

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)

October 25, 2018

NAVIDEA BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

001-35076

31-1080091

(State or other jurisdiction
of incorporation)

(Commission
File Number)

(IRS Employer
Identification No.)

4995 Bradenton Avenue, Suite 240, 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

As previously disclosed, on August 14, 2018, Navidea Biopharmaceuticals, Inc. (“*Navidea*” or the “*Company*”) received a notification (the “*Deficiency Letter*”) from the NYSE American LLC (the “*NYSE American*”) stating that Navidea was not in compliance with Section 1003(a)(ii) and Section 1003(f)(v) of the NYSE American continued listing standards, which relate to stockholders’ equity and the selling price per share of the Company’s securities. As required by the NYSE American, Navidea submitted a plan to the NYSE American by September 14, 2018 advising of actions it has taken or will take to regain compliance with the continued listing standards by February 14, 2020.

On October 25, 2018, the Company received a notification (the “*Acceptance Letter*”) from the NYSE American that the Company’s plan to regain compliance was accepted. The Acceptance Letter also stated that the NYSE American had inadvertently omitted an additional deficiency from the Deficiency Letter. Specifically, the Deficiency Letter should have stated that Navidea is not in compliance with Section 1003(a)(iii) of the NYSE American Company Guide, which requires an issuer to have stockholders’ equity of \$6.0 million or more if it has reported losses from continuing operations and/or net losses in its five most recent fiscal years.

The Acceptance Letter noted that Navidea had stockholders’ equity of \$2.1 million as of June 30, 2018, and has reported losses from continuing operations and/or net losses in its five most recent fiscal years ended December 31, 2017, and its shares have been selling at a low price per share.

The Company must provide quarterly updates to the NYSE American staff (the “*Staff*”) concurrent with its interim/annual SEC filings. The Staff has granted Navidea a plan period through February 14, 2020 to regain compliance with Sections 1003(a)(ii) and (iii), and through February 14, 2019 to regain compliance with Section 1003(f)(v), or else the Staff may commence delisting procedures.

Navidea’s Common Stock will continue to be listed on the NYSE American while it attempts to regain compliance with the listing standards noted, subject to Navidea’s compliance with other continued listing requirements. The Common Stock will continue to trade under the symbol “NAVVB,” but will have an added designation of “.BC” to indicate that Navidea is not in compliance with the NYSE American’s listing standards. The NYSE American notification does not affect Navidea’s business operations or its SEC reporting requirements and does not conflict with or cause an event of default under any of Navidea’s material agreements.

On October 30, 2018, Navidea issued a press release announcing that it had received the notice of acceptance and additional noncompliance. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit 99.1 [Press release issued by Navidea Biopharmaceuticals, Inc., dated October 30, 2018.](#)

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: October 30, 2018

By: /s/ Jed A. Latkin

Jed A. Latkin
Chief Executive Officer, Chief
Operating Officer, and Chief Financial Officer

Navidea Biopharmaceuticals Receives Acceptance Letter from NYSE American

DUBLIN, Ohio--(BUSINESS WIRE)—As previously disclosed, on August 14, 2018, Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) (“Navidea” or the “Company”), a company focused on the development of precision immunodiagnostic agents and immunotherapeutics, received a notification (the “Deficiency Letter”) from the NYSE American LLC (the “NYSE American”) stating that Navidea was not in compliance with Section 1003(a)(ii) and Section 1003(f)(v) of the NYSE American continued listing standards, which relate to stockholders’ equity and the selling price per share of the Company’s securities. As required by the NYSE American, Navidea submitted a plan to the NYSE American by September 14, 2018 advising of actions it has taken or will take to regain compliance with the continued listing standards by February 14, 2020.

On October 25, 2018, the Company received a notification (the “Acceptance Letter”) from the NYSE American that the Company’s plan to regain compliance was accepted. The Acceptance Letter also stated that the NYSE American had inadvertently omitted an additional deficiency from the Deficiency Letter. Specifically, the Deficiency Letter should have stated that Navidea is not in compliance with Section 1003(a)(iii) of the NYSE American Company Guide, which requires an issuer to have stockholders’ equity of \$6.0 million or more if it has reported losses from continuing operations and/or net losses in its five most recent fiscal years.

The Acceptance Letter noted that Navidea had stockholders’ equity of \$2.1 million as of June 30, 2018, and has reported losses from continuing operations and/or net losses in its five most recent fiscal years ended December 31, 2017, and its shares have been selling at a low price per share.

The Company must provide quarterly updates to the NYSE American staff (the “Staff”) concurrent with its interim/annual SEC filings. The Staff has granted Navidea a plan period through February 14, 2020 to regain compliance with Sections 1003(a)(ii) and (iii), and through February 14, 2019 to regain compliance with Section 1003(f)(v), or else the Staff may commence delisting procedures.

Navidea’s Common Stock will continue to be listed on the NYSE American while it attempts to regain compliance with the listing standards noted, subject to Navidea’s compliance with other continued listing requirements. The Common Stock will continue to trade under the symbol “NAVB,” but will have an added designation of “.BC” to indicate that Navidea is not in compliance with the NYSE American’s listing standards. The NYSE American notification does not affect Navidea’s business operations or its SEC reporting requirements and does not conflict with or cause an event of default under any of Navidea’s material agreements.

About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) is a biopharmaceutical company focused on the development of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products based on its Manocept™ platform to enhance patient care by identifying the sites and pathways of disease and enable better diagnostic accuracy, clinical decision-making, and targeted treatment. Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Tc 99m tilmanocept, the first product developed and commercialized by Navidea based on the platform. The development activities of the Manocept immunotherapeutic platform are being conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics, Inc. 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.

Forward-Looking Statements

This release and any oral statements made with respect to the information contained in this release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: general economic and business conditions, both nationally and in our markets; our history of losses and uncertainty of future profitability; the final outcome of the CRG litigation in Texas; our ability to successfully complete research and further development of our drug candidates; the timing, cost and uncertainty of obtaining regulatory approvals of our drug candidates; our ability to successfully commercialize our drug candidates; our expectations and estimates concerning future financial performance, financing plans and the impact of competition; our ability to raise capital sufficient to fund our development and commercialization programs; our ability to implement our growth strategy; anticipated trends in our business; advances in technologies; our ability to comply with the NYSE American continued listing standards; and other risk factors set forth in this report and detailed in our most recent Annual Report on Form 10-K and other SEC filings. You are urged to carefully review and consider the disclosures found in our SEC filings, which are available at www.sec.gov or at <http://ir.navidea.com>.

Investors are urged to consider statements that include the words "will," "may," "could," "should," "plan," "continue," "designed," "goal," "forecast," "future," "believe," "intend," "expect," "anticipate," "estimate," "project," and similar expressions, as well as the negatives of those words or other comparable words, to be uncertain forward-looking statements.

You are cautioned not to place undue reliance on any forward-looking statements, any of which could turn out to be incorrect. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this report. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

Contacts

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