

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 16, 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 | <u>(614) 793-7500</u> | |

(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))
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Item 8.01. Other Events.

Neoprobe Corporation (the "Company") announced on June 16, 2011, that it had filed with the United States Food and Drug Administration a response (the "Response") to the Citizen Petition (the "Petition"), filed on June 7, 2011 by MSMB Capital Management LLC, a purported hedge fund with an acknowledged short position in the Company's common stock. The Petition was submitted in anticipation of the Company's pending New Drug Application (NDA) for its lead radiopharmaceutical product, Lymphoseek®. The Response points out that the Petition is replete with factual and regulatory misstatements, demonstrates that the three central premises of the Petition are factually incorrect or misleading, and shows that the Petition mischaracterizes and misstates the regulatory requirements for approval of Lymphoseek as well as generally accepted medical practice in the diagnosis and treatment of breast cancer and melanoma.

On June 16, 2011 the Company also issued a press release announcing the filing of the Response.

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.

| <u>Exhibit Number</u> | <u>Exhibit Description</u> |
|---------------------------|---|
| 99.1 | Response to MSMB Capital Management Citizen Petition, Docket No. FDA-2011-P-0450. |
| 99.2 | Neoprobe Corporation press release dated June 16, 2011, entitled "Neoprobe Files Response to Citizen Petition-- Response Addresses Key Flaws in Arguments Raised in Petition; Company Defends Shareholder and Patient Interests." |

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 16, 2011

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

June 16, 2011

Paul D. Rubin
202-457-5646
prubin@pattonboggs.comDivision of Dockets Management
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852**Re: Response to MSMB Capital Management Citizen Petition, Docket No. FDA-2011-P-0450**

Dear Sir or Madam:

On behalf of our client, Neoprobe Corporation (“Neoprobe”), we submit these comments in response to a Citizen Petition recently filed by a hedge fund manager who acknowledged being a short-seller who could potentially benefit financially from a decline in Neoprobe’s stock price.¹ In connection with the filing of the Citizen Petition, the short-seller disseminated multiple press releases and articles repeating many of the unfounded allegations and erroneous misrepresentations contained in the Citizen Petition. Regardless of whether the Citizen Petition is ultimately found to be a “sham” by any regulatory agency,² we are submitting these comments in order to correct the record.

As explained below, the Citizen Petition is baseless and replete with factual and regulatory misstatements, served under a cloak of legitimacy. The petitioner selectively cites Neoprobe press releases, SEC filings and literature references, yet omits information from public filings, disclosures, and statements made by the company, as well as other relevant references from the literature, which are unfavorable to the Petition. FDA regulations, however, require the disclosure of information, known to the petitioner, even if unfavorable to the Petition.³

¹ The FDA and SEC, in 2004, announced specific steps both agencies would take in order to coordinate activities in support of FDA and SEC objectives. Use of the Citizen Petition process as a tactic by a short-seller to achieve financial objectives would presumably implicate FDA/SEC cooperative efforts.

² FDA previously acknowledged the abuse of the Citizen Petition process via filing of “sham” petitions. *See* 64 Fed. Reg. 66822, 66822-23 (Nov. 30, 1999) (“Questions have also arisen whether a citizen petition can be used for improper purposes, such as delaying competition (see, e.g., Noah, L., Sham Petitioning as a Threat to the Integrity of the Regulatory Process, 74 N. Carolina L. Rev. 1 (1995) (also noting that the Federal Trade Commission, in 1993, had concerns that petitions were being submitted to FDA for anticompetitive reasons) or delaying agency action.”).

³ 21 C.F.R. § 10.30(b).

In addition, the Petition requests that FDA refrain from approving, and take the unprecedented step of denying the opportunity for review of, an NDA not filed yet with the agency – asking FDA to prejudge an application regardless of its scientific merit or potential public health impact. However, as FDA stated as recently as this month, the Citizen Petition process was not intended to vitiate an NDA applicant's procedural rights by requiring FDA to respond to a Citizen Petition and “make decisions on complex scientific issues specific to pending applications”⁴

While the Petition's factual inaccuracies, mischaracterizations, and misstatements are numerous, three allegations, in particular, serve as the crux of the petitioner's baseless request.

First, the Citizen Petition is premised upon the mischaracterization of Neoprobe's intended label indication for Lymphoseek as “sentinel lymph node mapping.” This fundamentally mischaracterizes Neoprobe's regulatory focus for the soon to be filed NDA, developed after multiple discussions with FDA during the IND process, for the approval of Lymphoseek. Indeed, as Neoprobe has repeatedly noted in SEC filings and other public disclosures, Neoprobe's regulatory-appropriate clinical trials were designed to achieve an indication for “anatomical delineation of lymphatic tissue,” not “sentinel lymph node mapping.” Anatomic delineation of lymphatic tissue is used in regulatory settings to describe the general identification of lymphatic tissue without regard to specific position or location. In contrast, sentinel lymph node mapping is used for precise identification of the first predictive lymph node(s) in the regional basin of neoplasms. The distinction is critical to understanding the study design, and exemplifies the types of flaws evident throughout the Petition.

Second, the Citizen Petition repeatedly asserts that Neoprobe's studies should be entirely discounted because vital blue dye was used as the “truth standard” or comparator in the design of the studies, rather than using vital blue dye plus sulfur colloid as the comparator. This assertion reveals the petitioner's fundamental mischaracterization of the facts, and the legal and regulatory framework for the design of studies required for drug approval. FDA has not reviewed prospective, adequate, well-controlled studies for sulfur colloid for anatomic delineation of lymphatic tissue, and sulfur colloid is not approved by FDA for this indication. Thus, the only appropriate comparator in the instant case is vital blue dye, which received FDA approval for the indication sought by Lymphoseek.

⁴ Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, to Teva Neuroscience, Inc. (June 8, 2011) (responding to December, 2010 Citizen Petition (Docket No. FDA-2010-P-0642)). FDA also referenced the extensive procedural protections applicable to NDA applicants, and the circumscribed procedures governing FDA review of such applications.

Finally, the petitioner asserts that a “truth standard” should be required for the assessment of all radiopharmaceutical diagnostics, and claims that the appropriate “truth standard” in the instant case should be axillary nodal dissection. Not surprisingly, however, the petitioner fails to cite any FDA regulations that support this conclusion. Instead, rather than evaluating current medical literature, the petitioner cites an outdated 1994 article as support for his assertion. Petitioner conveniently ignores the substantial scientific advancement during the past seventeen years, demonstrating that axillary nodal dissection in the instant case would, in fact, have subjected patients to numerous, unnecessary risks, representing safety and ethical considerations in the conduct of such a study. Paradoxically, the petitioner also asserts that “[s]entinel lymph node mapping, dissection and diagnosis is the standard of care for patients with breast and melanoma cancer” – citing two references from 2011 in support of this statement. This statement completely contradicts the assertion that axillary nodal dissection should be used as the comparator, or “truth standard,” in the instant case. This fundamental internal inconsistency further exemplifies the flaws inherent throughout the Petition.

Accordingly, for the reasons stated above, we respectfully request that FDA deny the Citizen Petition expeditiously.

Sincerely,

/s/ Paul D. Rubin, Esq.

Paul D. Rubin, Esq.

IMMEDIATE RELEASE

June 16, 2011

NEOPROBE FILES RESPONSE TO CITIZEN PETITION***Response Addresses Key Flaws in Arguments Raised in Petition; Company Defends Shareholder and Patient Interests***

DUBLIN, OH – June 16, 2011 – Neoprobe Corporation (NYSE Amex: NEOP), a diversified developer of innovative oncology surgical and diagnostic products, today announced that a formal response has been filed to a Citizen Petition submitted to the Food and Drug Administration on June 7, 2011 regarding the Company's pending New Drug Application (NDA) for its lead radiopharmaceutical product, Lymphoseek®. The response was filed by Patton Boggs, Neoprobe Corporation's counsel for regulatory matters, and addresses the core arguments of the petition filed with FDA by a third party which contains inaccurate and misleading statements about the science underlying Lymphoseek and FDA-regulated clinical trials.

Neoprobe's management and Board of Directors take seriously any action aimed at harming our shareholders or delaying the availability to patients of a potentially helpful diagnostic agent. We believe that we are appropriately addressing the current set of unwarranted or misleading statements and/ or filings made by parties whose motives and actions stand contrary to the interests of our shareholders and the patients and physicians we serve.

We remain confident in our approach to filing of the Lymphoseek NDA and that we are well positioned to effectively respond should there be additional statements or filings of a similar nature.

Below is the full text of Neoprobe's Citizen Petition Response filed this morning with FDA:

"On behalf of our client, Neoprobe Corporation ("Neoprobe"), we submit these comments in response to a Citizen Petition recently filed by a hedge fund manager who acknowledged being a short-seller who could potentially benefit financially from a decline in Neoprobe's stock price. In connection with the filing of the Citizen Petition, the short-seller disseminated multiple press releases and articles repeating many of the unfounded allegations and erroneous misrepresentations contained in the Citizen Petition. Regardless of whether the Citizen Petition is ultimately found to be a "sham" by any regulatory agency, we are submitting these comments in order to correct the record.

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In addition, the Petition requests that FDA refrain from approving, and take the unprecedented step of denying the opportunity for review of, an NDA not filed yet with the agency – asking FDA to prejudge an application regardless of its scientific merit or potential public health impact. However, as FDA stated as recently as this month, the Citizen Petition process was not intended to vitiate an NDA applicant's procedural rights by requiring FDA to respond to a Citizen Petition and "make decisions on complex scientific issues specific to pending applications"

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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

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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.

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.
