

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) February 14, 2020

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

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-35076</u> (Commission File Number)	<u>31-1080091</u> (IRS Employer Identification No.)
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<u>4995 Bradenton Avenue, Suite 240, Dublin, 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))

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. ☐

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock	NAVB	NYSE American

Item 1.01 Entry into a Material Definitive Agreement.

On February 13, 2020, Navidea Biopharmaceuticals, Inc. (the “Company”) executed agreements with two existing investors, including John K. Scott, Jr. (collectively, the “Investors”), to purchase approximately 4.0 million shares of the Company’s common stock, par value \$0.001 per share, for aggregate gross proceeds to Navidea of approximately \$3.4 million. The securities to be issued to the Investors will represent approximately 16.5% of the Company’s outstanding common stock after such issuance.

In addition, the Company executed a binding term sheet to sell the judgment entered by the Ohio Court of Common Pleas in favor of Navidea in the amount of \$4.3 million plus interest (the “Judgment”), for \$4.2 million of proceeds to Navidea. The Company has the option, within 45 days of the sale, to repurchase the Judgment for a 10% premium. Such repurchase option may be in the form of the Company’s common stock at a 10% discount to the then-current market price.

Navidea intends to use the net proceeds from these transactions to fund its research and development programs, including continued advancement of its two Phase 2b and Phase 3 clinical trials of Tc99m tilmanocept in patients with rheumatoid arthritis, and for general working capital purposes and other operating expenses.

The securities offered and to be sold by Navidea in the private placement to Mr. Scott have not been registered under the Securities Act of 1933 (the “Securities Act”), as amended, or state securities laws and may not be offered or sold in the United States absent registration with the Securities and Exchange Commission (the “SEC”) or an applicable exemption from registration requirements. Navidea has agreed to file a registration statement with the SEC covering the resale of the shares of common stock to be issued to Mr. Scott.

The shares of common stock being offered and sold to the other existing investor are being issued pursuant to a shelf registration statement previously filed with and declared effective by the SEC. A prospectus supplement and accompanying prospectus relating to the offering will be filed with the SEC and will be available for free on the SEC’s website at www.sec.gov.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy any of Navidea’s securities. No offer, solicitation or sale will be made in any state or other jurisdiction in which such offering, solicitation or sale would be unlawful.

On February 14, 2020, the Company issued a press release regarding the matters discussed above. A copy of this press release is attached as Exhibit 99.1 hereto and incorporated in this Item 1.01 by reference.

Item 8.01 Other Information.

As previously reported, on August 14, 2018, the Company received a Deficiency Letter from the NYSE American stating that Navidea was not in compliance with certain NYSE American continued listing standards relating to stockholders’ equity. Specifically, Navidea was not in compliance with Sections 1003(a)(i), (ii) and (iii) of the NYSE American Company Guide (the “Guide”), the highest of such standards requiring 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. Navidea was advised by the NYSE American staff that if we failed to regain compliance with the stockholders’ equity standards by February 14, 2020, the NYSE American would commence delisting procedures.

As shown below, our pro forma stockholders’ equity as of December 31, 2019, is approximately \$6.0 million, which is the amount required to comply with Sections 1003(a)(i), (ii) and (iii) of the Guide. As a result, we believe that we have regained compliance with Sections 1003(a)(i), (ii) and (iii) of the Guide as of the end of the plan period. Subject to review by the NYSE American, the Company may be deemed back in compliance with the NYSE American’s continued listing standards.

The following table sets forth (on an unaudited basis) the Company's stockholders' equity position as of December 31, 2019, and as adjusted on a pro-forma basis as of February 14, 2020:

	December 31, 2019*	Adjustments*	February 14, 2020*
Stockholders' equity:			
Preferred stock; \$.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	\$ —	\$ —	\$ —
Common stock; \$.001 par value; 300,000,000 shares authorized; 20,204,247 and 24,377,896 shares issued and outstanding at December 31, 2019 and February 14, 2020, respectively	211,134	4,174	215,308
Additional paid-in capital	345,847,676	3,563,326	349,411,002
Accumulated deficit	(347,667,249)	4,050,000	(343,617,249)
Total Navidea stockholders' equity	(1,608,439)	7,617,500	6,009,061
Noncontrolling interest	731,303	—	731,303
Total stockholders' equity	<u>\$ (877,136)</u>	<u>\$ 7,617,500</u>	<u>\$ 6,740,364</u>

*Unaudited

The pro forma financial information above is provided for informational purposes only, has not been audited by our independent auditors, may be subject to additional changes, adjustments and modifications as part of the audit process, and may not accurately reflect our stockholders' equity as presented in our audited or reviewed financial statements as of the periods presented and/or as of December 31, 2019 and/or March 31, 2020.

On February 14, 2020, the Company issued a press release regarding the matters discussed above. A copy of this press release is attached as Exhibit 99.2 hereto and incorporated in this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Press Release dated February 14, 2020.
99.2	Press Release dated February 14, 2020.

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: February 14, 2020

By: /s/ Jed A. Latkin
Jed A. Latkin
Chief Executive Officer, Chief Operating Officer
and Chief Financial Officer

Navidea Biopharmaceuticals Announces \$4.2 Million Sale of Ohio Court Judgment and \$3.4 Million Equity Raise Representing \$7.6 Million in Additional Funding

DUBLIN, Ohio--(BUSINESS WIRE) – February 13, 2020 -- Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) (“Navidea” or the “Company”), a company focused on the development of precision immunodiagnostic agents and immunotherapeutics, today announced that they have executed agreements with two existing investors, including John K. Scott, Jr. (collectively, the “Investors”), to purchase approximately 4.0 million shares of the Company’s common stock, par value \$0.001 per share, for aggregate gross proceeds to Navidea of approximately \$3.4 million. The securities to be issued to the Investors will represent approximately 16.5% of the Company’s outstanding common stock after such issuance.

In addition, the Company executed a binding term sheet to sell the judgment entered by the Ohio Court of Common Pleas in favor of Navidea in the amount of \$4.3 million plus interest (the “Judgment”), for \$4.2 million of proceeds to Navidea. The Company has the option, within 45 days of the sale, to repurchase the Judgment for a 10% premium. Such repurchase option may be in the form of the Company’s common stock at a 10% discount to the then-current market price.

Navidea intends to use the net proceeds from these transactions to fund its research and development programs, including continued advancement its two Phase 2b and Phase 3 clinical trials of Tc99m tilmanocept in patients with rheumatoid arthritis, and for general working capital purposes and other operating expenses.

John K. Scott commented, “I continue to support management and the Board of Directors. They have made great strides over the past 18 months to move Navidea into its next chapter of success. My family and I look forward to the continued development of Navidea’s rheumatoid arthritis and pipeline assets.”

“This financing allows Navidea to advance through several key milestones and maintain our NYSE listing,” commented Jed Latkin, Chief Executive Officer of Navidea. “We’re pleased to continue to receive support from current shareholders and look forward to providing updates as the company moves ahead. Navidea is encouraged with the clinical study results announced in the fourth quarter, and we will provide further update on the third cohort as the data is finalized. We are moving ahead as planned and thank our shareholders for their support during this time.”

The securities offered and to be sold by Navidea in the private placement to Mr. Scott have not been registered under the Securities Act of 1933 (the “Securities Act”), as amended, or state securities laws and may not be offered or sold in the United States absent registration with the Securities and Exchange Commission (the “SEC”) or an applicable exemption from registration requirements. Navidea has agreed to file a registration statement with the SEC covering the resale of the shares of common stock to be issued to Mr. Scott.

The shares of common stock being offered and sold to the other existing investor are being issued pursuant to a shelf registration statement previously filed with and declared effective by the SEC. A prospectus supplement and accompanying prospectus relating to the offering will be filed with the SEC and will be available for free on the SEC's website at www.sec.gov.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy any of Navidea's securities. No offer, solicitation or sale will be made in any state or other jurisdiction in which such offering, solicitation or sale would be unlawful.

About Navidea Biopharmaceuticals

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 Tc99m tilmanocept, the first product developed and commercialized by Navidea based on the platform. 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 press 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. Forward looking statements include our expectations regarding pending litigation and other matters. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: our history of losses and uncertainty of future profitability; the final outcome of any pending litigation (including the case described above); 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; dependence on royalties and grant revenue; our ability to implement our growth strategy; anticipated trends in our business; our limited product line and distribution channels; advances in technologies and development of new competitive products; our ability to comply with the NYSE American continued listing standards; our ability to maintain effective internal control over financial reporting; and other risk factors 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 <http://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.

Contact

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Navidea Biopharmaceuticals Regains Compliance with NYSE American Continued Listing Standards

DUBLIN, Ohio--(BUSINESS WIRE) – February 14, 2020 -- Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) (“Navidea” or the “Company”), a company focused on the development of precision immunodiagnostic agents and immunotherapeutics, today announced that following the recently-announced funding transactions, the Company is back in compliance with the NYSE American’s continued listing standards.

As previously reported, on August 14, 2018, the Company received a Deficiency Letter from the NYSE American stating that Navidea was not in compliance with certain NYSE American continued listing standards relating to stockholders’ equity. Specifically, Navidea was not in compliance with Sections 1003(a)(i), (ii) and (iii) of the NYSE American Company Guide, the highest of such standards requiring 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. Navidea was advised by the NYSE American staff that if the Company failed to regain compliance with the stockholders’ equity standards by February 14, 2020, the NYSE American would commence delisting procedures. Following the recently-announced funding transactions, the Company now has stockholders’ equity of \$6.0 million, and therefore has regained compliance with the NYSE American’s continued listing standards.

About Navidea Biopharmaceuticals

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 Tc99m tilmanocept, the first product developed and commercialized by Navidea based on the platform. 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.

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This press 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. Forward looking statements include our expectations regarding pending litigation and other matters. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: our history of losses and uncertainty of future profitability; the final outcome of any pending litigation; 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; dependence on royalties and grant revenue; our ability to implement our growth strategy; anticipated trends in our business; our limited product line and distribution channels; advances in technologies and development of new competitive products; our ability to comply with the NYSE American continued listing standards; our ability to maintain effective internal control over financial reporting; and other risk factors 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 <http://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.

Contact

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