

NAVIDEA BIOPHARMACEUTICALS, INC.

Form 8-K

September 05, 2013

**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) August 29, 2013

NAVIDEA BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware 001-35076 31-1080091
(State or other jurisdiction (Commission (IRS Employer
of incorporation) File Number) Identification No.)

425 Metro Place North, Suite 450, Dublin, Ohio 43017
(Address of principal executive offices) (Zip Code)

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 1.01. Entry into a Material Definitive Agreement.

On August 29, 2013, Navidea Biopharmaceuticals, Inc. (the “Company”) entered into an Office Lease (the “Lease”) with BRE/COH OH LLC (“BRE”), pursuant to which the Company will lease premises located at 5600 Blazer Parkway, Dublin, Ohio 43017 (the “Premises”). The Premises will serve as the Company’s principal place of business. The term of the Lease will commence on the earlier of (i) the first date on which the Company conducts business in the Premises or (ii) the date occurring 150 days after the date on which BRE tenders exclusive possession of the Premises to the Company free from occupancy by any party (the “Commencement Date”). The term of the Lease will expire on the last day of the 104th full calendar month commencing on or after the Commencement Date.

The foregoing description of the Lease is qualified in its entirety by reference to the complete text of the Lease, a copy of which is attached hereto as Exhibit 10.1 and which is incorporated herein in its entirety by reference.

Item 8.01 Other Events.

On September 4, 2013, the Company issued a press release announcing the award of a Small Business Innovation Research (SBIR) grant from the National Institute on Aging (NIA) of the National Institutes of Health (NIH), in connection with the development of the Company's NAV4694 beta-amyloid imaging agent. This grant, which follows the recent SBIR award for the Company’s Phase 3 study with NAV4694, will partially support the Phase 2b clinical study which is evaluating NAV4694 as a diagnostic imaging agent that may aid physicians in identifying those individuals with mild cognitive impairment who are at greatest risk of progressing to Alzheimer’s disease. The SBIR grant has the potential to provide up to \$2.3 million in support, if fully funded, through the conclusion of the clinical study. Funding for the approved first stage of the grant (\$152,000) is intended to provide support for initiation activities of the clinical trial program. Funding of the second stage of the grant is contingent upon meeting specific aims related to the first stage of the grant such as clinical site contracting, investigator training and institutional review board approvals. The Company announced the initiation of the Phase 2b trial in March 2013.

A copy of the complete text of the Company’s September 4, 2013, press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and each is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

Number Exhibit Description

- | | |
|------|---|
| 10.1 | Office Lease, dated August 29, 2013, by and between Navidea Biopharmaceuticals, Inc. and BRE/COH OH LLC (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the United States Securities and Exchange Commission). |
| 99.1 | Navidea Biopharmaceuticals, Inc. press release dated September 4, 2013, entitled “Navidea Awarded an Additional NIH SBIR Grant for NAV4694 Beta-Amyloid Imaging Agent for Study in Mild Cognitive Impairment.” |

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 filings with the United States Securities and Exchange Commission. 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: September 5, 2013 By: /s/ Brent L. Larson
Brent L. Larson, Executive Vice President and
Chief Financial Officer