
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

November 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))
-

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 November 10, 2005, Threshold Pharmaceuticals, Inc. issued a press release regarding its financial results for the quarter ended September 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 November 10, 2005 regarding its financial results for the quarter ended September 30, 2005

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: November 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 November 10, 2005 regarding its financial results for the quarter ended September 30, 2005

Contact Information:

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

Threshold Pharmaceuticals Reports Third Quarter 2005 Financial Results**Redwood City, CA – November 10, 2005**

Threshold Pharmaceuticals, Inc. (Nasdaq: THLD), today reported financial results for the quarter and nine months ended September 30, 2005.

For the third quarter of 2005, Threshold reported a net loss of \$11.5 million compared to a net loss of \$6.6 million for the third quarter of 2004. The increase in the net loss primarily reflects the costs of the Company's U.S. phase 2 and European phase 3 multi-center clinical studies of TH-070 for the treatment of benign prostatic hyperplasia (BPH). During the quarter, the Company recognized revenue of \$0.3 million related to an upfront payment pursuant to a pre-existing development agreement.

"During the third quarter, Threshold continued to execute on its objectives," said Barry Selick, Threshold's chief executive officer. "We initiated a phase 3 multi-center trial in Europe to treat men with BPH and we finalized a clinical development plan with MediBIC, our development partner for glufosfamide in Asia. In addition, in October we completed a follow-on public offering and received net proceeds of \$62.5 million," added Dr. Selick.

For the nine months ended September 30, 2005, Threshold reported a net loss of \$29.3 million compared to a net loss of \$15.7 million for the same period last year. This \$13.6 million increase in the net loss primarily reflects the costs of the Company's U.S. phase 2 and European phase 3 multi-center clinical studies of TH-070 for the treatment of BPH, its ongoing phase 3 study of glufosfamide for the second-line treatment of patients with pancreatic cancer and its phase 1/2 study of glufosfamide in combination with gemcitabine for the first-line treatment of pancreatic cancer.

At September 30, 2005, Threshold had \$46.1 million in cash and marketable securities, a decrease of \$8.4 million for the third quarter. Cash and marketable securities at September 30, 2005 does not include \$62.5 million of net proceeds from the public offering the Company completed in October.

Third Quarter Operating Expense Analysis:

- Research and development expenses totaled \$9.1 million for the third quarter of 2005 versus \$4.7 million for the same quarter of the prior year. This increase was primarily due to additional clinical trial and development expenses for the TH-070 phase 2 and phase 3 clinical trials and, to

a lesser extent, for activities associated with the Company's discovery research activities. Additionally, there were higher expenses associated with increased staffing in the third quarter of 2005.

- General and administrative expenses were \$3.2 million for the third quarter of 2005 versus \$2.0 million for the same quarter of the prior year. This increase was primarily due to increased expenses associated with increased staffing, legal fees related to patent application filings and accounting fees.
- Non-cash stock compensation expenses were \$2.3 million for the third quarter of 2005 versus \$2.1 million for the same quarter of the prior year.

Third Quarter 2005 Highlights

Threshold's BPH clinical program is primarily focused on the execution of the U.S. phase 2 study and the European phase 3 study of TH-070. The Company expects to enroll 200 men with symptomatic BPH in the phase 2 study in approximately 35 centers across the U.S. The primary objective of this study is to evaluate the dose response relationship of TH-070 versus placebo in patients with symptomatic BPH.

In the European phase 3 study, the Company expects to enroll 480 patients across approximately 65 centers in various European countries. The primary objective of the phase 3 study is to evaluate the safety and efficacy of TH-070 versus placebo as measured by the International Prostate Symptom Score (IPSS).

The Company continued to enroll patients in its phase 3 study of glufosfamide for the second-line treatment of pancreatic cancer and its phase 1/2 study of glufosfamide in combination with gemcitabine for the first-line treatment of pancreatic cancer.

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

- results from the glufosfamide phase 1 study in combination with gemcitabine for the treatment of first-line pancreatic cancer by year end 2005;
- results from the phase 3 glufosfamide study for the second-line treatment of pancreatic cancer by year end 2006;
- results from the U.S. phase 2 TH-070 study in patients with BPH by year end 2006;
- results from the European phase 3 TH-070 study in patients with BPH by year end 2006.

In 2004, the Company entered into an agreement with MediBIC Co., Ltd. to develop glufosfamide in Japan and several other Asian countries and received an upfront payment of \$5.0 million contingent upon the finalization of the clinical development plan. In July, the Company finalized the clinical development plan with MediBIC and, consequently, has begun recognizing revenue from that upfront payment. Going forward, revenue will be recognized on a straight line basis over the period of performance, which is expected to be through 2008.

2005 Financial Guidance

The Company continues to expect fiscal year 2005 cash requirements to be in the range of \$32 to \$38 million. The Company continues to expect the net loss for 2005, including non-cash stock compensation expenses, to be in the range of \$36 to \$44 million.

The Company expects to provide financial guidance for 2006 when it reports fourth quarter and year end financial results in February 2006. At that time, the Company will host a conference call to summarize the accomplishments during 2005 and outline its corporate objectives for 2006.

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 August 12, 2005 and Threshold's most recent prospectus related to the follow-on public offering which was filed with the Securities Exchange Commission on October 12, 2005, and are 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 and abnormally proliferating 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 our website (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 September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Revenue	\$ 331	\$ —	\$ 331	\$ —
Operating expenses				
Research and development (1)	9,110	4,722	22,233	10,852
General and administrative (1)	3,215	2,040	8,520	5,137
Total Operating Expenses	12,325	6,762	30,753	15,989
Loss from operations	(11,994)	(6,762)	(30,422)	(15,989)
Interest and other income	476	120	1,195	313
Interest expense	(8)	(6)	(25)	(27)
Net Loss	\$(11,526)	\$(6,648)	\$(29,252)	\$(15,703)
Net loss per basic and diluted loss per common share	\$ (0.40)	\$ (4.80)	\$ (1.18)	\$ (26.57)
Weighted-average shares used in computing basic and diluted loss per common share	28,961	1,385	24,721	591

(1) Includes non-cash stock-based compensation of:

Research and development	\$ 1,363	\$ 1,116	\$ 2,921	\$ 1,931
General and administrative	923	1,013	2,675	1,887
Total	\$ 2,286	\$ 2,129	\$ 5,596	\$ 3,818

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

	September 30, 2005	December 31, 2004
	(unaudited)	(1)
Assets		
Cash, cash equivalents and marketable securities	\$ 46,089	\$ 28,665
Prepaid expenses and other current assets	1,417	1,689
Property and equipment, net	1,773	1,667
Other assets	217	192
	\$ 49,496	\$ 32,213
Liabilities and stockholders' equity (deficit)		
Total current liabilities	\$ 7,619	\$ 8,387
Long-term liabilities (2)	3,557	460
Redeemable convertible preferred stock (3)	—	49,839
Stockholders' equity (deficit)	38,320	(26,473)
	\$ 49,496	\$ 32,213

-
- (1) Derived from audited financial statements
(2) Includes \$3.2 million of deferred revenue related to the MediBIC development agreement.
(3) Converted into common stock upon the Company's initial public offering in February 2005