

Navidea Announces Fourth Quarter and Full-Year 2012 Results

- Management hosting conference call on March 7, 2013 at 8:30 a.m. EST -

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced consolidated results for the fourth quarter of 2012 and for the year ended December 31, 2012.

Financial Results

Navidea's revenues for 2012 relate primarily to reimbursement of certain Lymphoseek[®] commercialization activities by our U.S. distribution partner. Revenues for 2011 relate to grants received in support of the Company's drug development activities. Revenues for the year ended December 31, 2012 were \$79,000 compared to \$598,000 for 2011. Costs related to these reimbursements and grants received in support of development activities were recorded in operating expenses.

Fourth quarter 2012 operating expenses were \$7.0 million compared to \$9.0 million for the fourth quarter of 2011. Operating expenses for the year ended December 31, 2012 were \$28.1 million compared to \$24.7 million for 2011.

Research and development expenses decreased \$2.7 million to \$4.3 million during the fourth quarter of 2012 from \$7.0 million for the same period in 2011. The net decrease was primarily a result of net decreases in NAV4694 costs, which included a \$5.0 million license fee in the fourth quarter of 2011, and RIGScanTM development costs, offset by increases in Lymphoseek and NAV5001 development costs as well as increased headcount and related costs to support our expanded development efforts. Research and development expenses increased \$1.7 million to \$16.9 million during 2012 from \$15.2 million during 2011. The net increase from 2011 to 2012 was primarily a result of net increases in NAV5001 and Lymphoseek development costs, including NAV5001 option and sublicense fees of \$1.8 million (\$1.1 million of which was non-cash in nature), increased costs related to potential pipeline products, and increased headcount and related costs as described above, offset by decreases in NAV4694 and RIGScan development costs.

Selling, general and administrative expenses increased \$642,000 to \$2.7 million for the fourth quarter of 2012 from \$2.0 million for the same period in 2011. The net increase was primarily a result of our formation of a marketing and business development team during the second half of 2011 to prepare for the commercial launch of Lymphoseek, resulting in increased marketing costs related to the pending commercial launch of Lymphoseek and increased headcount and related costs in 2012. Selling, general and administrative expenses increased \$1.7 million to \$11.2 million during 2012 from \$9.5 million in 2011. The net

increase from 2011 to 2012 was primarily a result of increased marketing costs related to the pending commercial launch of Lymphoseek coupled with increased headcount and related costs as described above, offset by decreased separation costs of \$2.7 million related to our former President and CEO which were recorded in 2011.

Navidea's loss from operations for the fourth quarter of 2012 was \$7.0 million compared to \$9.0 million for the fourth quarter of 2011. Navidea's loss from operations for the year ended December 31, 2012 was \$28.0 million compared to \$24.1 million for the same period of 2011. For the fourth quarter of 2012, Navidea reported a loss attributable to common stockholders of \$7.2 million, or \$0.07 per share, compared to a loss attributable to common stockholders of \$7.6 million, or \$0.08 per share, for the fourth quarter of 2011. For the year ended December 31, 2012, Navidea reported a loss attributable to common stockholders of \$29.2 million, or \$0.29 per share, compared to income attributable to common stockholders of \$5.5 million, or \$0.06 per share, for the same period in 2011. Income attributable to common stockholders in 2011 was the result of the sale of Navidea's line of medical devices, the neoprobe® GDS gamma detection systems, to Devicor Medical Products, Inc. in August 2011 for approximately \$30 million.

Business Update

Key milestones achieved by Navidea in 2012 and to date in 2013 include:

Corporate/Financial

- Neoprobe Corporation became Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB)
 reflecting the Company's biopharmaceutical focus on precision diagnostics
 development and commercialization.
- Implemented a \$50 million credit facility with Platinum-Montaur Life Sciences LLC (Montaur), of which \$15 million was made immediately available, to provide flexible financial resources to fund short- and long-term development and growth plans. To date the Company has drawn a total of \$4 million under the credit facility. Montaur also exercised certain warrants in December 2012 and March 2013, providing \$1.9 million and \$1.4 million in proceeds, respectively.
- Completed an underwritten public offering of 1.5 million shares of common stock in February 2013, resulting in net proceeds to the Company of approximately \$4.4 million after deducting expenses associated with the offering.
- Appointed pharma industry veteran Cornelia Reininger, MD, PhD, as Chief Medical
 Officer to lead ongoing development of our pipeline agents, playing a key role in
 medical strategy, protocol design, product positioning and regulatory direction.
 Formerly, Dr. Reininger spearheaded development and registration of the
 neuroimaging agents, florbetaben for Alzheimer's disease and DaTScanTM for
 Parkinson's disease.
- Augmented management with the addition of key strategic positions to strengthen the Company's global regulatory, commercial and manufacturing functions including William Regan, Senior Vice President, Global Regulatory Strategy; David Pendleton, Vice President, Marketing and New Product Planning; Stephen Haber, Vice President, Development; and David Casebier, Vice President, Chemistry, Manufacturing and Control.

Pipeline

Lymphoseek

- Designation of April 30, 2013 as a Prescription Drug User Fee Act goal date for Lymphoseek by the U.S. Food and Drug Administration's (FDA). On September 10, 2012, the Company received a Complete Response Letter (CRL) from the FDA citing manufacturing deficiencies with the Company's contract manufacturers. The Company stated the CRL was not related to Lymphoseek safety or efficacy, and as a result, was able to quickly resubmit the New Drug Application for Lymphoseek to the FDA on October 30, 2012.
- Submitted the Lymphoseek Marketing Authorization Application to the European Medicines Agency in December 2012.
- Reached the interim analysis point of the NEO3-06 Phase 3 head and neck cancer study of Lymphoseek with results from the interim statistical analysis and reporting of the findings expected later in 2013.
- Initiated a collaboration with Maimonides Medical Center on an investigatorinitiated clinical trial utilizing Lymphoseek for lymphatic mapping in colorectal cancer.
- Presented data from Lymphoseek clinical trials at more than 15 major medical meetings, including: Society of Surgical Oncology, European Society of Surgical Oncology, American Society of Clinical Oncology, Society of Nuclear Medicine, International Conference on Head and Neck Cancer, European Association of Nuclear Medicine, American Society for Radiation Oncology and Radiology Society of North America.
- Published data from the Lymphoseek Phase 3 Clinical Trial for Intraoperative Lymphatic Mapping of Lymph Nodes in Breast Cancer Compared to Sulfur Colloid and Vital Blue Dye in the *Journal of Clinical Oncology Online* (2012; e21066).
- Published results from the Lymphoseek Phase 3 Clinical Trials in Melanoma in the *Annals of Surgical Oncology (DOI 10.1245/s10434-012-2612-z)*.

• NAV4694

- Initiated a Phase 2 clinical trial of NAV4694 as an aid in diagnosing Alzheimer's disease (AD) with the goal to compare images from subjects with probable AD with similarly aged and young healthy volunteers.
- Presented data from the NAV4694 studies six major neurological medical meetings including: Human Amyloid Imaging meeting, Alzheimer's Disease Neuroimaging Initiative, Society of Nuclear Medicine and the Alzheimer's Association International Conference on Alzheimer's Disease.

NAV5001

 Licensed NAV5001, an Iodine-123 radiolabeled imaging agent being developed as a potential aid in the diagnosis of Parkinson's disease, dementia with Lewy Bodies (DLB) and other movement disorders, thus expanding the Company's neuroimaging pipeline.

• RIGScan

Awarded a Small Business Innovation Research grant from the National Institutes
of Health for development of a radio-immuno-guided surgery agent aimed at
detecting metastatic cancer, with potential for grant money up to a total of \$1.5
million over three years if fully funded.

Management Commentary

"Through flexible access to multiple available funding sources, we have maintained a strong financial position in advance of expected revenue from our first radiopharmaceutical product, Lymphoseek," said Brent Larson, Navidea's Senior Vice President and CFO. "We believe that 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. In addition, we have spent considerable effort in 2012 to build relationships with potential institutional investors and catalyze interest in Navidea. As an example, our recent transaction led by J.P. Morgan Asset Management has provided us the opportunity to expand our institutional base with additional outstanding investors."

"During 2012, we continued to make important progress positioning Navidea as a leader in the area of precision diagnostics," said Dr. Mark Pykett, Navidea's President and CEO. "We are looking forward to an even more exciting year in 2013."

Dr. Pykett, Executive Vice President and CBO, Dr. Thomas Tulip, Senior Vice President, Pharmaceutical Research and Clinical Development, Dr. Frederick Cope, and Mr. Larson, will provide a business update and discuss the fourth quarter and full year 2012 financial results during a conference call with the investment community scheduled for Thursday, March 7, 2013 at 8:30 a.m. EST. The conference call can be accessed as follows:

Conference Call Information TO PARTICIPATE LIVE:

TO LISTEN TO A REPLAY:

Date: March 7, 2013 Available until: March 21, 2013

Time: 8:30 a.m. EST 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 #: 410082

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[®], NAV4694, NAV5001 and RIGScanTM – 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.

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, the ability to obtain, and timing of, regulatory approvals of the Company's products, the timing and anticipated results of commercialization efforts, and anticipated 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 regulatory approvals for and 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, 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, 2012 (unaudited) | December 31, 2011 | |
|--|-------------------------------------|----------------------|--|
| Assets: | | | |
| Cash | \$ 9,118,564 | \$ 28,644,004 | |
| Other current assets Non-current assets | 1,498,819 1,355,014 | , , | |
| Total assets | \$11,972,397 | | |
| Liabilities and stockholders' (deficit) equity: | | | |
| Notes payable, net of discount, current | \$2,756,718 | \$- | |
| Derivative liabilities, current | - | 568,930 | |
| Other current liabilities | 3,433,821 | 2,779,540 | |
| Notes payable, net of discount | 6,930,112 | 6,456,388 | |
| Other liabilities | 257,122 | 257,315 | |
| Stockholders' (deficit) equity | (1,405,376) | 21,131,747 | |
| Total liabilities and stockholders' (deficit) equity | \$11,972,397 | \$31,193,920 | |

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

Three Months Ended Twelve Months Ended

December 31, December 31, December 31, December 31,

| | 2012 (unaudited) | | 2011 (unaudited) | 2012 (unaudited) | 2011 |
|---|-------------------------------------|---|-------------------------------------|--|---------------------------------------|
| Revenue | \$6,807 | | \$- | \$78,738 | \$ 597,729 |
| Operating expenses: Research and development Selling, general and administrative Total operating expenses | 4,343,109 2,690,241 7,033,350 | | 6,994,373 2,048,325 9,042,698 | 16,890,482 11,177,559 28,068,041 | 15,154,365 9,547,779 24,702,144 |
| Loss from operations | (7,026,543 |) | (9,042,698) | (27,989,303) | (24,104,415) |
| Interest expense Change in derivative liabilities Other income, net | (235,994 25,268 2,559 |) | (10,101) 4,558 10,486 | (1,166,332) 32,110 (33,679) | (13,330) (952,375) 22,544 |
| Loss before income taxes | (7,234,710 |) | (9,037,755) | (29,157,204) | (25,047,576) |
| Benefit from income taxes | - | | 1,476,215 | - | 7,880,143 |
| Loss from continuing operations | (7,234,710 |) | (7,561,540) | (29,157,204) | (17,167,433) |
| Discontinued operations, net of income tax effect | - | | (46,382) | - | 22,780,425 |
| Net (loss) income | (7,234,710 |) | (7,607,922) | (29,157,204) | 5,612,992 |
| Preferred stock dividends | 31,667 | | (25,000) | (43,333) | (100,000) |
| (Loss) income attributable to common stockholders | \$ (7,203,043 |) | \$(7,632,922) | \$ (29,200,537) | \$5,512,992 |
| (Loss) income per common share (basic and diluted): | | | | | |
| Continuing operations | \$ (0.07 |) | \$ (0.08) | \$ (0.29) | \$ (0.17) |
| Discontinued operations | \$- | , | \$(0.00) | \$- | \$0.23 |
| (Loss) income attributable to common stockholders | \$ (0.07 |) | \$ (0.08) | \$ (0.29) | \$ 0.06 |
| Weighted average shares outstanding: Basic and diluted | 105,067,640 |) | 93,766,560 | 99,059,997 | 90,509,326 |

Navidea Biopharmaceuticals, Inc. Brent Larson, 614-822-2330 Sr. VP & CFO

Source: Navidea Biopharmaceuticals, Inc.