May 12, 2015

Navidea Reports First 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 first quarter of 2015. Navidea reported total revenue for the first quarter of 2015 of $2.1 million, including Lymphoseek® (technetium Tc 99m tilmanocept) injection sales revenue of $1.84 million. The net loss attributable to common stockholders was $7.3 million.

“Performance year-to-date reflects our aggressive transformation into an organization singularly focused on unlocking the value of our Manocept™ technology as a state-of-the-art cancer imaging agent and as a novel therapeutic platform,” said Rick Gonzalez, Navidea Chief Executive Officer. “We executed on our stated objectives to grow revenues sequentially, continued to take steps to reduce operating cash burn, strengthened our balance sheet, and are positioned to begin realizing the impact of a fully deployed surgical oncology field force in the second half of the year. Based on this progress, we reaffirm our $10 to $12 million Lymphoseek revenue guidance for 2015 and our expectation of achieving cash-flow breakeven from operations during the first quarter of 2016.”

Specific milestones achieved in the first quarter and year-to-date include the following:

- Achieved sequential quarter-on-quarter Lymphoseek revenue growth of 26% and continued improvement in key performance indicator growth targets;
- Hired Lymphoseek field force of 12 representatives which will be fully deployed in the second quarter;
- Entered a European commercial partnership for Lymphoseek with Norgine BV and received $2 million up-front payment;
- Reported additional validating data at the American Association for Cancer Research (AACR) meeting demonstrating the potential for our CD206 targeting platform, Manocept, to target and treat Kaposi’s sarcoma (KS), which is an ideal model for other tumor types and infectious diseases;
- Signed a new credit facility that will allow us to restructure our debt and provide us with over $18 million in additional net capital to support the Company’s growth and plans to reach cash flow breakeven;
- Completed an initial external investment into Macrophage Therapeutics, Inc. enabling further development of the promising, early-stage Manocept therapeutic platform; and,
- Completed the divestiture of the first of two non-core neuroimaging assets.

FINANCIALS

Total revenues for the quarter ended March 31, 2015 were $2.1 million compared to

$752,000 in the first quarter last year. First quarter product revenues recognized from the sale of Lymphoseek were $1.84 million, compared to $1.46 million in the fourth quarter of last year and $627,000 in the first quarter of last year. This represents a sequential quarter-on-quarter growth of 26% and year-over-year growth of approximately 200%. During the first quarter of 2015, the Company also received a $2.0 million up-front payment related to the execution of a sublicense for Lymphoseek in the EU with Norgine BV; however, this amount is being amortized over a two-year period in accordance with applicable revenue recognition rules.

Gross margins on Lymphoseek product sales remain strong at 76% for the first quarter of 2015 compared to 69% for the first quarter of 2014.

Research and development expenses for the first quarter of 2015 were $4.0 million, compared to $5.2 million in the first quarter of last year. Selling, general and administrative expenses for the first quarter of 2015 were $5.5 million, compared to $3.9 in the first quarter of last year. Total operating expenses were $9.5 million, compared to $9.1 million in the first quarter of last year. Operating expenses for the first quarter of 2015 included approximately $1.4 million in estimated one-time severance and stock compensation-related costs associated with the March 2015 reduction in force and approximately $1.5 million in out-of-pocket costs related to the Company's neuroimaging programs.

Navidea's net loss attributable to common stockholders for the quarter ended March 31, 2015 was $7.3 million, or $0.05 per share, compared to $11.7 million, or $0.08 per share, for the same period in 2014.

Navidea ended the quarter with $4.9 million in cash. Subsequent to the end of the quarter, the Company entered into a loan agreement with CRG which, after paying off certain outstanding debt, will increase our cash position by over $18 million. The CRG loan agreement provides for an initial funding of $50 million with up to $10 million of additional funding available to Navidea, at its option, through December 2016, subject to the satisfaction of certain revenue milestones and other borrowing conditions.

In connection with the CRG financing, the Company also announced certain amendments to the Company's existing line of credit currently in place with Platinum-Montaur Life Sciences, LLC (Platinum) are being made that allow this facility to remain in place in a subordinated position to the CRG loan. The amendments will allow Platinum to convert the Company's $7.7 million debt during a time period in which the Company's average stock price has exceeded $2.53 per share for 10 consecutive trading days.

The Company reiterates its 2015 Lymphoseek product revenue estimate of $10 million to $12 million. Additionally, margins on Lymphoseek product sales are expected to approach and possibly exceed 80% in the coming quarters. The Company also expects, following completion of the partnering activities for NAV4694, that cash operating expenses on a quarterly basis will continue to 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.

"Our first quarter results are on track with our operating budget and are reflective of the Company's goal to accomplish our objectives more efficiently," said Brent Larson, Chief

Financial Officer. “Consistent with this effort, we closed our Boston office, reduced headcount and have moved forward with our plans to discontinue development of our non-core neuroimaging products. These events, coupled with the restructuring of our debt, provide us with greater financial flexibility than we have enjoyed for some time. We believe this will not only help us through the point of achieving our stated goal of reaching cash flow break-even from operations early next year, but ultimately sets the stage for achievement of the longer term growth prospects for the Manocept platform.”

COMMERCIALIZATION

2015 commercialization efforts will focus initially on breast cancer, melanoma, and oral cavity head and neck cancers, where sentinel lymph node biopsies are already standard of care. Lymphoseek has a highly differentiated label, and the product provides a compelling clinical value proposition.

“Our commercial business achieved its stated objectives this quarter, which position us to realize the full effect of our new field force and commercial strategy,” said Thomas Klima, Chief Commercial Officer. “We have recruited a seasoned and highly-motivated sales team who will cover territories that capture more than 80% of Lymphoseek-applicable cancer diagnoses in the U.S. They will execute a new brand strategy reflective of Lymphoseek’s expanded label directed to the oncology treatment team with a focus on surgeons and other decision makers within the hospital. Based on the anticipated impact of the deployment of this sales force and our positive first quarter revenues and key performance indicators, we remain confident in our 2015 sales projections.”

MANOCEPT PIPELINE

The core Manocept CD206 targeting platform, upon which Lymphoseek is based, is central to our future business. As part of this effort, several critical new datasets have been, or are expected to be, reported at recent or upcoming medical conferences. Most recently, the company reported the following data at the AACR meeting:

- The Manocept molecule selectively binds to, and is continuously internalized by, tumor-associated macrophages and KS tumor cells in a preclinical model; and
- A single, subcutaneous injection of Lymphoseek, a product based on the Manocept platform, detects and localizes in both KS tumors and lymph nodes involved in draining the KS tumor fields.

“Our collective body of data reinforces our belief that the modulation or destruction of macrophage and KS expression profiles represents a potential for a paradigm-shifting immunotherapeutic strategy,” said Frederick O. Cope, Ph.D., Chief Scientific Officer of Navidea. “We believe these results indicate KS could serve as a model system for future immunotherapeutic development. We look forward to reporting additional data supporting the development of these efforts at upcoming medical conferences.”

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 Q1 2015 Financial Results Conference Call
Date/Time:	Tuesday, May 12, 2015 at 8:30 a.m. EDT
Webcast Link:	http://edge.media-server.com/m/p/yafuo9zw/lan/en
Dial-in Number – US:	1 (855) 897-5884
Dial in Number – Int'l:	1 (720) 634-2940
Confirmation Number:	39734236
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® (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

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.

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, 2015 (unaudited)	December 31, 2014
Assets:		
Cash	$ 4,884,189	$ 5,479,006
Other current assets	3,133,589	3,120,139
Non-current assets	2,900,131	3,321,035
Total assets	$ 10,917,909	$ 11,920,180
Liabilities and stockholders' deficit:		
Deferred revenue, current	$ 1,000,000	$ -
Notes payable, net of discount, current	6,092,442	4,383,472
Other current liabilities	5,803,976	4,711,619
Deferred revenue	916,667	-
Notes payable, net of discount	29,306,751	29,539,135
Other liabilities	3,161,885	3,089,420
Navidea stockholders' deficit	(35,846,713)	(29,803,466)
Noncontrolling interest	482,901	-
Stockholders' deficit	(35,363,812)	(29,803,466)
Total liabilities and stockholders' deficit	$ 10,917,909	$ 11,920,180

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended	
	March 31, 2015 (unaudited)	March 31, 2014 (unaudited)
Revenue:		
Lymphoseek sales revenue	$ 1,835,422	$ 626,631
Lymphoseek license revenue	83,333	-
Grant and other revenue	189,701	125,173
Total revenue	2,108,456	751,804
Cost of goods sold	449,057	193,220
Gross profit	1,659,399	558,584
Operating expenses:		
Research and development	3,981,288	5,226,794
Selling, general and administrative	5,494,168	3,910,833

Total operating expenses	9,475,456	9,137,627
Loss from operations	(7,816,057)	(8,579,043)
Interest expense	(966,859)	(943,838)
Equity in the loss of joint venture	(262,227)	
Change in fair value of financial instruments	1,727,103	392,483
Loss on extinguishment of debt	-	(2,610,196)
Other income (expense), net	26,815	41
Net loss	(7,291,225)	(11,740,553)
Net loss attributable to noncontrolling interest	(100)	-
Deemed dividend on beneficial conversion feature	(46,000)	-
Net loss attributable to common stockholders	$ (7,337,125)	$ (11,740,553)
Loss per common share (basic and diluted)	$ (0.05)	$ (0.08)
Weighted average shares outstanding (basic and diluted)	149,794,331	144,783,351

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Source: Navidea Biopharmaceuticals, Inc.