

May 7, 2014



# Navidea Biopharmaceuticals Announces First Quarter 2014 Financial Results

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced its financial results and business highlights for the first quarter of 2014.

"As we begin 2014, we are encouraged by the continued advances in utilization, market penetration and account growth for Lymphoseek®. We are realizing increasing traction in our commercial and medical education activities directed toward surgical oncologists and major lymphatic mapping centers," said Dr. Mark Pykett, Navidea Chief Executive Officer. "We continue to focus our efforts on expanding market opportunities in the U.S. and abroad by obtaining additional regulatory clearances, expanding the Lymphoseek label, and building strong commercial relationships to enhance the full potential of the product. The results we are seeing and building on enhance our confidence that our sustained efforts will culminate in market leadership for Lymphoseek. Throughout 2014, we also expect continued advances in our pipeline programs, including the Phase 2 and Phase 3 studies for our neuro-tracers in the neurodegenerative areas of dementia, mild cognitive impairment and movement disorders, and in other pipeline programs."

## Highlights:

- Realized revenue to Navidea of \$627,000 in Lymphoseek® (technetium Tc 99m tilmanocept) Injection sales in the first quarter of 2014 under the revenue sharing agreement with our U.S. distribution partner. This represents an 83% increase from the prior quarter, based in part on strong month-on-month growth in units, expansion of accounts and high customer retention, among other positive sales trends.
- Obtained Priority Review by the U.S. Food and Drug Administration (FDA) for the Supplemental New Drug Application (sNDA) to expand Lymphoseek labeling for sentinel lymph node detection in patients with head and neck cancer, with a Prescription Drug User Fee Act (PDUFA) date set for June 16, 2014.
- Received FDA acceptance of an additional sNDA for review to further expand the Lymphoseek label, focusing on more flexible and extended utilization practices with a PDUFA date set for October 16, 2014.
- Continued market expansion activities to drive product commercialization worldwide, highlighted by the signing of a sales and distribution agreement in Taiwan, continuing market preparation activities in Canada and continuing shipment of Lymphoseek to select medical centers in the Middle East.
- Advanced the Lymphoseek Marketing Authorization Application (MAA) in Europe, and subsequently received notice that the Committee for Medicinal Products for Human Use (CHMP) in Europe will convene a Scientific Advisory Group on Oncology meeting to discuss elements of the Lymphoseek clinical study in patients with head and neck

cancer.

- Reported positive, single-center results from the Phase 2b Trial of NAV4694 in subjects with Mild Cognitive Impairment (MCI) demonstrating the agent's ability to identify beta-amyloid in early stage patients.
- Presented encouraging results at several major scientific forums from Manocept™ platform studies in Kaposi Sarcoma and rheumatoid arthritis (RA) where, in an animal model of RA, Manocept constructs were shown to identify and localize to disease-state macrophages when administered intravenously, enabling detection of immune-mediated arthritis with preferential localization in affected joints with little to no localization in unaffected joints, opening potential avenues to new applications and product opportunities.
- Appointed Perry A. Karsen to the Navidea Board of Directors. Mr. Karsen is currently Executive Vice President and Chief Operations Officer at Celgene Corporation and Chief Executive Officer of Celgene Cellular Therapeutics.
- Closed a \$30 million loan transaction with Oxford Finance LLC providing the Company with an enhanced working capital position.

**First Quarter Ended March 31, 2014 Financial Results:** Total revenues for the first quarter of 2014 were \$752,000 compared to no revenue for the same period in 2013. Product revenues from sales of Lymphoseek in first quarter of 2014 were \$627,000 compared to \$343,000 in the fourth quarter of 2013. The fourth quarter of 2013 represented the first quarter of Lymphoseek sales under Centers for Medicare and Medicaid Services (CMS) reimbursement.

First quarter 2014 operating expenses were \$9.1 million compared to \$7.0 million for the first quarter of 2013. Research and development expenses were \$5.2 million in the first quarter of 2014 compared to \$3.6 million in the same period of 2013. The net increase was primarily a result of net increases in NAV4694, NAV5001 and Manocept platform product development costs, compensation and other support costs related to increased headcount. Selling, general and administrative expenses for the first quarter of 2014 were \$3.9 million compared to \$3.4 million in the same period of 2013.

First quarter 2014 net loss attributable to common stockholders was \$11.7 million, or \$0.08 per share, compared to a net loss attributable to common stockholders of \$7.3 million, or \$0.06 per share, in the first quarter of 2013. In addition to the changes in operating expenses reported above, the Company recorded a \$2.6 million loss on the extinguishment of debt related to the refinancing of its debt facilities during the first quarter of 2014.

**Financial Guidance:** Based on sales trends observed by the Company from launch through April 2014, Navidea is reiterating its full-year 2014 revenue expectation of between \$5 and \$6 million from Lymphoseek sales based on its revenue sharing agreement with its U.S. distribution partner.

**Conference Call Details:** Navidea will provide a business update and discuss the first quarter 2014 financial results during a conference call with the investment community scheduled for Wednesday, May 7, 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 Q1 2014 Financial Results Conference Call  
Date/Time: Wednesday, May 7, 2014 at 8:30 a.m. ET

Webcast Link: <http://www.media-server.com/m/p/2se8k7yt>

Dial-in Number – US: 1 (800) 708-4539  
Dial in Number – Int'l: 1 (847) 619-6396  
Participant Passcode: 37204450

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: NAVB) 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](http://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.*

### **Financial tables to follow**

**NAVIDEA BIOPHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

	March 31, 2014 (unaudited)	December 31, 2013
Assets:		
Cash	\$ 26,006,463	\$ 32,939,026
Other current assets	3,516,469	4,392,156
Non-current assets	3,116,544	2,985,335
Total assets	\$ 32,639,476	\$ 40,316,517
Liabilities and stockholders' deficit:		
Notes payable, net of discount, current	\$ -	\$ 4,095,650
Other current liabilities	5,445,579	7,195,312
Notes payable, net of discount	30,939,076	23,572,603
Derivative liabilities	7,693,351	7,692,087
Other liabilities	3,169,656	1,770,452
Stockholders' deficit	(14,608,186 )	(4,009,587 )
Total liabilities and stockholders' deficit	\$ 32,639,476	\$ 40,316,517

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended	
	March 31, 2014 (unaudited)	March 31, 2013 (unaudited)
Revenue:		
Net sales	\$ 626,631	\$ -
Grant and other revenue	125,173	-
Total revenue	751,804	-
Cost of goods sold	193,220	-
Gross profit	558,584	-
Operating expenses:		
Research and development	5,226,794	3,639,757
Selling, general and administrative	3,910,833	3,364,490
Total operating expenses	9,137,627	7,004,247
Loss from operations	(8,579,043 )	(7,004,247 )
Interest expense	(943,838 )	(363,082 )
Change in fair value of financial instruments	392,483	-
Loss on extinguishment of debt	(2,610,196 )	-
Other income, net	41	26,310
Net loss attributable to common stockholders	\$ (11,740,553 )	\$ (7,341,019 )
Loss per common share (basic and diluted)	\$ (0.08 )	\$ (0.06 )

Weighted average shares outstanding (basic and diluted)    144,783,351    113,763,600

Navidea Biopharmaceuticals

Brent Larson, Executive VP & CFO, 614-822-2330

Or

Sharon Correia, Associate Director, Corporate Communications, 978-655-2686

Source: Navidea Biopharmaceuticals, Inc.