

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

**Date of Report: October 9, 2009 (October 8, 2009)**  
(Date of earliest event reported)

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**THRESHOLD PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-32979**  
(Commission File Number)

**94-3409596**  
(IRS Employer  
Identification No.)

**1300 Seaport Boulevard, Suite 500  
Redwood City, California 94063**  
(Address of principal executive offices) (Zip Code)

**(650) 474-8200**  
(Registrant's telephone number, including area code)

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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**

On October 8, 2009, Threshold Pharmaceuticals, Inc. ("Threshold") issued a press release announcing clinical trial results related to Threshold's clinical stage hypoxia-activated prodrug, TH-302. The results were presented at the Perspectives in Melanoma XIII Conference taking place in Baltimore, Maryland from October 8 to 10, 2009. A copy of Threshold's press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits****(d) Exhibits**

99.1 Press Release dated October 8, 2009





## PRESS RELEASE

Contact:  
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### **THRESHOLD PHARMACEUTICALS PRESENTS INTERIM DATA FROM A PHASE 1/2 CLINICAL TRIAL OF TH-302 AT MELANOMA CONFERENCE**

*Data from a Subset of Patients With Metastatic Melanoma Presented in a Poster Session*

REDWOOD CITY, CA – October 8, 2009 – Threshold Pharmaceuticals, Inc. (Nasdaq: THLD) today announced clinical trial results related to Threshold's clinical stage hypoxia-activated prodrug, TH-302. The results were presented at the Perspectives in Melanoma XIII Conference taking place in Baltimore, Maryland from October 8 to 10, 2009.

As previously reported at ASCO in May 2009, the Phase 1/2 clinical trial evaluating the safety and preliminary efficacy of TH-302 in patients with advanced solid tumors, has completed the dose escalation component, reached the maximum tolerated dose (MTD) and is currently enrolling patients in the expansion phase of the trial at the MTD. The dose escalation component of the clinical trial is treating patients with various solid tumors, while the expansion component of the trial is enrolling only patients with metastatic melanoma, non-small cell lung cancer and small cell lung cancer. In the dose escalation and expansion components of the clinical trial, there are a total of 78 patients who have enrolled. Today's presentation focused entirely on the first nine patients with relapsed or refractory metastatic melanoma. The results of the trial were discussed today by Dr. Robert Weber from the Northern California Melanoma Center in San Francisco, California.

In today's presentation, eight of the nine patients with metastatic melanoma were assessed for response. Six of 8 (75%) evaluable melanoma patients had stable disease or better, including 3 (38%) patients with a partial response (one confirmed, one un-confirmed who discontinued treatment after their first tumor assessment due to seizures related to brain metastases, one on study yet to receive a second tumor assessment) as measured by RECIST (Response Evaluation Criteria In Solid Tumors). Four of the 8 patients continue to receive TH-302 after receiving TH-302 for 2.6 to 6.2 months. Additional patients are being enrolled to better define the extent of the tumor response activity.

"Historically, the response rates in metastatic melanoma have been only ten to fifteen percent at best," said Robert Weber, M.D., Associate Director, Northern California Melanoma Center, and a clinical investigator for the trial. "While we continue to explore the safety and efficacy of TH-302 in a larger group of patients, I am hopeful that this may provide another treatment option for patients with metastatic melanoma."

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www.thresholdpharm.com



TH-302 continues to be tolerated and there have been no new unexpected adverse events. Fatigue was the most commonly reported adverse event and was reported in 5 (55%) patients. Severe (grade 3/4/5) adverse events were reported in 4 (44%) patients and there was one study drug related severe adverse event of grade 3 vaginal mucositis. Two serious adverse events (ascites and seizures from brain metastases) were reported but neither was considered related to TH-302. Hematologic toxicity was not dose-limiting. Skin toxicity is common with 8 of the 9 patients having at least one skin adverse event of grade 1 or 2. Approximately half of the patients have had a mucosal adverse event of grade 1 with the exception of the one patient with grade 3 vaginal mucositis.

#### **About The Clinical Trial**

The trial is a Phase 1/2 clinical trial evaluating the safety and efficacy of TH-302 in patients with advanced solid tumors. The trial, which was initiated in 2007, was designed with an initial accelerated titration design followed by a standard dose escalation schema. TH-302 is administered as a 30 to 60 minute intravenous infusion weekly for three weeks followed by one week off therapy. Patients who have received one or more regimens of chemotherapy, or for whom no effective therapy is available, are eligible for the trial. Patients are not receiving any additional chemotherapy while receiving TH-302. Tumor response is being measured at the end of cycles 2, 4 and 6. The primary objectives of the trial are to determine the MTD and dose-limiting toxicities of TH-302 in patients with advanced solid tumors and to make an assessment of the efficacy of TH-302 as measured by response rate, duration of response and progression-free survival in patients with advanced/metastatic melanoma, small cell lung cancer and non-small cell lung cancer. The secondary objectives of the trial include establishing the pharmacokinetics and assessing the anti-tumor activity of TH-302, as measured by objective response rate and duration of response in patients with solid tumors.

A copy of the poster may be obtained by calling the Company.

The Company has two additional ongoing clinical trials of TH-302. The Company is in the process of completing a Phase 1/2 clinical trial of TH-302 in combination with various chemotherapies in patients with advanced solid tumors. The Company is also continuing a Phase 1/2 clinical trial of TH-302 in combination with doxorubicin in patients with advanced soft tissue sarcoma.

#### **About Threshold Pharmaceuticals**

Threshold is a biotechnology company focused on the discovery and development of drugs targeting Tumor Hypoxia, the low oxygen condition found in microenvironments of most solid tumors. This approach offers broad potential to treat most solid tumors. By selectively targeting tumor cells, we are building a pipeline of drugs that hold promise to be more effective and less toxic to healthy tissues than conventional anticancer drugs. For additional information, please visit the website ([www.thresholdpharm.com](http://www.thresholdpharm.com)).

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### **Forward-Looking Statements**

Except for statements of historical fact, the statements in this press release are forward-looking statements, including statements regarding TH-302's uses and potential benefits and clinical trial results and plans. These statements involve risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, Threshold's ability to enroll and complete its current and anticipated clinical trials, the time and expense required to conduct such clinical trials and analyze data, the possibility that results from these trials will not be confirmed, potential adverse side effects, issues arising in the regulatory or manufacturing process and the results of such clinical trials (including product safety issues and efficacy results). Further information regarding these and other risks is included under the heading "Risk Factors" in Threshold's Quarterly Report on Form 10-Q, which was filed with the Securities Exchange Commission on August 6, 2009 and is available from the SEC's website ([www.sec.gov](http://www.sec.gov)) and on our website ([www.thresholdpharm.com](http://www.thresholdpharm.com)) under the heading "Investors." Threshold does not intend to update any forward-looking statement made in this news release.

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