February 29, 2012

Navidea Announces Fourth Quarter and Full-Year 2011 Results

– Management to host conference call to discuss results and provide 2012 outlook on March 1, 2012 at 8:00 am ET –

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE Amex: NAVB), a specialty biopharmaceutical developer of innovative precision diagnostics products, today announced consolidated results for the fourth quarter of 2011 and for the year ended December 31, 2011.

Financial Results

During the second half of 2011, the Company sold its neoprobe® GDS line of gamma detection device systems to Devicor Medical Products, Inc. for $30.2 million in gross proceeds, resulting in a net gain on the sale of the GDS business of approximately $26.2 million, prior to estimated taxes. As such, results of operations related to the GDS business previously reported in various historical financial statement line items (i.e., revenues, research and development expenses) have been reclassified to discontinued operations for all periods presented. The cash received from the sale of the GDS business contributed to the Company's year-end cash balance of $28.6 million.

Navidea's non-GDS revenues for both 2011 and 2010 relate to grants received in support of the Company's drug development activities. Grant revenues for the year ended December 31, 2011 were $598,000 compared to $617,000 for the same period in 2010. Costs related to these grants received in support of development activities are recorded in research and development expenses.

Fourth quarter 2011 operating expenses were $9.0 million compared to $3.6 million for the fourth quarter of 2010. Operating expenses for the year ended December 31, 2011 were $24.7 million compared to $13.3 million for 2010. Of the $24.7 million in operating expenses incurred in 2011, approximately $9.0 million related to non-recurring items such as the Lymphoseek® New Drug Application (NDA) filing fee, executive separation costs and a $5.0 million up-front fee paid to AstraZeneca related to the license of AZD4694. Excluding the NDA filing fee and AZD4694 license fee, research and development costs decreased $329,000 during 2011 compared to 2010 as a result of decreased clinical trial costs and decreased costs related to chemistry, manufacturing and control validation activities, offset by increased headcount and other consulting costs incurred in support of the NDA. Excluding the separation costs related to our former CEO, selling, general and administrative expenses for 2011 increased $2.8 million compared to 2010 as a result of increased headcount and related costs devoted to marketing and business development, increased investor relations and professional services, and costs associated with increased activity by our Board of Directors during 2011.

Navidea's loss from operations before other expenses and taxes for the fourth quarter of 2011 was $9.0 million compared to $3.1 million for the fourth quarter of 2010. Navidea's loss from operations before other expenses and taxes for the year ended December 31, 2011 was $24.1 million compared to $12.7 million for 2010. For the fourth quarter of 2011, Navidea reported a loss attributable to common stockholders of $7.6 million, or $0.08 per share, compared to a loss attributable to common stockholders of $2.1 million, or $0.03 per share, for the fourth quarter of 2010. For the year ended December 31, 2011, Navidea reported income attributable to common stockholders of $5.5 million, or $0.06 per share, compared to a loss attributable to common stockholders of $58.2 million, or $0.72 per share, for 2010.

As discussed in the Company's periodic filings with the Securities and Exchange Commission, the net loss attributable to common stockholders for 2010 included significant non-cash losses and deemed dividends aggregating $51.1 million. The non-cash charges in 2010 were primarily due to the extinguishment accounting related to the June 2010 exchange of the Company's previous convertible debt and preferred stock for a new series of preferred stock and to mark-to-market adjustments related to derivative accounting treatment required for certain financial instruments on the Company's balance sheet.

Business Update

Key milestones achieved by Navidea in 2011 and to date in 2012 include:

Corporate/Financial

- Achieved listing of our common stock on the NYSE Amex Stock Exchange
- Appointed new senior management and board positions
- Filed a shelf registration on Form S-3 to allow the Company to raise capital as necessary through the sale of up to $100 million in a primary offering of securities
- Completed the sale of our GDS business to Devicor Medical Products, Inc. for $30.2 million in gross proceeds and up to an additional $20 million in potential future royalties
- Executed a Loan Agreement with Hercules Technology II, L.P. providing for a first advance of $7 million which was received in December 2011 and the availability of a second advance of an additional $3 million subject to certain milestone conditions

Pipeline

- Presented data from Lymphoseek trials at major medical meetings, including the American Society of Clinical Oncology and the Society of Nuclear Medicine Annual Meetings
- Filed and received notice of the acceptance of the Lymphoseek NDA from FDA with PDUFA date set for June 10, 2012
- Obtained positive guidance from EMA for Lymphoseek and announced our intent to file a Marketing Authorization Application (MAA) in the EU by the end of 2012 based on already completed clinical trials and supplementary information
- Completed meetings with the FDA and the European Medicines Agency (EMA) for RIGScan^{TM} and began manufacturing activities necessary to resume clinical evaluation
- Executed a license agreement with AstraZeneca AB for the exclusive worldwide license of AZD4694, a patented PET imaging agent intended for use as an aid in diagnosing Alzheimer's disease

- Entered into an option agreement with Alseres Pharmaceuticals, Inc. to license [^{123}I] E-IACFT Injection, an Iodine-123 radiolabeled imaging agent being developed as an aid in the diagnosis of Parkinson's disease and other movement disorders

Management Commentary

"The sale of the GDS business was a transformative event for the Company," said Brent Larson, Senior Vice President and CFO. "Proceeds from the sale and the subsequent debt-based transaction in 2011 have placed us in a strong financial position, with projected cash flow and financial resources expected to sufficiently fund planned program development and growth for 2012 and beyond."

"Navidea has entered 2012 with great momentum. We expect that our innovative precision diagnostics portfolio will drive a number of potential value-enhancing events through this year and going forward," said Dr. Mark Pykett, President and CEO. "We are well positioned with our expected approval and commercial launch of Lymphoseek this year, our planned advancement of the global registration process for Lymphoseek and our important later-stage clinical pipeline of candidates poised for additional clinical studies in 2012 and 2013. We look forward to updating our shareholders on our overall strategic plans and continued progress."

Navidea President and CEO, Dr. Mark Pykett, Executive Vice President and CBO, Dr. Thomas Tulip, and Senior Vice President and CFO, Brent Larson, will provide a business update and discuss the fourth quarter and full year 2011 financial results during a conference call with the investment community scheduled for Thursday, March 1, 2012 at 8:00 am ET. The conference call can be accessed as follows:

Conference Call Information

TO PARTICIPATE LIVE:		**TO LISTEN TO A REPLAY:**	
		Available until:	March 15, 2012
Date:	March 1, 2012	Toll-free (U.S.) Dial in # :	(877) 660-6853
Time:	8:00 am ET	International Dial in # :	(201) 612-7415
Toll-free (U.S.) Dial in # :	(877) 407-8033	Replay passcode:	
International Dial in # :	(201) 689-8033	Account #:	286
		Conference ID #:	390060

About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE Amex: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is actively developing three radiopharmaceutical agent platforms – Lymphoseek®, AZD4694 and RIGScan™ – to help identify the presence and status 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.

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2011 (unaudited)	December 31, 2010
Assets:		
Cash	$ 28,644,004	$ 6,420,506
Other current assets	1,402,517	3,812,497
Non-current assets	1,147,399	629,735
Total assets	$ 31,193,920	$ 10,862,738
Liabilities and stockholders' equity:		
Current liabilities, including current portion of derivative liabilities	$ 3,348,470	$ 3,944,439
Note payable, long-term (net of discount)	6,456,388	-
Derivative liabilities, long-term	-	2,077,799
Other liabilities	257,315	708,755
Stockholders' equity	21,131,747	4,131,745
Total liabilities and stockholders' equity	$ 31,193,920	$ 10,862,738

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Twelve Months Ended	
	December 31, 2011 (unaudited)	December 31, 2010 (unaudited)	December 31, 2011 (unaudited)	December 31, 2010
Grant revenue	$ -	$ 467,804	$ 597,729	$ 617,392
Operating expenses:				

Research and development	6,994,373	2,432,683	15,154,365	8,941,046
Selling, general and administrative	2,048,325	1,119,722	9,547,779	4,353,136
Total operating expenses	9,042,698	3,552,405	24,702,144	13,294,182
Loss from operations	(9,042,698)	(3,084,601)	(24,104,415)	(12,676,790)
Interest expense	(10,101)	(1,167)	(13,330)	(554,988)
Change in derivative liabilities	4,558	(664,874)	(952,375)	(1,336,234)
Loss on extinguishment of debt	-	-	-	(41,717,380)
Other income, net	10,486	37,907	22,544	41,398
Loss before income taxes	(9,037,755)	(3,712,735)	(25,047,576)	(56,243,994)
Benefit from income taxes	1,476,215	-	7,880,143	-
Loss from continuing operations	(7,561,540)	(3,712,735)	(17,167,433)	(56,243,994)
Discontinued operations, net of income tax effect	(46,382)	1,659,499	22,780,425	6,279,126
Net income (loss)	(7,607,922)	(2,053,236)	5,612,992	(49,964,868)
Preferred stock dividends	(25,000)	(25,000)	(100,000)	(8,206,745)
Income (loss) attributable to common stockholders	$ (7,632,922)	$ (2,078,236)	$ 5,512,992	$ (58,171,613)
Income (loss) per common share (basic and diluted):				
Continuing operations	$ (0.08)	$ (0.05)	$ (0.19)	$ (0.80)
Discontinued operations	$ (0.00)	$ 0.02	$ 0.25	$ 0.08
Income (loss) attributable to common stockholders	$ (0.08)	$ (0.03)	$ 0.06	$ (0.72)
Weighted average shares outstanding:				
Basic and diluted	93,766,560	82,439,262	90,509,326	80,726,498

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

Source: Navidea Biopharmaceuticals, Inc.