

July 30, 2015



# Navidea Reports Second Quarter 2015 Financial Results; Reiterates 2015 Lymphoseek® Revenue Guidance

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), today announced financial results for the second quarter of 2015. Navidea reported total revenue for the second quarter of 2015 of \$2.9 million, including Lymphoseek® (technetium Tc 99m tilmanocept) injection sales revenue of \$2.0 million. The net loss from operations was \$3.8 million and the net loss attributable to common stockholders was \$9.7 million.

“During the first half of this year we successfully undertook a strategy to transform the Company and we have been executing to that plan,” commented Rick Gonzalez, Navidea’s President and CEO. “We deployed a new commercial strategy, overhauled the Lymphoseek brand plan reflective of the brand’s clinical value proposition, optimized operational efficiencies across the organization, strengthened our financial position and made progress in a cost-effective fashion to expand our development pipeline of both imaging and therapeutic programs. Today we are on a clear path, whereby our revenue growth is quickly converging with our reduced operating expenses, getting us closer to the goal of achieving cash flow breakeven in the first quarter of next year.”

Specific events and milestones achieved since the beginning of the second quarter include the following:

## *Commercial*

- Achieved sequential quarter-on-quarter Lymphoseek revenue growth and continued improvement in key performance indicators;
- Fully deployed a Lymphoseek-dedicated field force mid-second quarter;
- Exercised pricing leverage, as per plan, resulting in a 39% Lymphoseek price increase beginning July 31<sup>st</sup>;
- Reported positive Lymphoseek comparative results from an injection site pain study in breast cancer presented at the 2015 Society of Nuclear Medicine and Molecular Imaging annual meeting;

## *Lymphoseek Lifecycle Management*

- Awarded NIH grants to explore new applications of the Manocept™ platform for cardiovascular disease and rheumatoid arthritis (RA) totaling up to \$2.0 million;
- Received confirmation of continued development funding under part 2 of a previously awarded NIH grant for Lymphoseek in cervical cancer totaling \$1.5 million;
- Reported clinical imaging data demonstrating Tc 99m tilmanocept localizes in Kaposi’s sarcoma (KS) tumor lesions including brain lesions;

- Verified Manocept CD206-targeting mechanism of action with publication in peer-reviewed *Journal of Immunology* providing clear clinical differentiation from other non-targeted agents and showing future potential for the delivery of therapeutics for cancer and other macrophage-dependent diseases;

### *Operational & Financial*

- Reduced cash burn by over 40% for the first half of 2015 compared to the first half of 2014;
- Secured approximately \$18 million in additional net capital;
- Completed the divestiture of the Company's investigational imaging agent for the detection of Parkinson's disease;
- Continued partnering/divestiture efforts for the Company's investigational imaging agent, NAV4694, for the detection of amyloid plaques in Alzheimer's disease;

### *Therapeutic & Diagnostic Development Pipeline*

- Reported data demonstrating that a Manocept-Doxorubicin (MT-1001) conjugate selectively targets tumor-associated macrophages and destroys the cells through an apoptotic mechanism;
- Formed a research collaboration with BIND Therapeutics to engineer CD206 targeted nanoparticles using Manocept;
- Reported positive Manocept proof-of-concept data demonstrating the potential for the Manocept platform as a diagnostic and therapeutic for rheumatologic conditions; and,
- Received confirmation of continued NIH-grant funding for clinical trials of NAV4694 in Alzheimer's Disease and Mild Cognitive Impairment totaling \$1.7 million.

## **Financials**

Total revenues for the quarter ended June 30, 2015 were \$2.9 million compared to \$1.1 million in the second quarter of last year. Second quarter 2015 product revenues recognized from the sale of Lymphoseek were \$2.0 million, compared to \$1.8 million in the first quarter of 2015 and \$1.0 million in the second quarter of last year. During the second quarter of 2015, the Company also reported \$904,000 in grant, licensing and other revenue. For the six months ended June 30, 2015, Navidea's total revenue was \$5.0 million compared to \$1.8 million for the same period in 2014, an increase of 172%. The primary driver of this increase was revenues recognized from the sale and license of Lymphoseek which exceeded \$4.1 million for the six months ended June 30, 2015 compared to \$1.7 million for the same period last year.

Gross margins on Lymphoseek product sales grew to 83% for the second quarter of 2015 compared to 74% for the second quarter of 2014 due in part to our success in lowering our manufacturing costs coupled with our ability to sell certain previously reserved inventory.

Research and development (R&D) expenses for the second quarter of 2015 were \$2.3 million, compared to \$5.1 million in the second quarter of last year. R&D expenses were \$6.3 million for the six months ended June 30, 2015 compared to \$10.3 million in the same period of 2014. The net decreases in R&D expenses were primarily a result of decreased project costs related to the Company's neuro assets coupled with decreased headcount costs. Selling, general and administrative (SG&A) expenses for the second quarter of 2015

were \$4.0 million, compared to \$4.9 million in the second quarter of last year. SG&A expenses were \$9.5 million for the six months ended June 30, 2015, compared to \$8.8 million for the same period in 2014 and included \$765,000 and \$1.4 million, respectively, in termination-related costs associated with reductions in force implemented in the impacted periods. The net increase in year-to-date SG&A expenses was due primarily to net increases in commercial headcount costs related to the addition of our internal sales force offset by decreased costs related to contracted medical science liaisons. Total operating expenses were \$6.3 million for the second quarter of 2015, compared to \$10.0 million in the second quarter of last year. Operating expenses were \$15.8 million for the six months ended June 30, 2015, compared to \$19.2 million for the same period in 2014.

Navidea's net loss from operations for the quarter ended June 30, 2015 was \$3.8 million compared to \$9.2 million for the same period in 2014. For the six months ended June 30, 2015, Navidea's net loss from operations was \$11.6 million compared to a net loss from operations of \$17.8 million for the same period in 2014. Navidea's net loss attributable to common stockholders for the quarter ended June 30, 2015 was \$9.7 million, or \$0.06 per share, compared to \$10.2 million, or \$0.07 per share, for the same period in 2014. For the six months ended June 30, 2015, Navidea's net loss attributable to common stockholders was \$17.0 million, or \$0.11 per share, compared to a net loss attributable to common stockholders of \$22.0 million, or \$0.15 per share, for the same period in 2014. Net losses attributable to common stockholders include the cash interest expense on our outstanding debt, as well as significant non-cash charges. For the six month periods ended June 30, 2015 and June 30, 2014, net loss attributable to common stockholders included \$3.4 million and \$2.7 million, respectively, in non-cash interest, losses on extinguishment of debt, and changes in the fair value of financial instruments.

Navidea ended the quarter with \$15.8 million in cash. The Company reiterates its 2015 Lymphoseek product revenue estimate of \$10 million to \$12 million. The Company also expects, following completion of the partnering activities for NAV4694, that cash operating expenses on a quarterly basis will decrease to the point necessary for the Company to achieve its goals of cash flow breakeven from operations. This guidance excludes therapeutic-related research and development costs for the Manocept platform which are expected to be funded separately by Macrophage Therapeutics, Inc.

"With each passing quarter, we continue to take steps towards achieving our goal of cash flow breakeven," said Brent Larson, Navidea's EVP and CFO. "We began this second quarter with a solid refinancing, positioning our balance sheet to support a pivotal second half of the year in which we expect to realize the impact of our new sales force on Lymphoseek's revenue growth. This growth, coupled with continued emphasis on controlling our spending, should put us in a strong position to achieve our goals."

## **Commercialization**

The new commercialization plan aligns our sales force to target the oncology treatment team focusing on the surgical oncologist. Initial commercial efforts are being concentrated in breast cancer, melanoma, and oral cavity head and neck cancers, where sentinel lymph node biopsies are already standard of care. The Lymphoseek clinical value proposition and its highly differentiated label provide compelling benefits to the oncology treatment team.

"We achieved our full field force deployment during the middle of the second quarter,

positioning us to ramp up Lymphoseek sales according to plan in the second half of 2015,” said Thomas Klima, SVP and Chief Commercial Officer. “We are on track with our key performance indicators including brand revenues, monthly procedure growth, brand awareness and message recall measurements. We are ahead of plan in the number of accounts purchasing for the first time and in our account product re-order rate. Based on the anticipated impact of the deployment of our sales force, our positive first half revenues, strong key performance indicators and a planned July 31<sup>st</sup> price increase, we remain confident in our ability to meet our 2015 sales projections.”

## **Manocept Pipeline**

Our future business will be dependent on development of the Manocept CD206 targeting platform for diagnostic and therapeutic applications. Recent Manocept presentations have reported proof-of-concept localization results in humans and early potential seen in Manocept-drug conjugate delivery resulting in apoptosis of tumor cells and associated macrophages in a KS pre-clinical study. At recent medical conferences, the company and its research collaborators reported the following data:

- Results were presented in RA at EULAR 2015 European Congress of Rheumatology which highlighted the potential of CD206-targeting Manocept constructs to detect immune-mediated inflammation in RA which could be used diagnostically, to monitor therapeutic efficacy or as a potential therapeutic platform;
- Data were presented at the 18<sup>th</sup> International Workshop on Kaposi's Sarcoma Herpesvirus and Related Agents demonstrating the imaging and therapeutic potential for our CD206 targeting platform, Manocept, including inducing apoptosis in KS tumor tissue and tumor associated macrophages.

“We continue to build growing evidence supporting the potential of immunotherapeutic applications for Manocept based on these encouraging results,” said Frederick O. Cope, Ph.D., SVP and Chief Scientific Officer of Navidea. “Our plans are to continue studies that will validate Lymphoseek’s ability to identify sites of disease and, through our Macrophage Therapeutics subsidiary, evaluate the modulation and/or destruction of macrophages and seek lucrative partnering and collaboration agreements to develop promising therapeutic applications.”

## **Conference Call Details**

Investors and the public are invited to access the live audio webcast through the link below. Participants who would like to ask questions during the question and answer session 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 Q2 2015 Financial Results Conference Call

Date/Time: Thursday, July 30, 2015 at 8:30 a.m. EDT

Webcast Link: <http://edge.media-server.com/m/p/amn8cqij/lan/en>

Dial-in Number – (855) 897-5884  
US:

Dial in Number – (720) 634-2940  
Int'l:

Confirmation  
Number: 92935833

Replay: A webcast replay will be available on the Investor Relations section of our website at <http://ir.navidea.com> for 30 days.

## About Lymphoseek

Lymphoseek<sup>®</sup> (technetium Tc 99m tilmanocept) injection is the first and only FDA-approved receptor-targeted lymphatic mapping agent. It is a novel, receptor-targeted, small-molecule radiopharmaceutical used in the evaluation of lymphatic basins that may have cancer involvement in patients. Lymphoseek is designed for the precise identification of lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek is approved by the U.S. Food and Drug Administration (FDA) for use in solid tumor cancers where lymphatic mapping is a component of surgical management and for guiding sentinel lymph node biopsy in patients with clinically node negative breast cancer, melanoma or squamous cell carcinoma of the oral cavity. Lymphoseek has also received European approval in imaging and intraoperative detection of sentinel lymph nodes in patients with melanoma, breast cancer or localized squamous cell carcinoma of the oral cavity.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. Overall in the U.S., solid tumor cancers may represent up to 1.2 million cases per year. The sentinel node label in the U.S. and Europe may address approximately 235,000 new cases of breast cancer, 76,000 new cases of melanoma and 45,000 new cases of head and neck/oral cancer in the U.S., and approximately 367,000 new cases of breast cancer, 83,000 new cases of melanoma and 55,000 new cases of head and neck/oral cancer diagnosed in Europe annually.

## Lymphoseek Indication and Important Safety Information

Lymphoseek is a radioactive diagnostic agent indicated with or without scintigraphic imaging for:

- Lymphatic mapping using a handheld gamma counter to locate lymph nodes draining a primary tumor site in patients with solid tumors for which this procedure is a component of intraoperative management.
- Guiding sentinel lymph node biopsy using a handheld gamma counter in patients with clinically node negative squamous cell carcinoma of the oral cavity, breast cancer or melanoma.

## Important Safety Information

In clinical trials with Lymphoseek, no serious hypersensitivity reactions were reported,

however Lymphoseek may pose a risk of such reactions due to its chemical similarity to dextran. Serious hypersensitivity reactions have been associated with dextran and modified forms of dextran (such as iron dextran drugs).

Prior to the administration of Lymphoseek, patients should be asked about previous hypersensitivity reactions to drugs, in particular dextran and modified forms of dextran. Resuscitation equipment and trained personnel should be available at the time of Lymphoseek administration, and patients observed for signs or symptoms of hypersensitivity following injection.

Any radiation-emitting product may increase the risk for cancer. Adhere to dose recommendations and ensure safe handling to minimize the risk for excessive radiation exposure to patients or health care workers. In clinical trials, no patients experienced serious adverse reactions and the most common adverse reactions were injection site irritation and/or pain (<1%).

FULL LYMPHOSEEK PRESCRIBING INFORMATION CAN BE FOUND AT:  
[WWW.LYMPHOSEEK.COM](http://WWW.LYMPHOSEEK.COM)

## **About Navidea**

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics, therapeutics and radiopharmaceutical agents. 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. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and therapeutics, and advancing the Company's pipeline through 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

	June 30, 2015 (unaudited)	December 31, 2014
Assets:		
Cash	\$ 15,790,235	\$ 5,479,006
Other current assets	3,740,817	3,120,139
Non-current assets	2,667,537	3,321,035
Total assets	\$ 22,198,589	\$ 11,920,180
Liabilities and stockholders' deficit:		
Deferred revenue, current	\$ 1,000,000	\$ -
Notes payable, net of discount, current	333,333	4,383,472
Other current liabilities	4,255,359	4,711,619
Deferred revenue	666,667	-
Notes payable, net of discount	58,836,254	29,539,135
Other liabilities	1,725,477	3,089,420
Total liabilities	66,817,090	41,723,646
Navidea stockholders' deficit	(45,088,427 )	(29,803,466 )
Noncontrolling interest	469,926	-
Total stockholders' deficit	(44,618,501 )	(29,803,466 )
Total liabilities and stockholders' deficit	\$ 22,198,589	\$ 11,920,180

#### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Six Months Ended	
	June 30, 2015 (unaudited)	June 30, 2014 (unaudited)	June 30, 2015 (unaudited)	June 30, 2014 (unaudited)
Revenue:				
Lymphoseek sales revenue	\$ 1,963,548	\$ 1,046,257	\$ 3,798,970	\$ 1,672,888
Lymphoseek license revenue	250,000	-	333,333	-
Grant and other revenue	654,360	28,433	844,061	153,606
Total revenue	2,867,908	1,074,690	4,976,364	1,826,494
Cost of goods sold	332,730	270,498	781,787	463,718
Gross profit	2,535,178	804,192	4,194,577	1,362,776
Operating expenses:				
Research and development	2,297,074	5,112,098	6,278,362	10,338,892
Selling, general and administrative	4,048,799	4,907,652	9,542,967	8,818,485
Total operating expenses	6,345,873	10,019,750	15,821,329	19,157,377
Loss from operations	(3,810,695 )	(9,215,558 )	(11,626,752 )	(17,794,601 )

Interest expense, net	(1,575,741 )	(909,051 )	(2,542,317 )	(1,846,096 )
Equity in the loss of joint venture	(6,205 )	-	(268,432 )	-
Change in fair value of financial instruments	(1,852,730 )	(92,332 )	(125,627 )	300,151
Loss on extinguishment of debt	(2,440,714 )	-	(2,440,714 )	(2,610,196 )
Other income (expense), net	(4,834 )	(5,293 )	21,698	(12,045 )
Net loss	(9,690,919 )	(10,222,234 )	(16,982,144 )	(21,962,787 )
Net loss attributable to noncontrolling interest	(387 )	-	(487 )	-
Deemed dividend on beneficial conversion feature	-	-	(46,000 )	-
Net loss attributable to common stockholders	\$ (9,690,532 )	\$ (10,222,234 )	\$ (17,027,657 )	\$ (21,962,787 )
Loss per common share (basic and diluted)	\$ (0.06 )	\$ (0.07 )	\$ (0.11 )	\$ (0.15 )
Weighted average shares outstanding (basic and diluted)	150,107,148	150,019,939	149,951,603	147,416,111

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<http://www.businesswire.com/news/home/20150730005398/en/>

Navidea Biopharmaceuticals

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