

NAVIDEA BIOPHARMACEUTICALS, INC.
Form NT 10-K
March 16, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 12b-25

NOTIFICATION OF LATE FILING

Commission File No. 001-35076

(Check One:) Form 10-K Form 20-F Form 11-K Form 10-Q
 Form N-SAR Form N-CSR

For Period Ended: December 31, 2016

Transition Report on Form 10-K Transition Report on Form 10-Q
 Transition Report on Form 20-F Transition Report on Form N-SAR
 Transition Report on Form 11-K

For the Transition Period Ended:

Nothing in this form shall be construed to imply that the Commission has verified any information contained herein.

If the notification relates to a portion of the filing checked above, identify the item(s) to which the notification relates:

PART I

REGISTRANT INFORMATION

Full Name of Registrant: Navidea Biopharmaceuticals, Inc.
Former Name if Applicable:
Address of Principal Executive Office (*Street and number*): 5600 Blazer Parkway, Suite 200
City, state, and zip code: Dublin, Ohio 43017-7550

PART II

RULES 12b-25(b) AND (c)

If the subject report could not be filed without unreasonable effort or expense and the registrant seeks relief pursuant to Rule 12b-25(b), the following should be completed. (Check box if appropriate)

- (a) The reasons described in reasonable detail in Part III of this form could not be eliminated without unreasonable effort or expense;
- (b) The subject annual report, semi-annual report, transition report on Form 10-K, Form 20-F, Form 11-K, Form N-SAR or Form N-CSR, or portion thereof, will be filed on or before the fifteenth calendar day following the prescribed due date; or the subject quarterly report or transition report on Form 10-Q or subject distribution report on Form 10-D, or portion thereof, will be filed on or before the fifth calendar day following the prescribed due date; and
- (c) The accountant's statement or other exhibit required by Rule 12b-25(c) has been attached if applicable.

PART III

NARRATIVE

State below in reasonable detail why Forms 10-K, 20-F, 11-K, 10-Q, 10-D, N-SAR, N-CSR, or the transition report or portion thereof, could not be filed within the prescribed time period.

As disclosed by Navidea Biopharmaceuticals, Inc. (the “Company”) in its Current Report on Form 8-K filed on March 3, 2017 with the SEC, on March 3, 2017, pursuant to an Asset Purchase Agreement, dated as of November 23, 2016 (the “Purchase Agreement”), between the Company and Cardinal Health 414, LLC (“Cardinal Health 414”), the Company completed its sale to Cardinal Health 414 of its assets used, held for use, or intended to be used in operating its business of developing, manufacturing and commercializing a product used for lymphatic mapping, lymph node biopsy, and the diagnosis of metastatic spread to lymph nodes for staging of cancer, including the Company’s radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the U.S. Food and Drug Administration (“FDA”) and similar indications approved by the FDA in the future, in Canada, Mexico and the United States. Due to the consummation of the transactions contemplated by the Purchase Agreement, significant management time and resources were diverted from the Company’s normal process of reviewing and completing the Company’s Annual Report on Form 10-K for the year ended December 31, 2016 (the “2016 Form 10-K”). As a result, the Company cannot, without unreasonable effort or expense, file the 2016 Form 10-K on or prior to the prescribed due date of March 16, 2017. The Company expects to file the 2016 Form 10-K on or before the fifteenth calendar day following the prescribed due date.

PART IV

OTHER INFORMATION

- (1) Name and telephone number of person to contact in regard to this notification

Jed A. Latkin 614-793-7500

(2) Have all other periodic reports required under Section 13 or 15(d) of the Securities Exchange Act of 1934 or Section 30 of the Investment Company Act of 1940 during the preceding 12 months or for such shorter period that the registrant was required to file such report(s) been filed? If answer is no, identify report(s).

Yes No

(3) Is it anticipated that any significant change in results of operations from the corresponding period for the last fiscal year will be reflected by the earnings statements to be included in the subject report or portion thereof?

Yes No

If so, attach an explanation of the anticipated change, both narratively and quantitatively, and, if appropriate, state the reasons why a reasonable estimate of the results cannot be made.

The Company expects to report revenues for the year ended December 31, 2016 of \$22.0 million compared to \$13.2 million for 2015. Navidea's revenues for 2016 consisted of \$17.0 million in sales of Lymphoseek, \$3.1 million from various federal grants and other revenue, and \$1.8 million from Lymphoseek license revenue, compared to \$10.3 million, \$1.9 million and \$1.1 million, respectively, for 2015. In addition, the Company recorded \$1.2 million in 2015 related to royalties on the device business that we sold in 2011.

The Company expects operating expenses for the year ended December 31, 2016 to be approximately \$21.9 million compared to \$30.0 million for 2015. Research and development expenses were \$8.9 million during 2016 compared to \$12.8 million during 2015. The net decrease was primarily a result of reductions in NAV4694, Lymphoseek and NAV5001 product development costs coupled with reduced headcount and related support costs, offset by increased Manocept diagnostic and therapeutic product development costs. Selling, general and administrative expenses were approximately \$13.0 million for 2016 compared to \$17.3 million for 2015. The net decrease was primarily due to reduced headcount and related support costs, contracted medical science liaisons, business development consulting services, market development expenses related to Lymphoseek, and investor relations, offset by increased legal and professional services.

The unaudited estimated financial results set forth above are preliminary and will not be final until the Company files its audited financial statements in its Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Notification of Late Filing on Form 12b-25 contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, which are subject to risks and uncertainties. All statements, other than statements of historical facts, are forward-looking statements. Although the Company believes that in making any such forward-looking statement its expectations are based on reasonable assumptions, any such forward-looking statement involves uncertainties and is qualified in its entirety by reference to the discussion of risk factors in the Company’s most recent Annual Report on Form 10-K and in its other filings with the Securities and Exchange Commission. Any forward-looking statement speaks only at the date on which it is made, and except as may be required by law, the Company undertakes no obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which it is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for the Company to predict all of them; nor can the Company assess the impact of each such factor or the extent to which any factor, or combination of factors, may cause results to differ materially from those contained in any forward-looking statement. As such, readers should not unduly rely on such forward-looking statements.

Navidea Biopharmaceuticals, Inc.

(Name of Registrant as Specified in Charter)

Has caused this notification to be signed on its behalf by the undersigned thereunto duly authorized.

Date: March 16, 2017 By: */s/ Jed A. Latkin*
Jed A. Latkin

Interim Chief
Operating Officer

INSTRUCTION: The form may be signed by an executive officer of the registrant or by any other duly authorized representative. The name and title of the person signing the form shall be typed or printed beneath the signature. If the statement is signed on behalf of the registrant by an authorized representative (other than an executive officer), evidence of the representative's authority to sign on behalf of the registrant shall be filed with the form.

ATTENTION

Intentional misstatements or omissions of fact constitute Federal criminal violations (see 18 U.S.C.1001)
