

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
(State or other jurisdiction
of incorporation)

0-26520
(Commission
File Number)

31-1080091
(IRS Employer
Identification No.)

425 Metro Place North, Suite 300, Columbus, Ohio
(Address of principal executive offices)

43017
(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.

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.

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	Neoprobe Corporation press release dated August 10, 2011, entitled “Neoprobe Submits New Drug Application for Lymphoseek.”

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

IMMEDIATE RELEASE

August 10, 2011

NEOPROBE SUBMITS NEW DRUG APPLICATION FOR LYMPHOSEEK***- Investor Conference Call Scheduled for Thursday, August 11th at 8:45AM ET -***

DUBLIN, OH – August 10, 2011 – Neoprobe Corporation (AMEX: NEOP), a diversified developer of innovative oncology surgical and diagnostic products, today announced it has submitted a New Drug Application (NDA) for Lymphoseek® (tilmanocept) to the U.S. Food and Drug Administration (FDA). Neoprobe 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. In the U.S. today, ILM is performed primarily for patients with breast cancer and melanoma. According to the American Cancer Society, approximately 209,000 new cases of breast cancer and 68,000 new cases of melanoma were diagnosed in the United States in 2010.¹

“The Lymphoseek NDA marks a significant clinical and regulatory milestone for our novel, receptor-targeted radiopharmaceutical agent, Lymphoseek, that has undergone extensive clinical evaluation over many years by nearly thirty investigators in over five hundred patients,” said Dr. Frederick O. Cope, Neoprobe Senior Vice President, Pharmaceutical Research and Clinical Development, of Neoprobe.

“We look forward to continuing to work closely with the FDA to shepherd the Lymphoseek NDA through its review process and to approval,” said Rodger A. Brown, Neoprobe Vice President, Regulatory Affairs and Quality Assurance.

About the Lymphoseek NDA Submission

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.

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"This NDA submission is an important step toward improving the lives of patients who undergo lymphatic mapping procedures for potential diagnosis of the spread of solid tumor cancers," said Dr. Mark J. Pykett, Neoprobe President and CEO. "We look forward to an efficient review process with the FDA and moving this important agent to commercialization. We remain confident – as we have throughout the entire clinical evaluation and regulatory process – that the two Phase 3 trials supporting drug registration were designed appropriately, that they met all of their primary and secondary endpoints, and that Lymphoseek is safe, all of which support the pathway for Lymphoseek to achieve regulatory approval and commercial success in the near future."

* * * * *

Dr. Pykett will discuss the NDA submission during a conference call with the investing public scheduled for Thursday, August 11, 2011 at 8:45 AM ET. Joining Dr. Pykett on the call will be Brent L. Larson, Neoprobe Senior Vice President and Chief Financial Officer. The call can be accessed as follows:

Conference Call Information

TO PARTICIPATE LIVE:

Date: August 11, 2011
Time: 8:45 AM ET

Toll-free (U.S.) Dial in # : (877) 407-8033
International Dial in # : (201) 689-8033

TO LISTEN TO A REPLAY:

Available until: August 25, 2011
Toll-free (U.S.) Dial in # : (877) 660-6853
International Dial in # : (201) 612-7415

Replay passcode:
Account #: 286
Conference ID #: 377322

About Lymphoseek

Lymphoseek is a proprietary radioactive diagnostic tracing agent being developed for use in connection with gamma detection devices in a surgical procedure known as Intraoperative Lymphatic Mapping. Two Phase 3 multi-center clinical trials (www.clinicaltrials.gov, trial registration numbers NCT00671918 and NCT01106040) for Lymphoseek in patients with breast cancer or melanoma have concluded. A third Phase 3 clinical study to evaluate the efficacy of Lymphoseek as a sentinel lymph node tracing agent in patients with head and neck squamous cell carcinoma is currently ongoing (www.clinicaltrials.gov, trial registration number NCT00911326).

About Neoprobe

Neoprobe is a biomedical company focused on enhancing oncology patient care and improving patient benefit through radiopharmaceutical product development. Neoprobe is actively developing two radiopharmaceutical agent platforms – Lymphoseek® and RIGScan™ CR – to help surgeons better identify and treat certain types of cancer. Neoprobe's subsidiary, Cira Biosciences, Inc., is also advancing a patient-specific cellular therapy technology platform called ACT. Neoprobe's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and advancing the Company's pipeline program through continued investment and selective acquisitions. For more information, please visit www.neoprobe.com.

Contacts:

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Public Relations/Media Relations – Mark Marmur, Makovsky & Co. -- (609) 354-8135

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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 in this news release, 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 and other Securities and Exchange Commission filings. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

¹ American Cancer Society: Cancer Facts and Figures 2010. Accessed on 2/4/11:
<http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-026238.pdf>
