NEOPROBE CORP
Form 8-K
May 04, 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)	May 3, 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 May 3, 2011, Neoprobe Corporation (the "Company") issued a press release announcing the top-line results from its Lymphoseek® (tilmanocept) NEO3-09 study. The NEO3-09 study met all primary and secondary endpoints and highlighted the superior performance by Lymphoseek compared to vital blue dye in intraoperative lymphatic mapping (ILM), a procedure in which lymph nodes are identified for biopsy to assess for the presence of tumor. The NEO3-09 Phase 3 clinical study, the Company's second successful Phase 3 study for Lymphoseek, enrolled over 150 subjects with either breast cancer or melanoma within the intent-to-treat (ITT) population. Lymphoseek performed equally well in both cancer types.

The primary endpoint of this study was the comparison, or concordance rate, of Lymphoseek versus vital blue dye in ILM, where vital blue dye was designated as the "Truth Standard" comparator. NEO3-09 study subjects yielded over 200 lymph nodes stained with vital blue dye. Of the vital blue dye stained nodes, Lymphoseek detected all of them, a concordance rate of 100%, which is highly statistically significant. This concordance rate was consistent with the rate observed in the NEO3-05 Phase 3 study of approximately 98%, which also was highly statistically significant.

Using Lymphoseek as the Truth Standard, the reverse concordance rate for vital blue dye was approximately 60%, a finding similar to the retrospective reverse concordance rate observed in the NEO3-05 Phase 3 study of approximately 69%. These data demonstrate that in these studies vital blue dye statistically was not equivalent to, and in fact was inferior to, Lymphoseek in this measure of lymph node detection. Use of the concordance data and reverse concordance data in a pre-specified, prospective test of superiority showed that Lymphoseek's performance was statistically superior to vital blue dye in lymph node detection.

Lymphoseek also demonstrated a superior ability to detect lymph nodes that contained cancer. In NEO3-09, the ILM procedures found pathology-confirmed, cancer-positive lymph nodes at a rate consistent with the general rate of nodal involvement typically observed in these cancer types. Of these pathology-confirmed, cancer-positive nodes, Lymphoseek detected all of them, for a failed detection rate of 0%. In contrast, vital blue missed over 25% of cancer-positive nodes. This prospective analysis confirmed the lower failed detection rate for Lymphoseek observed retrospectively in the NEO3-05 Phase 3 study. Lymphoseek's substantially lower failed detection rate means that it missed fewer lymph nodes containing cancer, a key finding given that the objective of ILM is to determine if the cancer has spread to the lymph nodes.

In both NEO3-09 and NEO3-05, Lymphoseek demonstrated no drug-related serious adverse events or clinically significant adverse events, whereas vital blue dye showed several significant drug-related adverse events. In over 500 subjects receiving Lymphoseek to date, no clinically significant drug-related adverse events have been reported.

In a full regional lymph node dissection procedure, a patient with breast cancer or melanoma may have as many as 20 to 30 lymph nodes removed in order to determine whether or not cancer has spread to other parts of their body. This very invasive procedure frequently causes significant side effects. In the NEO3-05 and NEO3-09 studies combined, Lymphoseek detected an average of 2.4 lymph nodes per patient, whereas vital blue dye detected a similar average of approximately 1.5 lymph nodes per patient. With this relatively small difference in number of nodes removed, Lymphoseek exhibited superior performance in detecting lymph nodes containing cancer, as evidenced by its lower failed detection rate noted above. The average number of lymph nodes detected by Lymphoseek in a much less invasive manner is still far below the number of lymph nodes removed in full regional node dissection procedures, thus potentially sparing the patient the morbidity and side effects commonly associated with more complete regional nodal dissection procedures. A copy of the complete text of the Company's May 3, 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 May 3, 2011, entitled “Lymphoseek® (Tilmanocept) Meets all Endpoints in NEO3-09 Phase 3 Study”

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: May 4, 2011	By:	/s/ Brent L. Larson Brent L. Larson, Senior Vice President and Chief Financial Officer