attributable to common stockholders of \$13.8 million, or \$0.10 per share, compared to a loss attributable to common stockholders of \$7.2 million, or \$0.07 per share, for the fourth quarter of 2012.

Financial Guidance and Commentary: "We continue to be pleased with the growth in a number of key Lymphoseek metrics and look forward to growing revenue over the coming months and years. For 2014, Navidea expects revenues from Lymphoseek sales to be between \$5 and \$6 million. Also, based on the parameters of the non-dilutive financing with Oxford announced earlier today, we believe we have significantly improved our access to the capital on our balance sheet enabling us to continue to pursue the core elements of our business, in particular Lymphoseek growth, while also advancing our compelling development initiatives," said Brent Larson, Navidea CFO.

Management Commentary

"2013 was a pivotal year for Navidea with the approval and initial launch of Lymphoseek in the U.S.," stated Dr. Mark Pykett, Navidea CEO. "We continue to see good momentum in many key sales metrics, including continuous growth in market penetration, increases in unit sales month over month and quarter over quarter, increases in total accounts, outstanding customer retention and repeat order rates, and encouraging formulary placement activity. Lymphoseek reimbursement was placed on solid footing with the implementation of a pass-through C Code from CMS followed by the granting of a permanent A Code. In addition, with the filing of the Lymphoseek sNDAs, one of which was granted Fast Track Status and Priority Review by FDA, we are looking forward to the June 16 and October 16, 2014 PDUFA target dates and toward potential expansion of utilization into additional areas of lymphatic mapping."

Dr. Pykett continued, "Recently, we have realized a number of important advances on which we aim to capitalize and which are enabled in part by the non-dilutive financing we announced today. Our Phase 2b study of NAV4694 in patients with MCI has generated exciting initial results that suggest that NAV4694 may be a highly effective agent at detecting low levels of beta-amyloid arising early in the course of cognitive impairment, an attribute that would be highly differentiated from other tracers to date and which would create opportunities in the early-stage diagnosis of dementia. We therefore are planning to accelerate our study activities to generate data and complete the trial sooner than originally projected which, if successful, may enable us to create important product differentiation. We believe NAV4694 may prove to be the most effective agent to address the needs of MCI patients, a demographic larger than the population of people with AD and where there is intense clinical and commercial pharma interest but for which no objective diagnostics agents exist."

The Company has also made important recent strides with its Manocept platform, the status of which has advanced more rapidly than anticipated, particularly in the area of RA where collaborators have demonstrated the ability to identify the underlying inflammatory component of RA in human disease, thereby differentiating it from other joint diseases. Just

five months after unveiling the platform in a supplement of the journal *Nature*, near-term opportunities are being explored to begin initial clinical study in RA, a large incidence population both in the U.S. and worldwide where many patients present atypically and for whom diagnostic uncertainty remains high.

Conference Call:

Navidea will provide a business update and discuss the fourth quarter and full year 2013 financial results during a conference call with the investment community scheduled for Thursday, March 6, 2014 at 8:30 a.m. ET. Investors and the public are invited to access the live webcast through the link below. Participants who would like to ask questions during the question and answer session following the presentation must participate by telephone also. Participants are encouraged to log-in and/or dial-in fifteen minutes before the conference call begins. The webcast replay is expected to be available on our investor website, <http://ir.navidea.com>, approximately two to four hours after the live event.

Event: Navidea Biopharmaceuticals Q4 2013 and Full-Year Financial Results Conference Call

Date/Time: Thursday, March 6, 2014 at 8:30 a.m. ET

Webcast Link: <http://www.media-server.com/m/p/dh2x4bbc>

Dial-in Number – US: 1 (800) 708-4539

Dial in Number – Int'l: 1 (847) 619-6396

Participant Passcode: 36792037

Replay A webcast replay will be available on the Investor Relations section of our website at <http://ir.navidea.com>

About Navidea Biopharmaceuticals Inc.

Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAV) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is developing multiple precision diagnostic products and platforms including NAV4694, NAV5001, Manocept™ and NAV1800 (RIGScan™), to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making 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. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and advancing the Company's pipeline through selective acquisitions, global partnering and commercialization efforts. For more information, please visit www.navidea.com.

The Private Securities Litigation Reform Act of 1995 (the Act) provides a safe harbor for forward-looking statements made by or on behalf of the Company. Statements in this news release, which relate to other than strictly historical facts, such as statements about the Company's plans and strategies, expectations for future financial performance, new and

existing products and technologies, anticipated clinical and regulatory pathways, and markets for the Company's products are forward-looking statements within the meaning of the Act. The words "believe," "expect," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date hereof. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, the Company's continuing operating losses, uncertainty of market acceptance of its products, reliance on third party manufacturers, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on limited product line and distribution channels, competition, limited marketing and manufacturing experience, risks of development of new products, regulatory risks and other risks detailed in the Company's most recent Annual Report on Form 10-K and other Securities and Exchange Commission filings. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2013	December 31, 2012
	(unaudited)	
Assets:		
Cash	\$ 32,939,026	\$ 9,118,564
Other current assets	4,392,156	1,498,819
Non-current assets	2,985,335	1,355,014
Total assets	\$ 40,316,517	\$ 11,972,397
Liabilities and stockholders' deficit:		
Notes payable, net of discount, current	\$ 4,095,650	\$ 2,756,718
Other current liabilities	7,195,312	3,433,821
Notes payable, net of discount	23,572,603	6,930,112
Derivative liabilities	7,692,087	-
Other liabilities	1,770,452	257,122
Stockholders' deficit	(4,009,587)	(1,405,376)
Total liabilities and stockholders' deficit	\$ 40,316,517	\$ 11,972,397

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Twelve Months Ended	
	December 31, 2013	December 31, 2012	December 31, 2013	December 31, 2012
	(unaudited)		(unaudited)	
Revenue:				
Net sales	\$ 342,803	\$ -	\$ 614,423	\$ -
Grant and other revenue	192,176	6,807	516,207	78,738
Total revenue	534,979	6,807	1,130,630	78,738
Cost of good sold	151,955	-	332,815	-
Gross profit	383,024	6,807	797,815	78,738

Operating expenses:				
Research and development	9,415,134	4,343,109	23,710,183	16,890,482
Selling, general and administrative	4,020,847	2,690,241	15,525,946	11,177,559
Total operating expenses	13,435,981	7,033,350	39,236,129	28,068,041
Loss from operations	(13,052,957)	(7,026,543)	(38,438,314)	(27,989,303)
Interest expense	(974,204)	(235,994)	(2,778,780)	(1,166,332)
Loss on extinguishment of debt	-	-	(1,372,266)	-
Change in fair value of financial instruments	265,401	25,268	(112,073)	32,110
Other income (expense), net	9,879	2,559	1,975	(33,679)
Net loss	(13,751,881)	(7,234,710)	(42,699,458)	(29,157,204)
Preferred stock dividends	-	31,667	-	(43,333)
Loss attributable to common stockholders	\$(13,751,881)	\$(7,203,043)	\$(42,699,458)	\$(29,200,537)
Loss per common share (basic and diluted)	\$(0.10)	\$(0.07)	\$(0.35)	\$(0.29)
Weighted average shares outstanding (basic and diluted)	133,881,021	105,067,640	121,808,986	99,059,997

Navidea Biopharmaceuticals
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Source: Navidea Biopharmaceuticals, Inc.