

**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 29, 2010 (June 29, 2010)**

---

**THRESHOLD PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**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)

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))

---

**Item 8.01 Other Events.**

On June 29, 2010, the Company issued a press release announcing that it has initiated a Phase 1 clinical trial of TH-302 in patients with advanced leukemias. 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 29, 2010.

---

**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: June 29, 2010

---

**Exhibit Index**

| <u>Exhibit<br/>No.</u> | <u>Description</u>                 |
|------------------------|------------------------------------|
| Exhibit 99.1           | Press release dated June 29, 2010. |



## PRESS RELEASE

Contact:

Denise T. Powell  
Sr. Director, Corporate Communications  
Threshold Pharmaceuticals, Inc.  
650-474-8206  
dpowell@thresholdpharm.com

### THRESHOLD PHARMACEUTICALS INITIATES A CLINICAL TRIAL EVALUATING TH-302 IN PATIENTS WITH ADVANCED LEUKEMIAS

REDWOOD CITY, CA – June 29, 2010 — Threshold Pharmaceuticals, Inc. (Nasdaq: THLD), today announced that it has initiated a Phase 1 clinical trial of TH-302 in patients with advanced leukemias. TH-302 is a proprietary Hypoxia-Activated Prodrug (HAP) that specifically targets tumor hypoxia.

“There is an enduring unmet need for effective new treatments for patients with refractory hematological malignancies,” said Dr. Deborah Thomas, M.D., Associate Professor in the Department of Leukemia at MD Anderson Cancer Center. “There is a strong preclinical rationale to evaluate TH-302 in this patient population and we are excited to be leading this innovative clinical trial.”

#### Clinical Trial Design

Approximately 40 patients with advanced leukemias or other severe hematologic disorders affecting the marrow are planned to enroll in the clinical trial at the MD Anderson Cancer Center. Patients with relapsed/refractory chronic lymphocytic leukemia (CLL), acute lymphoblastic leukemia (ALL), acute myelogenous leukemia (AML), advanced phase chronic myelogenous leukemia (CML), high risk myelodysplastic syndrome (MDS) or advanced myelofibrosis (MF) will be eligible for the trial.

The initial dose escalation phase of the trial will enroll cohorts of up to 6 patients per dose. The starting dose will be 120mg/m<sup>2</sup> and will be administered as a 30 minute intravenous infusion daily for 5 days every 21 days. Sequential cohorts will be treated with TH-302 at 40% increments in dose until the maximum tolerated dose (MTD) is established. The primary objective of the dose escalation component of the study is to establish the MTD and dose limiting toxicities of TH-302 when administered daily for 5 days. The dose escalation phase of the trial will enroll up to 30 patients. Once the MTD has been established, up to 10 additional patients will be enrolled at the MTD in the dose expansion component of the trial. The objective of the dose expansion is to further assess the clinical activity of TH-302 in this population.

“Based on the growing body of work regarding hypoxia within the diseased marrow, we are excited to be launching this Phase 1 trial for the treatment of advanced leukemias,” said John Curd, M.D., Threshold’s President and Chief Medical Officer. “Targeting hypoxia within diseased marrow represents a novel approach to treating hematologic malignancies and it is our hope that we can provide a new approach to the treatment of diseased marrow in hematologic malignancies and provide a significant benefit to those affected by leukemia, multiple myeloma and lymphoma.”

#### Clinical Rationale

TH-302 is selectively activated in the hypoxic microenvironment of tumors. Preclinical data support the hypothesis that TH-302 targets hypoxic regions of solid tumors. Recent preclinical data from the Vrije Universiteit in Brussels and Threshold Pharmaceuticals has shown diseased marrow to be significantly more hypoxic than non-diseased marrow and that TH-302 has activity in multiple myeloma cells in vivo and in vitro. Additionally, recent data from MD Anderson demonstrated the marked expansion of the hypoxic bone marrow areas in diseased mice with ALL. These preclinical results suggest that an agent that selectively targets the hypoxic regions of tumors may be useful in treating advanced leukemias. Patients for whom no curative therapy exists are eligible for this trial.

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



#### **About Advanced Leukemia**

Advanced leukemia is an acute or chronic cancer involving the blood-forming tissues in the bone marrow. It may be classified as myeloid or lymphoid. According to the American Cancer Society, leukemia accounts for 3% of all cancers diagnosed in the United States in 2009, and about 22,000 people die annually of some form of leukemia. Chronic lymphocytic leukemia is the most common leukemia in the United States, accounting for a third of cases diagnosed each year. Acute myelogenous leukemia accounts for 28% of diagnosed adult leukemias.

#### **About TH-302**

Threshold has evaluated TH-302 in over 300 patients with various solid tumors. Currently the Company has three ongoing clinical trials including a Phase 1/2 study evaluating TH-302 in combination with doxorubicin in soft tissue sarcoma, a Phase 1/2 trial of TH-302 in combination with various chemotherapeutic agents in advanced pancreatic cancer, castrate-resistant prostate cancer and non-small cell lung cancer, and a Phase 1 trial of TH-302 as monotherapy. Additionally, the Company has recently opened a Phase 2 controlled trial of TH-302 in combination with gemcitabine in patients with advanced pancreatic cancer.

#### **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 commence its anticipated clinical trials, whether the Company's clinical trials will show results predicted by the Company's pre-clinical trials or confirm the results of earlier trials, 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.

###

1300 Seaport Boulevard, Suite 500, Redwood City, CA 94063 tel: 650.474.8200 fax: 650.474.2529 [www.thresholdpharm.com](http://www.thresholdpharm.com)