

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) January 25, 2012

NAVIDEA BIOPHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>0-26520</u> (Commission File Number)	<u>31-1080091</u> (IRS Employer Identification No.)
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<u>425 Metro Place North, Suite 300, Columbus, Ohio</u> (Address of principal executive offices)	<u>43017</u> (Zip Code)
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Registrant's telephone number, including area code (614) 793-7500

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- £ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- £ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- £ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- £ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 8.01 Other Events.**

On January 25, 2012, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release announcing that it had entered into an option agreement with Alseres Pharmaceuticals, Inc. to license [<sup>123</sup>I]-E-IAFCT Injection, an Iodine-123 radiolabeled imaging agent, being developed as an aid in the diagnosis of Parkinson's disease and movement disorders. A copy of the complete text of the Company's January 25, 2012, press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.****(d) Exhibits.**

*Exhibit  
Number*

*Exhibit Description*

99.1	Navidea Biopharmaceuticals, Inc. press release dated January 25, 2012, entitled "Navidea Biopharmaceuticals Enters into Option Agreement to License Parkinson's Disease Imaging Agent."
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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 contained or incorporated by reference in this Current Report on Form 8-K, 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, Quarterly Reports on Form 10-Q, and other SEC filings. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Navidea Biopharmaceuticals, Inc.

Date: January 25, 2012

By: /s/ Brent L. Larson  
Brent L. Larson, Senior Vice President and  
Chief Financial Officer



Press Release

**Navidea Biopharmaceuticals Enters into Option Agreement  
to License Parkinson's Disease Imaging Agent**

*-- Licensing would add second neuro-imaging candidate to growing Navidea Biopharmaceuticals pipeline --*

January 25, 2012 - DUBLIN, OH - Navidea Biopharmaceuticals, Inc. (NYSE Amex: NAVB), a specialty pharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that it has entered into an option agreement with Alseres Pharmaceuticals, Inc. (Alseres) to license [<sup>123</sup>I]-E-IACFT Injection, also called Altropane®, an Iodine-123 radiolabeled imaging agent, being developed as an aid in the diagnosis of Parkinson's disease and movement disorders.

"This option agreement has effectively secured the right for Navidea to obtain a license for [<sup>123</sup>I]-E-IACFT within the next six months. Should we exercise the option, [<sup>123</sup>I]-E-IACFT would provide us not only with another strong Phase 3 diagnostic imaging asset, but also one that has great synergy with our AZD4694 PET imaging agent which we are developing as an aid in the diagnosis of Alzheimer's disease. Together, we believe these programs provide us with a robust franchise in precision neuro-imaging diagnostics," said Dr. Thomas Tulip, EVP and Chief Business Officer of Navidea.

The option agreement provides Navidea with exclusive rights for a period of up to six months to perform final due diligence and prepare the documentation necessary to enter into a definitive license agreement for [<sup>123</sup>I]-E-IACFT. Under the terms of the option agreement, Navidea paid Alseres an option fee of \$500,000 for the exclusive right to negotiate a definitive license agreement by June 30, 2012. Navidea can extend the option period from June 30, 2012, to July 31, 2012, for an additional \$250,000. The option agreement anticipates that Navidea will issue Alseres 400,000 shares of Navidea common stock upon execution of the definitive license agreement. The option also anticipates that the license agreement will provide for contingent milestone payments of up to \$3.0 million, \$2.75 million of which will principally occur at the time of product registration or upon commercial sales, and the issuance of up to an additional 1.05 million shares of Navidea stock, 950,000 shares of which are issuable at the time of product registration or upon commercial sales. In addition, the license terms outlined in the option agreement anticipate royalties on net sales of the approved product which are consistent with industry-standard terms.

[<sup>123</sup>I]-E-IACFT is a patented, novel, small molecule radiopharmaceutical used with single photon emission computed tomography (SPECT) imaging to identify the status of specific regions in the brains of patients suspected of having Parkinson's disease. The agent binds to the dopamine transporter (DAT) on the cell surface of dopaminergic neurons in the striatum and substantia nigra regions of the brain. Loss of these neurons is a widely recognized hallmark of Parkinson's disease.

[<sup>123</sup>I]-E-IACFT has been administered to over 600 subjects to date. A Phase 3 Special Protocol Assessment (SPA) for [<sup>123</sup>I]-E-IACFT is already in place with the U.S. Food and Drug Administration (FDA) and over 50 subjects have been enrolled to establish a training data base. Results from clinical trials have demonstrated that [<sup>123</sup>I]-E-IACFT has high affinity for DAT and rapid kinetics which enable the generation of clean images quickly, beginning within about 20 minutes after injection while other agents typically have waiting periods from 4 to 24 hours before imaging can occur. In addition to its potential use as an aid in the differential diagnosis of Parkinson's disease and movement disorders, [<sup>123</sup>I]-E-IACFT may also be useful in the diagnosis of Dementia with Lewy Bodies (DLB), one of the most common forms of dementia after Alzheimer's disease.

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**NAVIDEA BIOPHARMACEUTICALS**  
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“The diagnostic dilemma in movement disorders remains a pressing medical need. It is difficult for physicians to differentiate Parkinson’s disease from non-degenerative movement disorders, especially during the period soon after onset of symptoms, where diagnostic uncertainty and inaccuracy can be high,” said Dr. Tulip. “Having worked with this agent previously, I am very familiar with its strong performance characteristics and potential marketplace advantages. We believe that [<sup>123</sup>I]-E-IACFT has the potential to be a best-in-class imaging agent to improve diagnostic accuracy in this class of disorders.”

“[<sup>123</sup>I]-E-IACFT is a compelling, Phase 3 diagnostic agent that may be able to help the millions of patients with movement disorders and their physicians arrive at a more timely and accurate diagnosis,” said Peter G. Savas, CEO of Alseres. “We are pleased to have identified in Navidea a potential partner with the focus, dedication, expertise and resources to complete the development and commercialization of this promising agent. We look forward to completing the license agreement with Navidea and to Navidea moving forward with development and commercialization of [<sup>123</sup>I]-E-IACFT.”

“We are pleased to have found another high-quality, late-stage diagnostic radiopharmaceutical that is well aligned with our overall growth plans,” said Dr. Mark Pykett, President and CEO of Navidea. “The [<sup>123</sup>I]-E-IACFT program is consistent with our strategy to build our precision radiopharmaceutical pipeline with later stage, high value diagnostics aimed at important unmet medical needs. We believe this program represents an excellent strategic fit for us at this time.”

**About Navidea Biopharmaceuticals**

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](http://www.navidea.com).

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**NAVIDEA BIOPHARMACEUTICALS**  
**ADD – 3**

*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.*

**Contact:**

*Navidea Biopharmaceuticals, Inc. – Brent Larson, Sr. VP & CFO – (614) 822-2330*

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