

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)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>0-26520</u> (Commission File Number)	<u>31-1080091</u> (IRS Employer Identification No.)
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<u>425 Metro Place North, Suite 300, Columbus, Ohio</u> (Address of principal executive offices)	<u>43017</u> (Zip Code)
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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](http://www.neoprobe.com/ASCO2011.asp).

The NEO3-09 study, presented as a clinical poster and discussed Monday at the ASCO meeting, reaffirmed superior Lymphoseek® (<sup>99m</sup>Tc-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® (<sup>99m</sup>Tc-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.

<i>Exhibit Number</i>	<i>Exhibit Description</i>
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

IMMEDIATE RELEASE

June 6, 2011



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## INVESTIGATORS REPORT FULL PHASE 3 LYMPHOSEEK (TILMANOCEPT) STUDY RESULTS AT ASCO

### *Results Reaffirm Earlier NEO3-09 Positive Top-Line Results Showing Superiority to Vital Blue Dye*

Chicago, IL – June 6, 2011 – Independent investigators reported today full results from the NEO3-09 study, reaffirming earlier top-line results that showed Lymphoseek® (<sup>99m</sup>Tc-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 today 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.

“NEO3-09 is intended to be the final Phase 3 study for initial U.S. registration of the lymphatic tissue tracing agent originally developed at UC San Diego Moores Cancer Center, where we went from bench to bedside to use this agent in helping diagnose breast cancer patients in clinical trials,” said Dr. Wallace. “Lymphoseek compared very favorably to the standard of care, vital blue dye, was well tolerated without side effects, and as noted by prior studies, continued to show superior performance characteristics. As a surgeon who has worked with Lymphoseek for years, I find it easy to localize the sentinel node and appreciate its ease of use.”

### **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.

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**NEOPROBE CORPORATION**  
**ADD - 2**

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.

“Both on a per-node and per-patient basis, the NEO3-09 data presented here at ASCO continue to reinforce the findings of previous clinical studies that suggest Lymphoseek provides significantly higher specificity and sensitivity, and a significantly lower failed detection rate, than vital blue dye,” said Dr. Vernon Sondak of the H. Lee Moffitt Cancer Center in Tampa, Florida. “With the diagnostic and safety limitations of vital blue dye, these results should be a welcome sign for clinicians searching for potential innovative technologies to help in the diagnostic process for breast cancer or melanoma patients.”

**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.

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**NEOPROBE CORPORATION**  
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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.

“The results presented today reinforce prior clinical evidence indicating that Lymphoseek provides an improved modality for surgical oncologists to identify and diagnose potentially cancerous lymph nodes in breast cancer and melanoma versus the only currently approved agent, vital blue dye,” said Dr. Fred Cope, Neoprobe’s Senior Vice President, Pharmaceutical Research and Clinical Development. “Interestingly, these data also showed the potential ability for Lymphoseek to provide additional benefit to some patients by identifying cancerous lymph nodes that were missed by vital blue dye, which results in more accurate disease staging and ultimately patient treatment.”

**Contacts:**

*Neoprobe Corporation — Brent Larson, Sr. VP & CFO – (614) 822-2330*

*Investor Relations – Michael Rice, LifeSci Advisors — (201) 408-4923*

*Public Relations/Media Relations – Mark Marmur, Makovsky & Co. — (212) 508-9670*

**About Lymphoseek (Tilmanocept)**

Lymphoseek (tilmanocept) 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](http://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](http://www.clinicaltrials.gov), trial registration number NCT00911326).

**About Neoprobe**

Neoprobe Corporation (NYSE AMEX: NEOP) is a biomedical company focused on enhancing patient care and improving patient outcome by meeting the critical intraoperative diagnostic information needs of physicians and therapeutic treatment needs of patients. Neoprobe recently announced the sale of its neoprobe® GDS line of gamma detection systems to Devicor Medical Products, Inc. The move was made to allow the Company to focus its efforts on the development of and radiopharmaceutical and related agents such as Lymphoseek® and RIGScan™. 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 maximizing its strong position in gamma detection technologies and diversifying into new, synergistic biomedical markets through continued investment and selective acquisitions. [www.neoprobe.com](http://www.neoprobe.com)

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**NEOPROBE CORPORATION**

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IMMEDIATE RELEASE

June 7, 2011



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**ASCO PRESENTATIONS REINFORCE LYMPHOSEEK CLINICAL  
DEVELOPMENT APPROACH AND REGULATORY PATHWAY**

**- Company Remains Confident in Regulatory Pathway for Lymphoseek -**

DUBLIN, OHIO – June 7, 2011 — Neoprobe Corporation (NYSE Amex: NEOP), a diversified developer of innovative oncology surgical and diagnostic products, today announced that, following the presentation of full the data set from the NEO3-09 clinical trial of Lymphoseek at the American Society of Clinical Oncology (ASCO) Meeting yesterday in Chicago, two of the principal investigators in the trial participated with Company representatives in an event for analysts and institutional investors last evening following the poster session. 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](http://www.neoprobe.com/ASCO2011.asp).

The NEO3-09 study, presented as a clinical poster and discussed Monday at the ASCO Meeting, reaffirmed superior Lymphoseek® (<sup>99m</sup>Tc-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.

“The design of both Phase 3 clinical trials, NEO3-05 and NEO3-09, have met the safety and efficacy expectations as discussed with FDA. Neoprobe has conducted the trials in accordance with the parameters discussed and reviewed with FDA. Direct comparison of Lymphoseek to vital blue dye – the only FDA-approved product for ILM procedures – is the appropriate comparator regulatory pathway to demonstrate the comparative clinical value of tilmanocept,” said George Mills, MD, former Director, Division of Medical Imaging and Radiopharmaceutical Drug Products at FDA and a Neoprobe consultant.

“We are confident the NDA package that will be filed with FDA will meet the standards of products that have an existing approved indication of use, said Fred Cope, Ph.D, Neoprobe's Senior Vice President, Pharmaceutical Research and Clinical Development.”

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**NEOPROBE CORPORATION**  
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**Contacts:**

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**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](http://www.neoprobe.com).

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IMMEDIATE RELEASE

June 8, 2011



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**NEOPROBE DISPUTES PREMISE OF CITIZENS PETITION****- Company Confirms Confidence in Regulatory Pathway for Lymphoseek -**

DUBLIN, OHIO – June 8, 2011 — Neoprobe Corporation acknowledges that a Citizen’s Petition has been filed with the U.S. Food & Drug Administration (FDA) by a holder of a short interest in the Company’s stock. We strongly believe the premise of the Citizen’s Petition is flawed and we continue to believe in the clinical and scientific validity of our trials including the use of vital blue dye as the appropriate comparator for registration purposes based on discussions with the FDA. We remain confident that Lymphoseek is approvable based on the regulatory pathway we have laid and continue to move forward with our plans to file an NDA in the third quarter. Neoprobe Corporation is continuing to assess options with our public relations, regulatory and legal advisors to address the unfounded information presented in the petition.

**Contacts:**

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**NEOPROBE CORPORATION**  
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IMMEDIATE RELEASE

June 09, 2011



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**PHASE 3 LYMPHOSEEK (TILMANOCEPT) STUDY RESULTS  
FEATURED AT SOCIETY OF NUCLEAR MEDICINE ANNUAL  
MEETING**

***- Primary, Secondary Endpoints Met, for Lymph Node Mapping -***

Dublin, OH – June 9, 2011 – Neoprobe Corporation (NYSE Amex: NEOP), a diversified developer of innovative oncology surgical and diagnostic products, today announced that full results from the NEO3-05 study, demonstrating Lymphoseek® (<sup>99m</sup>Tc-tilmanocept) met all primary and secondary endpoints in intraoperative lymphatic mapping (ILM) procedures. These results were featured yesterday at the Society for Nuclear Medicine (SNM) Annual Meeting in San Antonio. Recognition of these results by SNM follows closely the presentation and discussion at the American Society of Clinical Oncology (ASCO) Meeting in Chicago on June 6.

The primary endpoint of the NEO3-05 study was the comparison (the Concordance Rate, or the rate of agreement) of Lymphoseek versus vital blue dye (VBD). As is typical of regulatory comparator-based trials, which routinely compare a novel agent to an on-label agent approved in the indication being studied, Lymphoseek was tested against the only on-label agent approved in the U.S. for lymphatic mapping, vital blue dye. The FDA approved agents are used as the appropriate comparator for registration studies because they are supported by evidence from adequate and well controlled clinical trials to establish and demonstrate their expected performance. VBD meets this standard; no other compound currently does. Accordingly, and in consultation with the FDA, the Lymphoseek registration studies were designed to compare Lymphoseek performance to the required, on-label, approved agent, vital blue dye, in order to position Lymphoseek for FDA approval.

“The NEO3-05 data presented here at SNM reinforce findings of other clinical studies that suggest Lymphoseek provides significantly higher specificity and sensitivity, and a lower failed detection rate, than vital blue dye,” said Dr. Vernon Sondak of the H. Lee Moffitt Cancer Center in Tampa, Florida.

Following the presentation of the Lymphoseek study data at the Society of Nuclear Medicine meeting, Dr. Robert Carretta, past president of the SNM and former Vice President, Medical Affairs at Mallinckrodt Medical, the imaging pharmaceuticals division of Covidien, commented, “Having dealt with the FDA approval process for radiopharmaceuticals in a number of roles, including physician, clinical trial investigator, professional society leader and head of a commercial imaging agent development organization, I am well aware of FDA requirements for pivotal comparative studies. It is clear that only products specifically approved for the indication under investigation may be included as the appropriate comparator for purposes of registration with the FDA.”

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Also following the presentation, George Mills, M.D., former Director, Division of Medical Imaging and Radiopharmaceutical Drug Products at FDA and a Neoprobe consultant, also commented, “The design of both of Neoprobe’s Phase 3 clinical trials for Lymphoseek, NEO3-05 and NEO3-09, have met the safety and efficacy expectations as planned with FDA. Neoprobe has conducted the trials in accordance with the parameters discussed and agreed with FDA. Direct comparison of Lymphoseek to vital blue dye – the only FDA-approved product for ILM procedures – is the appropriate comparator to demonstrate the clinical value of Lymphoseek.”

**NEO3-05 Primary Endpoint Met**

The primary endpoint of the NEO3-05 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 NEO3-05, study subjects yielded a total of 215 lymph nodes stained with vital blue dye. Of these blue-stained nodes, Lymphoseek detected 210, for a Concordance Rate of 97.67%, which was a highly statistically significant finding ( $p < 0.0001$ ).

On a per-patient basis, the NEO3-05 study yielded a total of 136 patients with lymph nodes stained with vital blue dye. Of these patients, Lymphoseek detected the same blue-stained nodes in all 131 patients, for a Concordance Rate of 96.32%, a highly statistically significant finding ( $p < 0.0001$ ).

“The results presented yesterday reinforce prior clinical evidence indicating that Lymphoseek is an encouraging modality for surgical oncologists to intraoperatively identify and diagnose potentially cancerous lymph nodes in neoplastic disease versus the only currently approved agent, vital blue dye,” said Dr. Fred Cope, Neoprobe’s Senior Vice President, Pharmaceutical Research and Clinical Development.

**About Lymphoseek (Tilmanocept)**

Lymphoseek (tilmanocept) 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](http://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](http://www.clinicaltrials.gov), trial registration number NCT00911326).

**About Neoprobe**

Neoprobe Corporation (NYSE AMEX: NEOP) is a biomedical company focused on enhancing patient care and improving patient outcome by meeting the critical intraoperative diagnostic information needs of physicians and therapeutic treatment needs of patients. Neoprobe recently announced the sale of its neoprobe® GDS line of gamma detection systems to Devicor Medical Products, Inc. The move was made to allow the Company to focus its efforts on the development of and radiopharmaceutical and related agents such as Lymphoseek® and RIGScan™. 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 maximizing its strong position in gamma detection technologies and diversifying into new, synergistic biomedical markets through continued investment and selective acquisitions.  
[www.neoprobe.com](http://www.neoprobe.com)

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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.*

**Contacts**

*Neoprobe Corporation  
Brent Larson, 614-822-2330  
Sr. VP & CFO*

*or*

*Investor Relations  
LifeSci Advisors*

*Michael Rice, 201-408-4923*

*or*

*Public Relations/Media Relations  
Makovsky & Co.  
Mark Marmor, 212-508-9670*

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