
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

August 10, 2005

Date of Report

(Date of earliest event reported)

THRESHOLD PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

000-51136
(Commission File Number)

94-3409596
(I.R.S. Employer
Identification No.)

1300 Seaport Boulevard
Redwood City, California 94063
(Address of principal executive offices) (Zip code)

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

(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:

- 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 2.02. Results of Operations and Financial Condition

The information in this Current Report (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Current Report (including Exhibit 99.1) shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

On August 10, 2005, Threshold Pharmaceuticals, Inc. issued a press release regarding its financial results for the quarter ended June 30, 2005. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Threshold Pharmaceuticals, Inc. dated August 10, 2005 regarding its financial results for the quarter ended June 30, 2005, furnished in accordance with Item 2.02 of this Current Report on Form 8-K

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.

Date: August 10, 2005

Threshold Pharmaceuticals, Inc.

By: /s/ Janet I. Swearson

Janet I. Swearson
Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Threshold Pharmaceuticals, Inc. dated August 10, 2005 regarding its financial results for the quarter ended June 30, 2005

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Threshold Pharmaceuticals Announces Second Quarter 2005 Results

Company confirms the start of Phase 2 and Phase 3 studies for patients with benign prostatic hyperplasia, initiating a global registration program.

Redwood City, CA – August 10, 2005

Threshold Pharmaceuticals, Inc. (Nasdaq: THLD) today announced its 2005 second quarter earnings. The net loss for the quarter was \$10.2 million compared to \$6.3 million for the same period last year. The increase in the net loss primarily reflects the advancement of TH-070 (lonidamine) into two clinical studies for the treatment of benign prostatic hyperplasia (BPH), the first of which is a Phase 2 study in the US and the second of which is a Phase 3 study in Europe. Also included in the increase in the net loss are expenses related to the glufosfamide Phase 3 study in patients with refractory pancreatic cancer.

“During the quarter we achieved several significant milestones,” said Barry Selick, Threshold’s chief executive officer. “After publishing the results of our Italian Phase 2 BPH clinical trial, we initiated our US registrational program of TH-070 with the start of a Phase 2 placebo-controlled, multicenter trial in the US. And earlier this week, we announced the start of a Phase 3 study for BPH in Europe. When these two studies are completed, we will have treated more than 500 BPH patients with this promising drug candidate,” concluded Dr. Selick.

“BPH is a serious medical condition that impacts millions of men worldwide. TH-070 may offer the potential to not only improve the symptoms of BPH that lead to a decreased quality of life but also to directly address the underlying disease progression that can lead to serious medical problems,” said Alan Colowick, Threshold’s chief medical officer. “We are also making significant progress in our oncology discovery and clinical development programs,” added Dr. Colowick.

At June 30, 2005, Threshold had \$54.5 million in cash and marketable securities.

Operating Expense Analysis:

- Research and development expenses totaled \$7.9 million for the second quarter of 2005 versus \$4.1 million for the same quarter of the prior year. This increase was primarily due to additional clinical trial and development expenses for the product candidates TH-070 and glufosfamide and, to a lesser extent, for activities associated with the company's discovery research activities. Additionally, there were expenses associated with increased staffing and non-cash stock compensation.
- General and administrative expenses were \$2.7 million for the second quarter of 2005 versus \$2.2 million for the same quarter of the prior year. This increase was primarily due to increased staffing and headcount-related expenses, and non-cash stock compensation expenses.
- Non-cash stock compensation expenses were \$1.7 million for the second quarter of 2005 versus \$1.4 million for the same quarter of the prior year.

Second Quarter 2005 Product Candidate Highlights

Threshold's clinical programs are focused on cancer and benign prostatic hyperplasia, a disease characterized by an overgrowth of the prostate. BPH results in a variety of lower urinary tract symptoms such as frequent and sometimes difficult urination. Symptomatic BPH affects more than 54 million men worldwide and up to 18 million men in the US alone. With the initiation of the US Phase 2 and European Phase 3 studies, Threshold has met its objective of initiating two BPH studies by mid-2005. Both studies will investigate the effects of TH-070 on clinically important efficacy endpoints, including, but not limited to, the impact on symptoms as measured by IPSS, the International Prostate Symptom Score. IPSS is a questionnaire completed by patients that enables medical practitioners to gauge the severity of the patient's condition. It includes an assessment of, among other things, the frequency and difficulty of urination and the bothersome symptom of sleep interruption due to the need to urinate frequently.

Threshold's cancer program has three clinical trials ongoing: a Phase 3 pivotal study of glufosfamide for the treatment of patients with second-line pancreatic cancer, a Phase 1/2 study of glufosfamide in combination with gemcitabine for the first-line treatment of patients with advanced pancreatic cancer and other solid tumors, and a Phase 1 study with 2-Deoxyglucose (2DG) alone and in combination with Taxotere for the treatment of various solid tumors. During the second quarter the company, in conjunction with its collaborators, presented data at ASCO from 12 patients from the 2DG Phase 1 study in solid tumors. These data demonstrated that 2DG appears to be safe and well tolerated. All studies continue to enroll patients.

The company anticipates the following clinical milestones in its development programs:

- data available for the glufosfamide Phase 1 study in combination with gemcitabine in Q4 2005

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- additional data available from the 2DG Phase 1 study in solid tumors in Q4 2005
 - complete enrollment of the Phase 3 glufosfamide study in second-line pancreatic cancer patients in Q1 2006
 - data available for the Phase 3 glufosfamide study in second-line pancreatic cancer in Q4 2006
 - data available for the US Phase 2 TH-070 study in patients with BPH in Q4 2006
 - data available for the European Phase 3 TH-070 study in patients with BPH in Q4 2006

2005 Financial Guidance

The company continues to expect fiscal year 2005 cash requirements to be in the range of \$32 to \$38 million, (potentially offset by proceeds from licensing or development agreements, if any). The company continues to expect the net loss for 2005, including non-cash compensation expenses, to be in the range of \$36 to \$44 million.

For more information on Threshold Pharmaceuticals, please refer to the Threshold website at <http://www.thresholdpharm.com>.

Forward-Looking Statements

Except for statements of historical fact, the statements in this press release are forward-looking statements. Such forward-looking statements include statements regarding Threshold's cash balances, anticipated earnings/losses, product candidates, anticipated clinical trials, clinical trial plans and potential therapeutic benefits of our product candidates. 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 initiate, enroll and complete its anticipated clinical trials, the time and expense required to conduct such clinical trials, the results of such clinical trials (including unanticipated product safety issues), and Threshold's ability to enter into licensing or development agreements with third parties. 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 13, 2005 and is available from the SEC's website (www.sec.gov) and on our website (www.thresholdpharm.com) under the heading "Investors". We undertake no duty to update any forward-looking statement made in this news release.

About Threshold Pharmaceuticals

Threshold is a biotechnology company focused on the discovery, development and commercialization of small molecule therapeutics based on Metabolic Targeting, an approach that offers broad potential to treat most solid tumors and certain other diseases. By selectively targeting tumor cells, the company is building a pipeline of drug

candidates that hold promise to be more effective and less toxic to healthy tissues than conventional drugs. Threshold's initial clinical focus is the treatment of cancer and benign prostatic hyperplasia, or BPH, a disease afflicting tens of millions of men worldwide. For additional information, please visit <http://www.thresholdpharm.com>

THRESHOLD PHARMACEUTICALS, INC.
(A Development Stage Enterprise)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Operating expenses				
Research & development	\$ 7,872	\$ 4,133	\$ 13,123	\$ 6,130
General and administrative	2,741	2,225	5,306	3,097
Total Operating Expenses	10,613	6,358	18,429	9,227
Loss from operations	(10,613)	(6,358)	(18,429)	(9,227)
Interest income	436	101	720	193
Interest expense	(9)	(5)	(17)	(21)
Net Loss	\$(10,186)	\$(6,262)	\$(17,726)	\$(9,055)
Net loss per basic and diluted loss per common share	\$ (0.36)	\$ (5.83)	\$ (0.79)	\$ (7.20)
Weighted-average shares used in computing basic and diluted loss per common share	28,679	1,075	22,559	1,258

THRESHOLD PHARMACEUTICALS, INC.
(A Development Stage Enterprise)
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	June 30, 2005	December 31, 2004
	<u>(unaudited)</u>	<u>(1)</u>
Assets		
Cash, cash equivalents and marketable securities	\$ 54,531	\$ 28,665
Prepaid expenses and other current assets	1,324	1,689
Property and equipment, net	1,878	1,667
Other assets	218	192
Total assets	<u>\$ 57,951</u>	<u>\$ 32,213</u>
Liabilities and stockholders' equity (deficit)		
Total current liabilities	10,817	8,387
Long term liabilities	351	460
Redeemable convertible preferred stock (2)	—	49,839
Stockholders' equity (deficit)	46,783	(26,473)
Total liabilities and stockholders' equity (deficit)	<u>\$ 57,951</u>	<u>\$ 32,213</u>

(1) Derived from audited financial statements

(2) Converted into common stock upon the Company's Initial Public Offering in February, 2005