

May 8, 2013



# Navidea Biopharmaceuticals Announces First Quarter 2013 Results

**– Business Update / Quarterly Conference Call Set for Today, May 8, 2013 at 8:30 am EDT –**

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced business highlights and consolidated results for the first quarter ended March 31, 2013.

“We are energized by the Lymphoseek® approval and launch in the U.S. while we continue to advance our global registration process for the product in other markets,” said Dr. Mark Pykett, Navidea CEO. “As we do this, we are increasingly turning our attention to the clinical programs for our important later-stage pipeline candidates as well. Through the rest of 2013, we expect to advance our innovative precision diagnostics portfolio and drive a number of potential value-enhancing events, including our Phase 3 studies set to begin for our Alzheimer’s and Parkinson’s programs and the possible filing of a supplemental New Drug Application for Lymphoseek in the U.S. for use in sentinel lymph node biopsy by year end.”

## First Quarter 2013 Financial Results

For the quarter ended March 31, 2013, Navidea reported a net loss attributable to common stockholders of \$7.3 million, or \$0.06 per share, compared with a net loss attributable to common stockholders of \$7.0 million, or \$0.07 per share, for the same period in 2012.

Research and development expenses were \$3.6 million for the quarter ended March 31, 2013, compared to \$3.9 million for the same period in 2012. The decrease of \$304,000 was primarily a result of net decreases in Lymphoseek, NAV5001, RIGScan, and potential pipeline product development costs, offset by net increases in NAV4694 development costs and increased headcount and related costs to support these development efforts.

Selling, general and administrative expenses were \$3.4 million for the quarter ended March 31, 2013, compared to \$2.6 million for the same period in 2012. The net increase of \$790,000 was primarily due to increased headcount and related costs, medical affairs costs to support Lymphoseek adoption and increased investor relations costs, offset by decreased out-of-pocket marketing costs incurred in preparation for the commercial launch of Lymphoseek.

As of March 31, 2013, Navidea had cash and cash equivalents totaling approximately \$9.8 million.

“We remain focused on increasing shareholder value through two primary objectives: the successful execution of Lymphoseek launch and commercialization, and progress on our

pipeline programs to create a foundation for sustained long-term growth. We believe we are in a solid financial position in advance of expected revenue from Lymphoseek with a strong balance sheet to accomplish these objectives,” said Brent Larson, Navidea’s Chief Financial Officer. “We maintain flexible access to multiple available funding sources, and we believe our cash flow and available financial resources are sufficient to support the ongoing advances in our pipeline programs and operating needs for the foreseeable future.”

## Recent Business Updates

Key milestones achieved by Navidea to date in 2013 include:

### Pipeline

- Lymphoseek®
  - Launched Lymphoseek (technetium Tc 99m tilmanocept) Injection on May 1<sup>st</sup> with Cardinal Health, Inc. following the March 13<sup>th</sup> approval by the U.S. Food and Drug Administration. Lymphoseek is indicated for use in lymphatic mapping for breast cancer and melanoma and will be sold and distributed by Cardinal Health to health care professionals in the United States through its network of nuclear pharmacies.
  - Reported top-line data from the planned interim analysis of the NEO3-06 Phase 3 head and neck cancer clinical study of Lymphoseek demonstrating that Lymphoseek met its primary endpoint in identification of sentinel lymph nodes as compared to the gold standard of pathology assessment of multi-level node resection.
  - Published results of Lymphoseek Phase 3 clinical trials in breast cancer in *Annals of Surgical Oncology* showing that Lymphoseek met its primary efficacy endpoint in assessment of lymphatic mapping performance in patients with breast cancer.
  - Announced commencement of an investigator-initiated study by Maimonides Medical Center to evaluate the utility of Lymphoseek in lymphatic mapping procedures for colorectal cancer.
- NAV4694
  - Published results from a NAV4694 clinical trial in the *Journal of Nuclear Medicine* demonstrating positive head-to-head comparison of NAV4694 and Pittsburgh Compound B, PiB, the academic gold standard imaging biomarker for Alzheimer’s disease (AD) and dementia  $\beta$ -amyloid imaging. The study was conducted by collaborators at Austin Health in Melbourne, Australia.
  - Commenced enrollment in a Phase 2b, open-label, safety and efficacy PET imaging study of NAV4694 for detection of cerebral  $\beta$ -amyloid in subjects diagnosed with mild cognitive impairment.
  - Completed a study of NAV4694 as a biomarker for visual detection and quantification of cerebral  $\beta$ -amyloid in diagnosing AD, a study designed and conducted by Navidea’s partner, AstraZeneca.
- NAV5001
  - Enrolled the first subject in a clinical study to investigate the performance of NAV5001 in a SPECT imaging procedure of the brain in connection with Navidea’s program to evaluate NAV5001 in dementia with Lewy bodies.

### Corporate/Financial

- Completed two underwritten public offerings totaling 3.6 million shares of common stock in February and April 2013, resulting in net proceeds to the Company of approximately \$9.3 million.
- Drew \$4 million under the \$50 million credit facility with Platinum-Montaur Life Sciences, LLC (Montaur). Montaur also exercised certain warrants in March 2013, providing \$1.4 million in proceeds.
- Dr. Thomas Tulip was appointed President in addition to his continuing duties as Chief Business Officer effective May 1<sup>st</sup>. Dr. Mark Pykett retained the title of Chief Executive Officer.

## Conference Call Details

Navidea's Chief Executive Officer, Dr. Mark Pykett, Chief Business Officer, Dr. Thomas Tulip, and Chief Financial Officer, Brent Larson, will provide a development and business update and will discuss the Company's financial results for the first quarter of 2013 during the conference call. The conference call can be accessed as follows:

### CONFERENCE CALL INFORMATION

#### TO PARTICIPATE LIVE:

Date: May 8, 2013

Time: 8:30 a.m. EDT

#### TO LISTEN TO A REPLAY:

Available until: May 22, 2013

Toll-free (U.S.) Dial in #: (877) 660-6853

International Dial in #: (201) 612-7415

Toll-free (U.S.) Dial in #: (877) 407-8031

International Dial in #: (201) 689-8031

Replay passcode:

Account #: 268

Conference ID #: 414024

## 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 actively developing four radiopharmaceutical agent platforms – Lymphoseek<sup>®</sup>, NAV4694, NAV5001 and RIGScan<sup>™</sup> – to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. 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.*

#### **NAVIDEA BIOPHARMACEUTICALS, INC.**

#### **CONDENSED CONSOLIDATED BALANCE SHEETS**

	March 31, 2013 (unaudited)	December 31, 2012
Assets:		
Cash	\$ 9,845,773	\$ 9,118,564
Other current assets	2,187,749	1,498,819
Non-current assets	1,571,542	1,355,014
Total assets	\$ 13,605,064	\$ 11,972,397

#### Liabilities and stockholders' deficit:

Notes payable, net of discount, current	\$ 2,769,080	\$ 2,756,718
Other current liabilities	3,058,342	3,433,821
Notes payable, net of discount	10,240,613	6,930,112
Other liabilities	256,422	257,122
Stockholders' deficit	(2,719,393 )	(1,405,376 )
Total liabilities and stockholders' deficit	\$ 13,605,064	\$ 11,972,397

#### **CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended	
	March 31, 2013 (unaudited)	March 31, 2012 (unaudited)
Revenue	\$ -	\$ 11,931
Operating expenses:		
Research and development	3,639,757	3,943,714
Selling, general and administrative	3,364,490	2,574,630
Total operating expenses	7,004,247	6,518,344
Loss from operations	(7,004,247 )	(6,506,413 )

Interest expense	(363,082 )	(293,671 )
Change in derivative liabilities	-	(184,084 )
Other income, net	26,310	(4,904 )
Net loss	(7,341,019 )	(6,989,072 )
Preferred stock dividends	-	(25,000 )
Loss attributable to common stockholders	\$ (7,341,019 )	\$ (7,014,072 )
Loss per common share (basic and diluted)	\$ (0.06 )	\$ (0.07 )
Weighted average shares outstanding (basic and diluted)	113,763,600	94,074,918

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Source: Navidea Biopharmaceuticals, Inc.