

March 23, 2016



# Navidea Announces Fourth Quarter and Full Year 2015 Results

*- Company provides 2016 total revenue guidance of \$23 to \$25 Million –*

*– Management hosting webcast and conference call on March 23, 2016 at 8:00 a.m. ET –*

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAV), today announced results for the fourth quarter and year ended December 31, 2015. Navidea reported total revenue for 2015 of \$13.2 million including Lymphoseek® (technetium Tc 99m tilmanocept) injection sales revenue of \$10.3 million compared to total revenue of \$6.3 million for 2014, which included Lymphoseek sales revenue of \$4.2 million.

“2015 was marked by a strong turnaround in our commercial business, more than doubling total brand sales to approximately \$20 million and recognizing revenue to Navidea of more than \$10 million, meeting guidance for the first time under the leadership of our new management team,” said Rick Gonzalez, Navidea President and Chief Executive Officer. “Importantly, we have advanced several innovative programs in our pipeline and have begun clinical testing for new large market opportunities, leveraging our Manocept™ immune-cell targeting platform. These achievements were accomplished while managing our operations within very restrictive capital constraints. Looking forward to 2016, we will continue our efforts to aggressively streamline operations and manage expenses while working towards our goals of doubling sales for the second year in a row, achieving operational cash flow break-even, and advancing our development pipeline, which is essential to sustaining our long-term growth.”

## Financial Results

Revenues for the year ended December 31, 2015 were \$13.2 million compared to \$6.3 million for 2014. Navidea’s revenues for 2015 consisted of \$10.3 million in sales of Lymphoseek, \$1.1 million related to licensing milestones and \$1.9 million from various federal grants and other revenue, compared to \$4.2 million, \$300,000 and \$1.7 million, respectively, for 2014. The Company also recorded \$1.2 million related to royalties on the gamma detection device business we sold in 2011 (which is reported net of tax as income from discontinued operations).

Operating expenses for the year ended December 31, 2015 were \$30.0 million compared to \$32.3 million for 2014. Research and development expenses were \$12.8 million during 2015 compared to \$16.8 million during 2014. The net decrease from 2014 to 2015 was primarily a result of reductions in NAV4694 and NAV5001 product development costs coupled with reduced headcount and related support costs, offset by increased Lymphoseek EU-related manufacturing and regulatory activities, support for our therapeutics initiatives, and Manocept diagnostic product development costs. Selling, general and administrative

expenses were \$17.3 million for 2015 compared to \$15.5 million for 2014. The net increase is due to increased costs related to the establishment and operation of our internal sales team coupled with one-time costs related to the first quarter 2015 reduction in force and increased professional services, license fees related to Lymphoseek, and other support costs which were partially offset by decreased launch-related marketing costs.

Navidea's loss from operations for the year ended December 31, 2015 was \$18.6 million compared to \$27.6 million for the same period in 2014. For the year ended December 31, 2015, Navidea reported a loss attributable to common stockholders of \$27.6 million, or \$0.18 per share, compared to a loss attributable to common stockholders of \$35.7 million, or \$0.24 per share, for the same period in 2014.

Fourth Quarter Financial Results: Revenues for the fourth quarter of 2015 were \$4.3 million compared to \$2.2 million for the same period in 2014 representing an increase of 95% period over period. Navidea's revenues for the fourth quarter of 2015 consisted of \$3.5 million in sales of Lymphoseek, \$250,000 related to licensing milestones and \$541,000 from various federal grants and other revenue, compared to \$1.5 million, \$0 and \$738,000, respectively, for the same period in 2014.

Fourth quarter 2015 operating expenses were \$6.4 million compared to \$6.4 million for the fourth quarter of 2014. Research and development expenses were \$2.6 million during the fourth quarter of 2015 compared to \$2.3 million during fourth quarter of 2014. The net increase from 2014 to 2015 was primarily a result of increased Lymphoseek EU-related manufacturing and regulatory activities and therapeutics product development costs, offset by decreased NAV4694 product development costs coupled with reduced headcount and related support costs. Selling, general and administrative expenses were \$3.8 million for the fourth quarter of 2015 compared to \$4.1 million for the same period in 2014 for reasons consistent with the annual variances discussed above.

Navidea's loss from operations for the fourth quarter of 2015 was \$2.6 million compared to \$4.5 million for the fourth quarter of 2014. For the fourth quarter of 2015, Navidea reported a loss attributable to common stockholders of \$2.5 million, or \$0.02 per share, compared to a loss attributable to common stockholders of \$6.9 million, or \$0.05 per share, for the fourth quarter of 2014.

"Over the last year and a half, we have made dramatic progress streamlining operations and cutting expenses. Based on our current projections and plans, we expect total operating expenses for 2016 to be roughly 25% lower than 2015 levels, while moving Lymphoseek forward commercially and continuing the development of our Manocept platform," said Brent Larson, Chief Financial Officer. "These measures, coupled with growing revenue, continue to bring us closer to our goal of cash flow break-even in the second half of 2016, which will further support the long term sustainability of the business. In addition, the recently reaffirmed Platinum line of credit will also provide flexibility in the near-term to ensure we have ample capital to support interim needs, but we expect the draws will not exceed \$5 million during 2016, leaving us over \$20 million of available credit in reserve."

## **2016 Financial Guidance**

- Navidea expects Total Revenues for 2016 to range from \$23 million to \$25 million including Lymphoseek product sales revenue, license revenue, grant and other

revenue.

- Navidea expects its 2016 total operating expenses, excluding costs related to its Macrophage Therapeutics subsidiary, to be in the range of \$21.5 million to \$23.5 million.

## **Milestones & Highlights**

Select milestones and highlights that the Company achieved in 2015 and year to date in 2016 include:

- Achieved 2015 Lymphoseek revenue guidance with \$10.3 million in sales to NAVB, more than doubling year-over-year revenue;
- Reduced total operating expenses and, in combination with record total revenues of \$13.2 million, reduced the overall corporate cash burn by 35% over the prior year;
- Recorded income from discontinued operations related to royalty payments from the Neoprobe/Devicor GDS business of \$1.2 million;
- Received notice of award for \$3.8 million in non-dilutive NIH grants to advance Lymphoseek pipeline expansion programs through Phase 1/2;
- Advanced our immunodiagnostics development pipeline, initially into rheumatoid arthritis, addressing a far greater number of patients than our current Lymphoseek label;
- Reported investigator initiated clinical study results demonstrating that Lymphoseek reduces sentinel lymph node biopsy imaging time, facilitates patient throughput and workflow efficiencies and enhanced patient experience;
- Presented promising data demonstrating that a Manocept-doxorubicin immunotherapeutic conjugate induced apoptosis in Kaposi's Sarcoma and tumor associated macrophages;
- Initiated patient enrollment in Lymphoseek expansion trials for pediatric cancer and cervical cancer;
- Published 4 articles in noteworthy medical journals and presented data on Lymphoseek and Manocept compounds at 13 scientific and medical meetings; and,
- Strengthened the Board of Directors by appointing two new shareholder-nominated candidates, Dr. Mark Greene and Dr. Anthony Fiorino.

## **Conference Call**

Navidea will provide a business update and discuss the fourth quarter and full year 2015 financial results during a conference call with the investment community scheduled for Wednesday, March 23, 2016 at 8:00 a.m. ET. 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 Q4 and Year-End 2015 Financial Results Conference Call

Date/Time: Wednesday, March 23, 2016 at 8:00 a.m. ET

Webcast Link: <http://edge.media-server.com/m/p/ji54i8si>

Dial-in Number – 1 (855) 897-5884  
US:  
Dial in Number – 1 (720) 634-2940  
Int'l:  
Participant  
Passcode: 56356081

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

## About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. 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. The development activities of the Manocept immunotherapeutic platform will be conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel products 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.*

**NAVIDEA BIOPHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

December 31, December 31,  
2015 2014  
(unaudted)

Assets:		
Cash	\$ 7,166,260	\$ 5,479,006
Other current assets	5,410,914	3,120,139
Non-current assets	2,387,339	3,231,163
Total assets	\$ 14,964,513	\$ 11,830,308

Liabilities and stockholders' deficit:		
Deferred revenue, current	\$ 1,044,281	\$ -
Notes payable, net of discount, current	333,333	4,348,678
Other current liabilities	4,806,236	4,711,619
Deferred revenue	192,728	-
Notes payable, net of discount	60,746,002	29,484,057
Other liabilities	1,677,633	3,089,420
Total liabilities	68,800,213	41,633,774
Navidea stockholders' deficit	(54,305,258)	(29,803,466)
Noncontrolling interest	469,558	-
Total stockholders' deficit	(53,835,700)	(29,803,466)
Total liabilities and stockholders' deficit	\$ 14,964,513	\$ 11,830,308

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Twelve Months Ended	
	December 31, 2015 (unaudited)	December 31, 2014 (unaudited)	December 31, 2015 (unaudited)	December 31, 2014 (unaudited)
Revenue:				
Lymphoseek sales revenue	\$ 3,502,860	\$ 1,459,994	\$ 10,254,352	\$ 4,233,953
Lymphoseek license revenue	250,000	-	1,133,333	300,000
Grant and other revenue	540,806	738,291	1,861,622	1,740,896
Total revenue	4,293,666	2,198,285	13,249,307	6,274,849
Cost of good sold	515,386	314,547	1,754,763	1,586,145
Gross profit	3,778,280	1,883,738	11,494,544	4,688,704
Operating expenses:				
Research and development	2,607,216	2,282,612	12,787,733	16,779,589
Selling, general and administrative	3,771,753	4,076,995	17,257,329	15,542,071
Total operating expenses	6,378,969	6,359,607	30,045,062	32,321,660
Loss from operations	(2,600,689)	(4,475,869)	(18,550,518)	(27,632,956)
Other income (expense):				
Interest expense, net	(2,183,050)	(925,946)	(6,873,736)	(3,690,068)
Equity in the loss of joint venture	(10,036)	(261,611)	(305,253)	(523,809)
Change in fair value of financial instruments	1,088,120	(1,232,890)	(614,782)	(1,342,389)
Loss on extinguishment of debt	-	-	(2,440,714)	(2,610,196)
Other income (expense), net	708	31,330	26,808	72,749
Net loss	(3,704,947)	(6,864,986)	(28,758,195)	(35,726,669)
Benefit from income taxes	436,051	-	436,051	-
Loss from continuing operations	(3,268,896)	(6,864,986)	(28,322,144)	(35,726,669)
Income from discontinued operations, net of tax	758,609	-	758,609	-
Net loss	(2,510,287)	(6,864,986)	(27,563,535)	(35,726,669)
Less loss attributable to noncontrolling interest	(174)	-	(855)	-
Deemed dividend on beneficial conversion feature	-	-	(46,000)	-
Net loss attributable to common stockholders	\$ (2,510,113)	\$ (6,864,986)	\$ (27,608,680)	\$ (35,726,669)
Income (loss) per common share (basic and diluted):				
Continuing operations	\$ (0.02)	\$ (0.05)	\$ (0.19)	\$ (0.24)
Discontinued operations	\$ 0.00	\$ -	\$ 0.01	\$ -
Attributable to common stockholders	\$ (0.02)	\$ (0.05)	\$ (0.18)	\$ (0.24)
Weighted average shares outstanding (basic and diluted)				
	154,591,487	149,888,696	151,180,222	148,748,396

View source version on businesswire.com:

<http://www.businesswire.com/news/home/20160323005416/en/>

Navidea Biopharmaceuticals

Investors

Tom Baker, 617-532-0624

[tbaker@navidea.com](mailto:tbaker@navidea.com)

or

Media

Sharon Correia, 978-655-2686

Associate Director, Corporate Communications

or

David Schull, 858-717-2310

[david.schull@russopartnersllc.com](mailto:david.schull@russopartnersllc.com)

Source: Navidea Biopharmaceuticals, Inc.