NEOPROBE CORP
Form 8-K
June 09, 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) June 6, 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):

¨ 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))

Item 8.01. Other Events.

Announcement of NEO3-09 Results

On June 6, 2011, Neoprobe Corporation (the "Company") issued a press release announcing that independent investigators have reported the full results from the NEO3-09 study, reaffirming earlier top-line results that showed Lymphoseek® (99mTc-tilmanocept) met all primary and secondary endpoints and exhibited superior performance to vital blue dye in intraoperative lymphatic mapping (ILM) procedures. The results were presented during a moderated poster-discussion session on June 6, 2011, by Anne Wallace, MD, Moores Cancer Center, University of California San Diego, and Vernon Sondak, MD, H. Lee Moffitt Cancer Center in Tampa, Florida, at the American Society of Clinical Oncology ("ASCO") Meeting in Chicago.

The June 6, 2011, press release announced the following regarding the NEO3-09 study:

NEO3-09 Primary Endpoint Met – Strong Findings Across Both Phase 3 Studies

The primary endpoint of the NEO3-09 study was the comparison (the Concordance Rate, or the rate of agreement) of Lymphoseek versus vital blue dye, where vital blue dye is considered by FDA as the only approved, on-label agent for lymphatic mapping, thus making it the appropriate requisite "Truth Standard" comparator for registration purposes. The Concordance Rate was analyzed on both a per-node and per-patient basis.

In NEO3-09, study subjects yielded a total of 229 lymph nodes stained with vital blue dye. Of these blue-stained nodes, Lymphoseek detected 229, for a Concordance Rate of 100%, which was a highly statistically significant finding ($p<0.0001$). This Concordance Rate was consistent with the 97.67% rate observed in the NEO3-05 study ($p<0.0001$).

On a per-patient basis, the NEO3-09 study yielded a total of 133 patients with lymph nodes stained with vital blue dye. Of these patients, Lymphoseek detected the same blue-stained nodes in all 133 patients, for a Concordance Rate of 100%, a highly statistically significant finding ($p<0.0001$). This Concordance Rate was consistent with the 96.32% rate observed in the NEO3-05 study ($p<0.0001$).

Key Findings in Detection of Lymph Nodes Bearing Cancer

The NEO3-09 Phase 3 clinical study enrolled 133 subjects with either breast cancer or melanoma (n = 68 and 65 patients, respectively) in the intent-to-treat (ITT) population. On a per node basis, Lymphoseek exhibited a failed detection rate (FDR) of 0%, whereas vital blue exhibited an FDR of 25%. The prospective analysis confirmed the earlier retrospective analysis of Lymphoseek's lower FDR observed in the first Phase 3 study, NEO3-05. This low failed detection rate of tumor-bearing lymph nodes for Lymphoseek compared to vital blue dye means Lymphoseek missed fewer lymph nodes that contained cancer, a key finding given that the objective of ILM is to determine if cancer has spread to the lymph nodes.

Lymphoseek also exhibited a lower the FDR on a per-patient basis. Across the replicate NEO3-05 and NEO3-09 Phase 3 studies, among the 55 patients identified to have lymph nodes containing pathology-confirmed tumor, Lymphoseek missed 0 patients, for an FDR of 0%, whereas vital blue dye missed 4 patients (2 breast cancer and 2 melanoma diagnoses) for an FDR of 7.3%($p<0.044$). Additionally, Lymphoseek also identified 2 patients with lymphoma that were not identified by vital blue dye. Thus, Lymphoseek facilitated the identification of 6 patients out of a total of 55 patients with lymph node-positive pathology (10.9%) whose cancer status would not have been accurately identified by vital blue dye.

NEO3-09 Secondary Endpoint Findings

A secondary analysis treated Lymphoseek as the “Truth Standard” in ILM procedures; this Reverse Concordance Rate was also analyzed on a per-node and per-patient basis. In NEO3-09, 378 lymph nodes labeled with Lymphoseek were obtained. Of these, vital blue dye was observed in 229 nodes. Using Lymphoseek as the Truth Standard, the Reverse Concordance Rate for vital blue dye was 60.58%, which was not statistically significant (p=1.0000). This finding was similar to the retrospective Reverse Concordance Rate observed in the NEO3-05 Phase 3 study of 68.63% (p=1.0000, not significant). These data demonstrate vital blue dye did not perform equivalently to, and in fact was inferior to, Lymphoseek in these measures of lymph node detection.

In the per-patient analysis, the NEO3-09 study yielded a total of 152 patients with lymph nodes labeled with Lymphoseek. Of these patients, vital blue dye detected the same blue-stained nodes in only 76 patients, a Reverse Concordance Rate of 50.00% (p=1.0000, not significant). This Reverse Concordance Rate was consistent with the 54.17% rate observed in the NEO3-05 study (p=1.0000, not significant). Thus, the per-patient data demonstrate the inferiority of vital blue dye performance relative to Lymphoseek.

Using the Concordance Rate and Reverse Concordance Rate data from NEO3-09 in a pre-specified, prospective statistical test of superiority, Lymphoseek’s performance was significantly superior to vital blue dye in lymph node detection (p<0.0001).

NEO3-09 Safety & LN Identification Findings

In both NEO3-09 and NEO3-05, Lymphoseek demonstrated no drug-related serious adverse events or clinically significant adverse events, whereas vital blue dye exhibited 3 adverse events, including one significant drug-related adverse event, anaphylactic hypotension. In over 500 subjects receiving Lymphoseek to date, no clinically significant drug-related adverse events have been reported.

In a full regional nodal 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. The very invasive nature of such an extensive surgical procedure frequently causes significant side effects or morbidity (e.g., bleeding, pain, infection, neuropathy, seromas, and lymphedema). 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 an average of approximately 1.5 lymph nodes per patient. With this small difference, Lymphoseek exhibited superior performance in detecting lymph nodes containing cancer, as evidenced by its lower FDR, noted above. The average number of lymph nodes detected by Lymphoseek is still far below the number of lymph nodes removed in a full nodal dissection procedure, thus potentially sparing the patient the morbidity and side effects associated with more complete regional nodal dissection procedures. In addition, in over twelve months of post-surgical follow-up to date of the patients involved in the NEO3-05 study, no morbidity issues with Lymphoseek have been reported to date.

A copy of the complete text of the Company's June 6, 2011, press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Analyst Meeting to Discuss NEO3-09 Results

On June 7, 2011, the Company issued a press release announcing that, following the presentation of full the data set from the NEO3-09 clinical trial of Lymphoseek at the ASCO meeting, two of the principal investigators in the trial participated with representatives of the Company in an event for analysts and institutional investors. Dr. Anne Wallace of the Moores Cancer Center, University of California San Diego, and Dr. Vernon Sondak of the H. Lee Moffitt Cancer Center presented their experience in the trials to the select group of analysts and institutional investors. Copies of the slides presented by Dr. Wallace, Dr. Sondak and the Company at the event, along with audio recordings of their presentations, are available to investors and interested parties at the Company's website at www.neoprobe.com/ASCO2011.asp.

The NEO3-09 study, presented as a clinical poster and discussed Monday at the ASCO meeting, reaffirmed superior Lymphoseek® (99mTc-tilmanocept) performance compared to vital blue dye in ILM procedures. The Company remains confident that the NEO3-09 study design, execution, regulatory input, statistical analyses and clinical study results for Lymphoseek are consistent with FDA and expert guidance and responsibilities to patient care. In particular, the Company's approach has been built on the scientific method, with rigorous testing utilizing well-controlled clinical trials, the appropriate, on-label comparator, pre-specified endpoints, prospective statistical analysis plans, and consistent dialogue with regulatory authorities, to demonstrate the safe and effective performance of Lymphoseek.

A copy of the complete text of the Company's June 7, 2011, press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Response to Citizen's Petition

On June 8, 2011, the Company issued a press release acknowledging that a Citizen's Petition had been filed with the U.S. Food & Drug Administration (FDA) by a holder of a short interest in the Company's common stock. This press

release stated the Company's position that the premise of the Citizen’s Petition is flawed and that the Company continues to believe in the clinical and scientific validity of its trials, including the use of vital blue dye as the appropriate comparator for registration purposes based on discussions with the United States Food and Drug Administration. The Company also announced through this press release that it would assess options with its public relations, regulatory and legal advisors to address the unfounded information presented in the Citizen's Petition. A copy of the complete text of the Company’s June 8, 2011, press release is attached as Exhibit 99.3 to this Current Report on Form 8-K and is incorporated herein by reference.

Presentation NEO3-05 Study Results at Society for Nuclear Medicine Meeting

On June 9, 2011, the Company issued a press release announcing that full results from the NEO3-05 study, demonstrating Lymphoseek® (99mTc-tilmanocept) met all primary and secondary endpoints in intraoperative lymphatic mapping (ILM) procedures were presented at the Society for Nuclear Medicine Annual Meeting in San Antonio. A copy of the complete text of the Company’s June 9, 2011, press release is attached as Exhibit 99.4 to this Current Report on Form 8-K and is incorporated herein by reference.

The Private Securities Litigation Reform Act of 1995 (the Act) provides a safe harbor for forward-looking statements made by or on behalf of the Company. 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 within the meaning of the Act. 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, Quarterly Reports on Form 10-Q, and other SEC 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 June 6, 2011, entitled "Investigators Report Full Phase 3 Lymphoseek (Tilmanocept) Study Results at ASCO."
99.2	Neoprobe Corporation press release dated June 7, 2011, entitled "ASCO Presentations Reinforce Lymphoseek Clinical Development Approach and Regulatory Pathway."
99.3	Neoprobe Corporation press release dated June 8, 2011, entitled "Neoprobe Disputes Premise of Citizen's Petition."
99.4	Neoprobe Corporation press release dated June 9, 2011, entitled "Phase 3 Lymphoseek {Tilmanocept) Study Results Featured at Society of Nuclear Medicine Annual Meeting."

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: June 9, 2011	By:	/s/ Brent L. Larson Brent L. Larson, Senior Vice President and Chief Financial Officer