

THRESHOLD PHARMACEUTICALS INC

FORM 8-K (Current report filing)

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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): November 7, 2016

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.)

170 Harbor Way, Suite 300
South San Francisco, California 94080
(Address of principal executive offices, including 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 2.02. Results of Operations and Financial Condition

On November 7, 2016, Threshold Pharmaceuticals, Inc. issued a press release regarding its financial results for the third quarter ended September 30, 2016. A copy of the press release is furnished as Exhibit 99.1 to this Current Report and is incorporated herein by reference. The press release contains statements intended as “forward-looking statements” which are subject to the cautionary statements about forward-looking statements set forth therein.

The information furnished pursuant to this Item 2.02 (including Exhibit 99.1 hereto) shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, or the Securities Act. The information contained herein and in the accompanying exhibit shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits

Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release of Threshold Pharmaceuticals, Inc. dated November 7, 2016 regarding its financial results for the third quarter ended September 30, 2016.

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.

Threshold Pharmaceuticals, Inc.

By: /s/ JOEL A. FERNANDES

Name: JOEL A. FERNANDES

Title: Vice President, Finance and Controller

Date: November 7, 2016

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release of Threshold Pharmaceuticals, Inc. dated November 7, 2016, regarding its financial results for the third quarter ended September 30, 2016.



NEWS RELEASE

Threshold Pharmaceuticals Reports Third Quarter Financial Results

-- Planning to initiate a clinical trial of evofosfamide in combination with checkpoint inhibitors --

SOUTH SAN FRANCISCO, Calif., – November 7, 2016 – Threshold Pharmaceuticals, Inc. (Nasdaq:THLD), a clinical-stage biopharmaceutical company developing novel therapies for cancer, today reported financial results for the third quarter ended September 30, 2016 and provided an update on the Company's corporate and clinical development activities.

"We plan to initiate a clinical trial evaluating evofosfamide in combination with checkpoint inhibitors with our collaborators at MD Anderson Cancer Center while at the same time continue to pursue registration of evofosfamide in Japan for the treatment of pancreatic cancer. In addition, we continue to pursue potential collaborations to expand our development pipeline while we complete IND-enabling toxicology studies with TH-3424 with the goal of reaching the clinic with a new compound in 2017", said Barry Selick, Ph.D., Chief Executive Officer of Threshold.

Recent Highlights

Evofosfamide – The Company's lead product candidate is an investigational hypoxia-activated prodrug that is designed to be activated under tumor hypoxic conditions, a hallmark of many cancers.

- First meeting scheduled with the Japanese PMDA (Pharmaceutical and Medical Devices Agency) to present the improvement in overall survival that was observed in the Japanese sub-population of the MAESTRO Phase 3 trial;
- The Company announced a partnership with Caris Life Sciences to develop a customized assay for pancreatic cancer patients to predict likelihood of response to evofosfamide;
- Clinical development collaborations investigating evofosfamide in patients with pancreatic neuroendocrine tumors (pNET), recurrent glioblastoma (GBM) and hepatocellular carcinoma (HCC) remain ongoing;
- A recent presentation by one of the Company's collaborators from the MD Anderson Cancer Center highlighted the promise of evofosfamide in combination with a class of checkpoint inhibitor antibodies to improve the efficacy of this class of potent anti-cancer therapies; and
- The Company plans to initiate a clinical trial in various solid tumors evaluating evofosfamide in combination with one or more checkpoint inhibitor antibodies in development.

Tarloxotinib – The Company had been prosecuting Phase 2 proof of concept studies with tarloxotinib, a hypoxia-activated epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI), which was designed to selectively release an irreversible EGFR-TKI in hypoxic tumors.

- During the quarter, the Company announced interim results from two proof-of-concept, Phase 2 clinical trials in patients with advanced non-small cell lung cancer (NSCLC) and patients with metastatic squamous cell carcinoma of the head and neck and skin. While results in patients with squamous cell carcinoma of the skin were minimally sufficient for continuation, the response rate in the NSCLC trial and the head and neck arms of the squamous cell cancer trial did not meet the minimum response rate hurdles for study continuation. Accordingly, enrollment in both Phase 2 clinical trials and further development of tarloxotinib has been discontinued.
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NEWS RELEASE

TH-3424 – TH-3424 is the Company's small-molecule drug candidate being evaluated for the treatment of hepatocellular (liver) cancer (HCC), castrate resistant prostate cancer (CRPC), T-cell acute lymphoblastic leukemias (T-ALL), and other cancers expressing high levels of aldo-keto reductase family 1 member C3 (AKR1C3). Tumors overexpressing AKR1C3 can be resistant to radiation therapy, chemotherapy and anti-androgen therapy. TH-3424 is a prodrug that selectively releases a potent DNA cross-linking agent in the presence of AKR1C3.

- TH-3424 has been selected as a lead candidate and Investigational New Drug (IND)-enabling studies have been initiated in collaboration with Ascenta Pharmaceuticals, Ltd.

Third Quarter 2016 Financial Results

- Cash, cash equivalents and marketable securities totaled \$28.1 million at September 30, 2016 compared to \$33.6 million at June 30, 2016; the net decrease of \$5.5 million was a result of operating cash requirements for the quarter ended September 30, 2016. With the previously announced decision to cease joint development of evofosfamide under the Company's former collaboration with Merck KGaA, the decision in September to discontinue further development of tarloxotinib, and the workforce reduction, the Company continues to expect its operating cash requirements to be lower for the fourth quarter of fiscal year 2016 and fiscal year 2017.
 - No revenue was recognized in the third quarter ended September 30, 2016 compared to \$3.7 million for the same period of 2015. Revenue for the quarter ended September 30, 2015 related to the amortization of the aggregate of \$110 million in upfront and milestone payments received from the Company's former collaboration with Merck KGaA, Darmstadt, Germany. The revenue from the upfront payment and milestone payments received under the agreement were previously being amortized over the relevant performance period, rather than being immediately recognized when the upfront payment and milestones were earned or received. As a result of Merck KGaA, Darmstadt, Germany's and the Company's decision to cease further joint development of evofosfamide in December 2015, the Company immediately recognized all of the remaining deferred revenue into revenue during the quarter ending December 31, 2015. Also as a result of the termination of the agreement, the Company is no longer eligible to receive any further milestone payments from Merck KGaA, Darmstadt, Germany.
 - Research and development expenses were \$3.5 million for the third quarter ended September 30, 2016, compared to \$8.1 million for the same period in 2015. The decrease in research and development expenses, net of reimbursement for Merck KGaA, Darmstadt, Germany's 70 percent share of total eligible collaboration expenses for evofosfamide, was due primarily to a \$2.8 million decrease in employee related expenses, including a \$0.4 million decrease in non-cash stock-based compensation expense and a \$1.8 million decrease in clinical development expenses and consulting expenses. The Company expects research and development expenses to continue to decline in 2016 as a result of the decision to cease further joint development of evofosfamide under the Company's former collaboration with Merck KGaA and the workforce reduction.
 - General and administrative expenses were \$1.7 million for the third quarter ended September 30, 2016 compared to \$2.4 million for the same period in 2015. The decrease in general and administrative expenses was due primarily to a \$0.5 million decrease in employee related expenses and a \$0.2 million decrease in consulting expenses.
 - Non-cash stock-based compensation expense included in total operating expenses was \$0.8 million for the third quarter of 2016 compared to \$1.5 million for the same period in 2015. The decrease in stock-based compensation expense was due to the amortization of a smaller number of options with lower fair values.
 - Net loss for the third quarter of 2016 was \$5.7 million compared to \$6.4 million for the same period in 2015. Included in the net loss for the third quarter of 2016 was an operating loss of \$5.2 million and non-cash expense of \$0.5 million compared to an operating loss of \$6.8 million and non-cash income of \$0.3 million for the third quarter of 2015. The non-cash income or expense is related to changes in the fair value of the Company's outstanding and exercised warrants that was classified as other income (expense).
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NEWS RELEASE

About Evofosfamide

Evofosfamide (previously known as TH-302) is an investigational hypoxia-activated prodrug of a bis-alkylating agent that is preferentially activated under severe hypoxic tumor conditions, a feature of many solid tumors. Areas of low oxygen levels (hypoxia) in solid tumors are due to insufficient blood vessel supply. Similarly, the bone marrow of patients with hematological malignancies has also been shown, in some cases, to be severely hypoxic.

About Tarloxotinib Bromide

Tarloxotinib bromide (previously known as TH-4000), or "tarloxotinib", is a prodrug designed to selectively release a covalent (irreversible) EGFR tyrosine kinase inhibitor under severe hypoxia, a feature of many solid tumors. In September 2016, the Company announced the discontinuation of any further development of tarloxotinib.

About TH-3424

TH-3424 is small-molecule drug candidate being evaluated for the potential treatment of hepatocellular (liver) cancer (HCC), castrate resistant prostate cancer (CRPC), T-cell acute lymphoblastic leukemias (T-ALL), and other cancers expressing high levels of aldo-keto reductase family 1 member C3 (AKR1C3). Tumors overexpressing AKR1C3 can be resistant to radiation therapy and chemotherapy. TH-3424 is a prodrug that selectively releases a potent DNA cross-linking agent in the presence of AKR1C3. Preliminary nonclinical toxicology studies suggested an adequate therapeutic index that the Company believes warrants conducting Investigational New Drug (IND)-enabling toxicology studies, which are being done in collaboration with Ascenta Pharmaceuticals, Ltd.

About Threshold Pharmaceuticals

Threshold is a clinical-stage biopharmaceutical company focused on the development of drugs and diagnostic agents targeting the tumor microenvironment of solid tumors and hematologic malignancies. This approach offers broad potential to treat a variety of cancers. 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 Company's website.

Forward-Looking Statements

Except for statements of historical fact, the statements in this press release are forward-looking statements, including all statements regarding the therapeutic potential of evofosfamide and TH-3424; Threshold's plans to focus its resources on evofosfamide and TH-3424; anticipated development activities related to evofosfamide and TH-3424, and the anticipated timing thereof; Threshold's plans to continue to pursue discussions regarding potential registration pathways for evofosfamide in Japan, and the potential for evofosfamide to be approved for marketing in Japan; and Threshold's estimates of the total and non-cash charges it expects to incur in connection with the reduction in employees, and the anticipated timing thereof. 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: the difficulty and uncertainty of pharmaceutical product development, including the risks that the design of, or data collected from, the planned Phase I clinical trial of evofosfamide with immune checkpoint inhibitors may be inadequate to demonstrate safety or sufficient efficacy, or otherwise may be insufficient to support any further development of evofosfamide, and that Threshold's toxicology studies of TH-3424 may not demonstrate sufficient safety to support an investigational new drug application and to further the development of TH-3424 into the clinic; the uncertain and time-consuming regulatory approval process, including the risk that data from the completed MAESTRO clinical trial will not be sufficient to support the approval of evofosfamide for the treatment of patients with pancreatic cancer in Japan; Threshold's need for and the availability of resources to develop evofosfamide and TH-3424 and to support Threshold's operations, including the risks that Threshold's currently-available resources may be insufficient to further current development plans for evofosfamide and TH-3424 and that Threshold will otherwise need to raise substantial additional capital in order to advance the clinical development of evofosfamide and TH-3424; the risks that Threshold could determine to abandon the development of evofosfamide and TH-3424 as a result of inadequate resources, negative or inconclusive clinical trial or toxicology study results, the failure to obtain regulatory approval of evofosfamide in Japan, or otherwise; and risks related to Threshold's ability to implement the reduction in employees as currently anticipated, the impact of such reduction on Threshold's business and unanticipated charges not currently contemplated that may occur as a result of such reduction. Further information regarding these and other risks is included under the heading "Risk Factors" in Threshold's Quarterly Report on Form 10-Q, which has been filed with the Securities and Exchange Commission on November 7, 2016 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.

Source: Threshold Pharmaceuticals, Inc. (THLD)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue	\$ -	\$ 3,680	\$ -	\$ 11,041
Operating expenses				
Research and development	3,521	8,081	13,542	28,902
General and administrative	1,716	2,372	5,857	7,468
Total Operating Expenses	<u>5,237</u>	<u>10,453</u>	<u>19,399</u>	<u>36,370</u>
Loss from operations	(5,237)	(6,773)	(19,399)	(25,329)
Interest income (expense), net	39	27	111	99
Other income (expense) (1)	(498)	315	(1,124)	(661)
Net loss	<u>\$ (5,696)</u>	<u>\$ (6,431)</u>	<u>\$ (20,412)</u>	<u>\$ (25,891)</u>
Net loss per common share				
Basic	<u>\$ (0.08)</u>	<u>\$ (0.09)</u>	<u>\$ (0.29)</u>	<u>\$ (0.37)</u>
Diluted	<u>\$ (0.08)</u>	<u>\$ (0.09)</u>	<u>\$ (0.29)</u>	<u>\$ (0.37)</u>
Weighted-average shares used in per common share calculation:				
Basic	<u>71,536</u>	<u>71,382</u>	<u>71,512</u>	<u>69,833</u>
Diluted	<u>71,536</u>	<u>71,382</u>	<u>71,512</u>	<u>69,833</u>

(1) Noncash income (expense) related to change in the fair value of the Company's outstanding and exercised warrants, classified as other income (expense).



THRESHOLD PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2016 (unaudited)	December 31, 2015 (1)
Assets		
Cash, cash equivalents and marketable securities	\$ 28,110	\$ 48,680
Collaboration Receivable	400	1,891
Prepaid expenses and other current assets	1,022	2,599
Property and equipment, net	159	333
Other assets	-	166
Total assets	\$ 29,691	\$ 53,669
Liabilities and stockholders' equity		
Total current liabilities	\$ 3,719	\$ 10,828
Long-term liabilities (2)	3,051	1,995
Stockholders' equity (deficit)	22,921	40,846
Total liabilities and stockholders' equity (deficit)	\$ 29,691	\$ 53,669

(1) Derived from audited financial statements

(2) Includes as of September 30, 2016 and December 31, 2015, \$3.0 million and \$1.9 million of warrant liability, respectively.