NEOPROBE CORP
Form 8-K
October 20, 2011

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 19, 2011

NEOPROBE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	0-26520	31-1080091
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

425 Metro Place North, Suite 300, Columbus, 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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 October 19, 2011, Neoprobe Corporation (the "Company") issued a press release announcing that its New Drug Application ("NDA") for Lymphoseek® (tilmanocept) had been accepted for review by the U.S. Food and Drug Administration (FDA). The Company submitted the Lymphoseek NDA on August 10, 2011.

The Company seeks U.S. clearance to market Lymphoseek for use in Intraoperative Lymphatic Mapping ("ILM"), a surgical oncology procedure in which lymph nodes draining the area around a tumor are identified and biopsied to determine if cancer has spread to the lymph nodes. According to the American Cancer Society, approximately 230,000 new cases of breast cancer and 70,000 new cases of melanoma are expected to be diagnosed in the United States in 2011. The Lymphoseek NDA has proposed use of the agent in the identification of lymphatic tissue.

The NDA submission for Lymphoseek includes results from two Phase 3 studies of Lymphoseek, NEO3-05 and NEO3-09, performed in patients with either breast cancer or melanoma. The primary endpoint for both the NEO3-05 and NEO3-09 studies was the concordance (or the rate of agreement) on a lymph node count basis of Lymphoseek with vital blue dye, a long-standing, FDA-approved, on-label agent for lymphatic mapping and appropriate “Truth Standard” comparator for registration purposes. In both of the Phase 3 studies (NEO3-05, NEO3-09), the concordance of Lymphoseek to vital blue dye was highly statistically significant ($p<0.0001$). Lymphoseek met all primary and secondary endpoints across both studies.

Secondary endpoints were also assessed, including the false negative rate (or failed detection rate) of Lymphoseek versus vital blue dye. This analysis evaluated the ability of vital blue dye and Lymphoseek to detect lymph nodes that contained cancer cells, as determined by pathology evaluation. In both studies combined, vital blue dye exhibited a failed detection rate of more than 20%, whereas Lymphoseek showed a failed detection rate of approximately 1%, or twenty-fold lower than vital blue dye, a difference that was also highly statistically significant ($p<0.002$). Because the key objective of performing ILM is to identify cancer cells when they are present in lymph nodes, reduction of the failed detection rate is important.

In more than 500 subjects receiving Lymphoseek to date, including those studied as a part of the NEO3-05 and NEO3-09 studies, no drug-related serious adverse events or clinically significant drug-related adverse events have been reported. Lymphoseek works by binding to a specific receptor found on the surface of dendritic cells and macrophages, which reside in lymph-nodes. This receptor-targeted property of Lymphoseek enables it to attach to and remain within lymph nodes. To date Lymphoseek is the first and only receptor-targeted agent developed specifically for ILM.

A copy of the complete text of the Company’s October 19, 2011, press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Neoprobe Corporation press release, dated October 19, 2011, entitled “Neoprobe Receives FDA Acceptance of Lymphoseek® (tilmanocept) New Drug Application”

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.

Neoprobe Corporation

Date: October 20, 2011	By:	/s/ Brent L. Larson Brent L. Larson, Senior Vice President and Chief Financial Officer