# 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 cha	arter)
Delaware	0-26520	31-1080091
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
425 Metro Place Nort	43017	
(Address of prin	(Zip Code)	
Registrant's telephone number, including a code	area (614) 793-7500	
(F	Former name or former address, if changed since la	st report.)
Check the appropriate box below if the Fother following provisions (see General Inst	orm 8-K filing is intended to simultaneously satisfy ruction A.2. below):	the filing obligation of the registrant under any of
☐ Written communications pursuant to R	ule 425 under the Securities Act (17 CFR 230.425)	
☐ Soliciting material pursuant to Rule 14	a-12 under the Exchange Act (17 CFR 240.14a-12)	
☐ Pre-commencement communications p	ursuant to Rule 14d-2(b) under the Exchange Act (	17 CFR 240.14d-2(b))
☐ Pre-commencement communications p	ursuant 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, onlabel 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

<u>Number</u> <u>Exhibit Description</u>

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

#### IMMEDIATE RELEASE

#### NEOPROBE RECEIVES FDA ACCEPTANCE OF LYMPHOSEEK® (TILMANOCEPT) NEW DRUG APPLICATION

- Accepted NDA Includes Data from Pivotal Phase 3 Trials -

- Company to Discuss NDA Acceptance During 3rd Quarter Earnings Call Scheduled for October 27th -

DUBLIN, OH – October 19, 2011 – Neoprobe Corporation (NYSE Amex: NEOP), a diversified developer of innovative oncology surgical and diagnostic products, today announced that its New Drug Application (NDA) for Lymphoseek® (tilmanocept) has been accepted for review by the U.S. Food and Drug Administration (FDA). Neoprobe submitted the Lymphoseek NDA on August 10, 2011.

Neoprobe 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 anatomic delineation of lymphatic tissue.

"The acceptance of the Lymphoseek NDA filing marks a critical milestone for the clinical and regulatory development of this agent. Lymphoseek has undergone study in two prospective, well-controlled and designed Phase 3 clinical trials under the direction of nearly 30 investigators in more than 500 patients," said Rodger A. Brown, Vice President, Regulatory Affairs and Quality Assurance, of Neoprobe. "We look forward to working in collaboration with the FDA to prepare for its pending review of the NDA."

#### About the Lymphoseek NDA Submission

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.

### NEOPROBE CORPORATION ADD - 2

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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 lymphnodes. 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.

"FDA acceptance of the Lymphoseek NDA filing is another positive step for Neoprobe and this agent that holds promise in improving the lives of patients who undergo lymphatic mapping procedures for diagnosis of the spread of solid tumor cancers," said Dr. Mark Pykett, Neoprobe President and CEO. "The filing acceptance reinforces our position that the NEO3-05 and NEO3-09 trials were designed appropriately and conducted with scientific vigor. We now turn our focus toward preparing for next steps with the Agency and a potential approval of Lymphoseek in the coming months, which according to FDA guidelines we anticipate will be late in the second quarter to third quarter of 2012."

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Neoprobe management will provide an NDA acceptance review in connection with the Company's regular conference call to discuss earnings for the third quarter of 2011 which is scheduled for 8:30AM on Thursday, October 27, 2011. Further details regarding the conference call will be included in a subsequent release.

#### **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 (<a href="www.clinicaltrials.gov">www.clinicaltrials.gov</a>, 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 (<a href="www.clinicaltrials.gov">www.clinicaltrials.gov</a>, trial registration number NCT00911326).

#### **About Neoprobe**

Neoprobe Corporation (NYSE Amex: NEOP) 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<sup>TM</sup> CR – to help surgeons better identify and treat certain types of cancer. Neoprobe's subsidiary, Cira Biosciences, Inc., is also exploring development of 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 <a href="https://www.neoprobe.com">www.neoprobe.com</a>.

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.

#### **Contacts:**

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Investor Relations - Michael Rice, LifeSci Advisors -- (646) 597 - 6979

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

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