NEOPROBE CORP
Form 8-K
August 10, 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) August 10, 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 August 10, 2011, Neoprobe Corporation (the "Company") issued a press release announcing that it has submitted a New Drug Application (NDA) for Lymphoseek® (tilmanocept) to the U.S. Food and Drug Administration (FDA). The Company seeks clearance to market Lymphoseek in the United States 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.

The NDA submission for Lymphoseek includes results from two Phase 3 trials of Lymphoseek, NEO3-05 and NEO3-09. The primary endpoint for both the NEO3-05 and NEO3-09 trials was the comparison (the Concordance Rate, or the rate of agreement) of Lymphoseek versus vital blue dye, a long-standing, FDA-approved, on-label agent for lymphatic mapping and appropriate requisite "Truth Standard" comparator for registration purposes.

The Concordance Rate was analyzed on both a per-node and per-patient basis. On a per node basis, a meta-analysis of the results of the two Phase 3 studies (NEO3-05, NEO3-09) yielded a Concordance Rate of 99.99%, a highly statistically significant result ($p<0.0001$). A meta-analysis of the results of the two Phase 3 studies (NEO3-05, NEO3-09) yielded a per-patient Concordance Rate of 99.99%, again a highly statistically significant result ($p<0.0001$). In over 500 subjects receiving Lymphoseek to date, including those studied as a part of the NEO3-05 and NEO3-09 trials, no drug-related serious adverse events or clinically significant drug-related adverse events have been reported.

A copy of the complete text of the Company's August 10, 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 August 10, 2011, entitled "Neoprobe Submits New Drug Application for Lymphoseek." |

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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: August 10, 2011

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