

**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 (Date of earliest event reported): July 1, 2010 (June 30, 2010)**

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**THRESHOLD PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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

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**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)

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:

- ☐ 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 June 30, 2010, the Company issued a press release announcing that it has initiated a multi-center, randomized, controlled, crossover Phase 2 clinical trial of TH-302 in combination with gemcitabine in patients with first line pancreatic cancer. The press release is attached as Exhibit 99.1 to this Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

Exhibit 99.1	Press release dated June 30, 2010.
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**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 thereunto duly authorized.

**THRESHOLD PHARMACEUTICALS, INC.**

By:                     /s/ JOEL A. FERNANDES                      
**Joel A. Fernandes**  
**Senior Director, Finance and Controller**

Date: July 1, 2010

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**Exhibit Index**

<u>Exhibit No.</u>	<u>Description</u>
Exhibit 99.1	Press release dated June 30, 2010.



## PRESS RELEASE

### Contact:

Denise T. Powell  
 Sr. Director, Corporate Communications  
 Threshold Pharmaceuticals, Inc.  
 dpowell@thresholdpharm.com

### THRESHOLD PHARMACEUTICALS INITIATES A RANDOMIZED, CONTROLLED, PHASE 2 CLINICAL TRIAL EVALUATING TH-302 IN PATIENTS WITH ADVANCED PANCREATIC CANCER

**REDWOOD CITY, CA – June 30, 2010** — Threshold Pharmaceuticals, Inc. (Nasdaq: THLD), today announced that it has initiated a multi-center, randomized, controlled, crossover Phase 2 clinical trial of TH-302 in combination with gemcitabine in patients with first line pancreatic cancer. TH-302 is a proprietary tumor selective Hypoxia-Activated Prodrug (HAP) that specifically targets tumor hypoxia.

“TH-302 has been investigated in Phase 1/2 clinical trials in over 300 patients including 50 patients with pancreatic cancer. This new randomized clinical trial is designed to confirm the impressive results that were observed and recently reported in patients with pancreatic cancer,” said Dr. Mitesh Borad, Associate Director at the Mayo Clinic in Arizona and a clinical investigator for this and previous trials of TH-302. “Given the promising results observed to date in the Phase 1/2 trials with TH-302, I am looking forward to continuing our participation as TH-302 enters this next phase of clinical development.”

### Clinical Trial Design

Approximately 165 patients with previously untreated, locally advanced, unresectable or metastatic pancreatic adenocarcinoma are planned to enroll in the clinical trial at various sites in the United States and Canada. The primary endpoint of the trial is progression free survival. The secondary endpoints are overall response rate, overall survival, event-free survival, CA 19-9 response rate as well as various safety parameters. Tumor response will be evaluated at baseline and every six weeks using the Response Evaluation Criteria In Solid Tumors (RECIST). Patients for whom monotherapy with gemcitabine is considered standard therapy are eligible for the trial. Patients will be randomized equally into one of three cohorts: TH-302 at a dose of 240 mg/m<sup>2</sup> plus gemcitabine or TH-302 at a dose of 340 mg/m<sup>2</sup> plus gemcitabine or gemcitabine alone. Patients who successfully complete treatment of six cycles without evidence of significant treatment-related toxicity or progressive disease may continue to receive treatment. If a patient's cancer progresses while on gemcitabine alone, the patient may crossover into one of the TH-302 plus gemcitabine cohorts. Interim safety and efficacy analyses will occur approximately every 25 events, and a final analysis will be performed at a minimum of 122 events. If patient enrollment goes as planned, interim and primary endpoint results will be available quarterly during 2011.

### Clinical Rationale

In cancer, as a tumor grows, it rapidly outgrows its blood supply, leaving portions of the tumor with regions where the oxygen concentration is significantly lower than in healthy tissues. This condition is called tumor hypoxia. Several studies have shown that higher levels of tumor hypoxia correlate with poor treatment outcomes for a variety of solid tumors. This lack of oxygen in cancer cells compared to normal cells is exploited by TH-302, the Company's first Hypoxia-Activated Prodrug (HAP). TH-302 has the potential to treat slowly dividing tumor cells within hypoxic regions that generally evade traditional chemotherapeutic agents and ultimately contribute to relapse. The Phase 1/2 clinical trial results were discussed recently at ASCO and may be found on the Company's website.

1300 Seaport Boulevard, Suite 500, Redwood City, CA 94063 tel: 650.474.8200 fax: 650.474.2529 www.thresholdpharm.com



#### **About Pancreatic Cancer**

Pancreatic cancer is the fourth leading cause of cancer-related death in the United States. The National Cancer Institute estimates that in 2009 there were more than 42,000 new cases of pancreatic cancer and 35,000 deaths from the disease. Because diagnosis and intervention occur late in the course of this disease, the vast majority of patients already have metastatic disease at the time of diagnosis.

#### **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 our website ([www.thresholdpharm.com](http://www.thresholdpharm.com)).

#### **Forward-Looking Statements**

Except for statements of historical fact, the statements in this press release are forward-looking statements, including statements regarding TH-302 and its potential therapeutic uses and benefits. 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 patients in the Phase 2 trial of TH-302 in patients with advanced pancreatic cancer in a timely manner, whether this trial or any others that Threshold undertakes will confirm the results of earlier trials based on smaller numbers of patients, the time and expense required to conduct such clinical trials and analyze data, issues arising in the regulatory or manufacturing process and any unanticipated or increased side-effects observed in patients receiving TH-302. 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 May 6, 2010 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." We do not intend to update any forward-looking statement made in this news release.

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