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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D. C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2012

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-32979

Threshold Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**94-3409596**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

170 Harbor Way, Suite 300, South San Francisco, CA 94080
(Address of principal executive offices, including zip code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

On October 31, 2012, there were 56,251,350 shares of common stock, par value $0.001 per share, of Threshold Pharmaceuticals, Inc. outstanding.

Threshold Pharmaceuticals, Inc.

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FORM 10-Q
NINE MONTHS ENDED SEPTEMBER 30, 2012

The terms "Threshold," "we," "us," "the Company" and "our" as used in this report refer to Threshold Pharmaceuticals, Inc. Trademarks, trade names and service marks used in this report are the property of their respective owners.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Threshold Pharmaceuticals, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(unaudited)

	September 30, 2012	December 31, 2011 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,634	$ 5,882
Marketable securities	57,191	14,408
Collaboration receivable	17,457	—
Prepaid expenses and other current assets	1,149	254
Total current assets	84,431	20,544
Property and equipment, net	728	543
Other assets	1,059	1,349
Total assets	$ 86,218	$ 22,436
LIABILITIES AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)		
Current liabilities:		
Accounts payable	$ 739	$ 2,389
Accrued clinical and development expenses	6,445	4,465
Accrued liabilities	1,817	1,737
Deferred revenue, current	7,188	—
Total current liabilities	16,189	8,591
Warrant liability	67,373	9,209
Deferred revenue, non-current	46,467	—
Deferred rent	273	153
Total liabilities	130,302	17,953
Commitments and contingencies (Note 7)		
Stockholders' equity (net capital deficiency):		
Preferred stock, $0.001 par value, 2,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value, shares authorized: 150,000,000 shares; issued and outstanding: 56,216,122 shares at September 30, 2012 and 49,128,475 shares at December 31, 2011	56	49
Additional paid-in capital	307,497	256,563
Accumulated other comprehensive gain (loss)	14	(1)
Accumulated deficit	(351,651)	(252,128)
Total stockholders' equity (net capital deficiency)	(44,084)	4,483
Total liabilities and stockholders' equity (net capital deficiency)	$ 86,218	$ 22,436

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Threshold Pharmaceuticals, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenue	$ 1,797	$ —	$ 3,846	$ —
Operating expenses:				
Research and development	4,039	6,481	12,623	17,646
General and administrative	1,741	1,308	5,229	4,290
Total operating expenses	5,780	7,789	17,852	21,936
Loss from operations	(3,983)	(7,789)	(14,006)	(21,936)
Interest income (expense), net	25	5	55	20
Other income (expense)	2,967	3,659	(85,572)	1,538
Net loss	(991)	(4,125)	(99,523)	(20,378)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	27	(7)	15	(10)
Comprehensive loss	$ (964)	$ (4,132)	$(99,508)	$(20,388)
Net loss per common share:				
Basic	$ (0.02)	$ (0.08)	$ (1.86)	$ (0.45)
Diluted	$ (0.06)	$ (0.08)	$ (1.86)	$ (0.45)
Weighted average number of shares used in per share calculations:				
Basic	55,654	49,052	53,516	44,812
Diluted	64,405	49,052	53,516	44,812

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Threshold Pharmaceuticals, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net loss	$(99,523)	$(20,378)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	668	395
Stock-based compensation expense	2,087	743
Change in common stock warrant value	85,572	(1,538)
(Gain) loss on sale of investments, property and equipment	—	(15)
Changes in operating assets and liabilities:		
Collaboration receivable	(17,457)	—
Prepaid expenses and other assets	(606)	55
Accounts payable	(1,650)	53
Accrued clinical and development expenses	1,980	1,022
Accrued liabilities	80	798
Deferred rent	120	(244)
Deferred revenue	53,654	—
Net cash provided by (used in) operating activities	24,925	(19,109)
Cash flows from investing activities:		
Acquisition of property and equipment	(328)	(317)
Acquisition of marketable securities	(75,413)	(26,406)
Proceeds from sales and maturities of marketable securities	32,122	12,993
Net cash used in investing activities	(43,619)	(13,730)
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net of offering expenses	21,446	30,224
Net cash provided by financing activities	21,446	30,224
Net increase (decrease) in cash and cash equivalents	2,752	(2,615)
Cash and cash equivalents, beginning of period	5,882	8,691
Cash and cash equivalents, end of period	$ 8,634	$ 6,076
Supplemental schedule of non-cash investing and financing activities		
Change in unrealized gain (loss) on marketable securities	$ 15	$ (10)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Threshold Pharmaceuticals, Inc.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company

Threshold Pharmaceuticals, Inc. (the "Company" or "Threshold") is a biotechnology company focused on the discovery and development of drugs targeting the severe hypoxia in the microenvironment of solid tumors and the bone marrows of patients with some hematological malignancies. The Company was incorporated in the State of Delaware on October 17, 2001. In June 2005, the Company formed a wholly-owned subsidiary, THLD Enterprises (UK), Limited in the United Kingdom for purposes of conducting clinical trials in Europe. There is currently no financial activity related to this entity.

On February 2, 2012, the Company entered into a global license and co-development agreement with Merck KGaA, of Darmstadt, Germany, to co-develop and commercialize TH-302, the Company's small molecule hypoxia-targeted drug. Under the terms of the agreement, Merck will receive co-development rights, exclusive global commercialization rights and will provide the Company an option to co-commercialize TH-302 in the United States. Primarily as a result of the agreement with Merck, Threshold is no longer considered a Development Stage Company as of the first quarter of 2012. Threshold operates in one business segment.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments necessary for the fair statement of results for the periods presented, have been included. The results of operations of any interim period are not necessarily indicative of the results of operations for the full year or any other interim period.

The preparation of condensed consolidated financial statements requires management to make estimates and assumptions that affect the recorded amounts reported therein. A change in facts or circumstances surrounding the estimate could result in a change to estimates and impact future operating results.

The unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the interim unaudited condensed consolidated financial statements have read or have access to the audited consolidated financial statements for the preceding fiscal year. The condensed consolidated balance sheet at December 31, 2011 has been derived from the audited financial statements at that date but does not include all the information and footnotes required by accounting principles generally accepted in the United States of America. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2011 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 15, 2012.

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, and reflect the elimination of intercompany accounts and transactions.

Liquidity

The Company has a product candidate in various stages of development as well as other candidates in discovery and, since inception, has devoted substantially all of its time and efforts to performing research and development, raising capital and recruiting personnel. The Company has incurred significant losses since its inception. The Company continues to incur substantial expenses related to research and development and management believes that it will continue to do so for the foreseeable future. On February 2, 2012, the Company entered into an agreement with Merck KGaA, which provided for an upfront payment of $25 million. To date the Company has also earned $42.5 million in milestone payments, including a $10 million milestone payment earned subsequent to the quarter ended September 30, 2012. The $20 million milestone payment related to positive results from the randomized Phase 2 trial in pancreatic cancer was received during the quarter ended June 30, 2012 and the remaining $22.5 million in milestone payments are expected during the fourth quarter of 2012. The Company could also receive an additional $42.5 million in potential milestone payments in the near term. See further details in Note 3, "Collaboration Arrangements".

The Company may raise additional capital or incur indebtedness to fund new in-house development programs or to in-license or otherwise acquire and develop additional products or programs. The Company may seek to raise capital through a variety of sources, including:

- the public equity market;
- private equity financing;
- collaborative arrangements; and/or
- public or private debt.

The Company's ability to raise additional funds will depend on its clinical and regulatory events, its ability to identify promising new in-house development programs or in-licensing opportunities, and factors related to financial, economic, and market conditions, many of which are beyond its control. The Company cannot be certain that sufficient funds will be available when required or on satisfactory terms. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to existing stockholders. There are no assurances that the Company will be able to raise additional financing on terms acceptable to the Company.

Revenue Recognition

The Company recognizes revenue in accordance with ASC 605 "Revenue Recognition", subtopic ASC 605-25 "Revenue with Multiple Element Arrangements" and subtopic ASC 605-28 "Revenue Recognition-Milestone Method", which provides accounting guidance for revenue recognition for arrangements with multiple deliverables and guidance on defining the milestone and determining when the use of the milestone method of revenue recognition for research and development transactions is appropriate, respectively.

The Company's revenues are related to its collaboration arrangement with Merck KGaA, which was entered in February 2012. The collaboration with Merck provides for various types of payments to the Company, including non-refundable upfront license, milestone and royalty payments. The Company recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. The Company will also receive reimbursement for Merck's 70% share for eligible worldwide development expenses for TH-302. Such reimbursement is reflected as a reduction of operating expenses and not as revenue.

For multiple-element arrangements, each deliverable within a multiple deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in the Company's control. The deliverables under the Merck agreement have been determined to be a single unit of accounting and as such the revenue relating to this unit of accounting will be recorded as deferred revenue and recognized ratably over the term of its estimated performance period under the agreement, which is the product development period. The Company determines the estimated performance period and it will be periodically reviewed based on the progress of the related product development plan. The effect of a change made to an estimated performance period and therefore revenue recognized ratably would occur on a prospective basis in the period that the change was made.

Deferred revenue associated with a non-refundable payment received under a collaborative agreement for which the performance obligations are terminated will result in an immediate recognition of any remaining deferred revenue in the period that termination occurred provided that all performance obligations have been satisfied.

The Company recognizes revenue from milestone payments when: (i) the milestone event is substantive and its achievability has substantive uncertainty at the inception of the agreement, and (ii) the Company does not have ongoing performance obligations related to the achievement of the milestone earned. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either the Company's performance subsequent to the inception of the arrangement to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the Company's performance subsequent to the inception of the arrangement to achieve the milestone, (b) relates solely to past performance, and (c) is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement. See Note 3, "Collaboration Arrangements," for analysis of milestone events deemed to be substantive or non-substantive.

Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2011-04,*Financial Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* ("ASU 2011-04"). ASU 2011-04 provides a consistent definition of fair value and aligns the fair value measurement and disclosure requirements between U.S. GAAP and International Financial Reporting Standards ("IFRS"). ASU 2011-04 clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. This ASU was effective in the Company's first quarter of 2012. The Company's adoption of ASU 2011-04 did not have a material impact on its consolidated financial statements.

In June 2011, the FASB issued Accounting Standards Update No. 2011-05,*Comprehensive Income (Topic 220): Presentation of Comprehensive Income.* ASU 2011-05 requires an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 eliminates the option to present other comprehensive income as part of the statement of stockholders' equity. This ASU was effective in the Company's first quarter of 2012 and the Company elected to present other comprehensive income in a single continuous statement.

NOTE 2 — NET LOSS PER COMMON SHARE

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by giving effect to all potential dilutive common shares, including outstanding options and warrants.

Potential dilutive common shares also include the dilutive effect of the common stock underlying in-the-money stock options and warrants that were calculated based on the average share price for each period using the treasury stock method. Under the treasury stock method, the exercise price of an option or warrant, are assumed to be used to repurchase shares in the current period. In addition, the average amount of compensation cost for in-the-money options, if any, for future service that the Company has not yet recognized when the option is exercised, are also assumed to repurchase shares in the current period.

A reconciliation of the numerator and denominator used in the calculation is as follows (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Numerator:				
Net loss — basic	$ (991)	$ (4,125)	$(99,523)	$(20,378)
Less: noncash income from change in fair value of common stock warrants	(2,967)	—	—	—
Net loss — diluted	$ (3,958)	$ (4,125)	$(99,523)	$(20,378)
Denominator:				
Weighted average common shares outstanding	55,654	49,052	53,516	44,812
Dilutive effect of warrants	8,751	—	—	—
Weighted-average common shares outstanding and potential dilutive common shares — diluted	64,405	49,052	53,516	44,812
Net loss per share				
Basic	$ (0.02)	$ (0.08)	$ (1.86)	$ (0.45)
Diluted	$ (0.06)	$ (0.08)	$ (1.86)	$ (0.45)

The following outstanding warrants, options and purchase rights under the Company's 2004 Employee Stock Purchase Plan were excluded from the computation of diluted net loss per share for the periods presented because including them would have had an antidilutive effect. The amounts disclosed below are prior to the application of the treasury stock method (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Shares issuable upon exercise of warrants	—	16,643	11,726	16,643
Shares issuable upon exercise of stock options	5,129	3,531	5,129	3,531
Shares issuable related to the ESPP	48	40	48	40

NOTE 3 — COLLABORATION ARRANGEMENTS

On February 2, 2012, the Company entered into a global license and co-development agreement with Merck KGaA, of Darmstadt, Germany, to co-develop and commercialize TH-302, the Company's small molecule hypoxia-targeted drug. Under the terms of the agreement, Merck will receive co-development rights, exclusive global commercialization rights and will provide the Company an option to co-commercialize TH-302 in the United States. The Company received an upfront payment of $25 million. The Company has also earned another $42.5 million in milestone payments, including a $10 million milestone payment earned subsequent to the quarter ended September 30, 2012. The $20 million milestone payment based on positive results from its randomized Phase 2 trial in pancreatic cancer was received during the quarter ended June 30, 2012 and the remaining $22.5 million is expected during the fourth quarter of 2012. The milestones earned to date were not deemed to be substantive milestones because the work related to the achievement of these items was predominately completed prior to the inception of the arrangement. The Company is eligible to earn additional potential milestone payments of up to $142.5 million in regulatory and development milestones and $340 million in commercialization milestones. The Company could receive an additional $42.5 million of the regulatory and development milestones in the near term.

In the United States, the Company will have primary responsibility for development of TH-302 in the soft tissue sarcoma indication. The Company and Merck KGaA will jointly develop TH-302 in all other cancer indications being pursued. Merck KGaA will pay 70% of worldwide development expenses for TH-302. Subject to FDA approval in the United States, Merck KGaA will initially be responsible for commercialization of TH-302 with the Company receiving a tiered, double-digit royalty on sales. Under the royalty-bearing portion of the agreement, Threshold retains the option to co-promote TH-302 in the United States. Additionally, the Company retains the option to co-commercialize TH-302, upon the achievement of certain sales and regulatory milestones, allowing the Company to participate in up to 50% of the profits in the United States depending on total sales. Outside of the United States, Merck KGaA will be solely responsible for the

commercialization of TH-302 with the Company receiving a tiered, double-digit royalty on sales in these territories. The agreement became effective on March 12, 2012, upon termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. The agreement will continue on a country-by-country basis until the later of the last to expire patent covering TH-302 in such country or ten years following the commercial launch of a product containing TH-302 in such country, unless terminated earlier. Merck has the right to terminate the agreement after the achievement of certain milestones, and each party has the right to terminate the agreement following an uncured material breach by the other party.

The Company's deliverables under the Merck agreement, which include delivery of the rights and license for TH-302 and performance of research and development activities, have been determined to be a single unit of accounting. The delivered license does not have standalone value at the inception of the arrangement due to the Company's proprietary expertise with respect to the licensed compound and related ongoing developmental participation under the global license and co-development agreement, which is required for Merck to fully realize the value from the delivered license. Therefore, the revenue relating to this unit of accounting will be recorded as deferred revenue and recognized over the estimated performance period under the agreement, which is the product development period. The Company recorded the upfront payment and milestones earned as deferred revenue and is amortizing them ratably over its estimated period of performance. As a result, the Company recognized $1.8 million and $3.8 million of revenue for the three months and nine months ended September 30, 2012, respectively. The Company will periodically review and, if necessary, revise the estimated periods of performance of our collaboration. The Company also earned a $5.0 million and $10.0 million reimbursement for eligible worldwide development expenses for TH-302 from Merck during the three and nine months ended September 30, 2012, respectively. Such earned reimbursement has been reflected as a reduction of operating expenses.

Of the remaining potential future milestones, $142.5 million are related to development and regulatory milestones and $340 million are related to commercialization milestones that may be received under the Merck Agreement. Development milestones in the agreement include primarily the initiation of various phases of clinical trials. Regulatory milestones include the filing and acceptance of regulatory applications for marketing approval in major markets. Commercialization milestones include the achievement of first commercial sales in a particular market or annual product sales in excess of a pre-specified threshold. At the inception of the collaboration agreement the Company assessed development and regulatory milestones to be substantive where there was substantive scientific and regulatory uncertainty of achievement, the amounts of payments assigned were considered to be commensurate with the enhancement of the value of the delivered rights and license of TH-302 and the Company's performance is necessary to the achievement of the milestone. Accordingly, the Company will recognize payments related to the achievement of such milestones, if any, when such milestone is achieved. Development and regulatory milestones that do not meet these conditions were considered non-substantive and payments related to the achievement of such milestones, if any, will be recorded as deferred revenue and amortized ratably over the estimated period of performance. Final determination of whether a development or regulatory milestone is substantive will depend upon the Company's role in achieving the milestone. The specific role and responsibilities related to the development and regulatory activities for certain of these milestones have yet to be determined and may change during the development period. Under the Merck agreement, Merck will initially be responsible for commercialization activities and the Company initially may not be involved in the achievement of these commercialization milestones. These commercialization milestones would typically be achieved after the completion of the Company's development and regulatory activities. The Company would account for the commercialization milestones in the same manner as royalties, with revenue recognized upon achievement of the milestone.

NOTE 4 — STOCKHOLDERS' EQUITY

Common Stock

Pursuant to an amendment to the at the market issuance sales agreement and a prospectus supplement the Company filed on January 20, 2012 and pursuant to a new registration statement filed with the Securities and Exchange Commission, the Company may sell shares of its common stock having an aggregate offering price of up to $15.0 million from time to time through MLV & Co., LLC, formerly McNicoll, Lewis & Vlak LLC as its sales agent. During the three months ended March 31, 2012, the Company sold 2,022,144 shares of our common stock at an average price of $6.29 pursuant to the at market issuance sales agreement. Net proceeds from the sale of stock were $12.3 million. The sale of stock did not result in an adjustment to the exercise price of certain of our outstanding warrants. During the quarter ended September 30, 2012, there were no sales of common stock pursuant to the at market issuance sales agreement

Common Stock Warrants

The Company accounts for its common stock warrants under guidance now codified in ASC 815 that clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify for classification as liabilities. The guidance required the Company's outstanding warrants to be classified as liabilities and to be fair valued at each reporting period, with the changes in fair value recognized as other income (expense) in the Company's consolidated statement of comprehensive loss.

During the three and nine months ended September 30, 2012, warrants to purchase 872,451 shares and 4,584,474 of common stock were exercised for net proceeds of approximately $1.6 million and $8.5 million, respectively. As of the date of exercise of the warrants, the Company transferred the fair value of the warrants of approximately $5.4 million and $27.4 million from warrant liability into stockholders' equity for the three and nine months ended September 30, 2012, respectively.

At September 30, 2012 and December 31, 2011, the Company had warrants outstanding to purchase 3,058,811 and 3,588,221 shares of common stock, respectively, from the Company's August 2008 stock offering. The fair value of these warrants on September 30, 2012 and December 31, 2011 was determined using a Black-Scholes valuation model with the following level 3 inputs:

	September 30, 2012	December 31, 2011
Risk-free interest rate	0.17%	0.25%
Expected life (in years)	0.91	1.66
Dividend yield	—	—
Volatility	118%	84%
Exercise price	$ 1.86	$ 1.86
Stock price	$ 7.24	$ 1.22

During the three and nine months ended September 30, 2012, the change in fair value related to the August 2008 warrants of $0.5 million of non-cash income and $19.0 million of non-cash expense, respectively, was recorded as other income (expense) in the Company's consolidated statement of comprehensive income (loss).

At September 30, 2012 and December 31, 2011, the Company had warrants outstanding to purchase 4,287,940 and 7,329,819 shares of common stock, respectively, from the Company's October 2009 stock offering. The fair value of these warrants on September 30, 2012 and December 31, 2011 was determined using a Black Scholes valuation model with the following level 3 inputs:

	September 30, 2012	December 31, 2011
Risk-free interest rate	0.23%	0.36%
Expected life (in years)	2.01	2.76
Dividend yield	—	—
Volatility	105%	88%
Exercise price	$ 2.05	$ 2.05
Stock price	$ 7.24	$ 1.22

During the three and nine months ended September 30, 2012 the change in fair value related to the October 2009 warrants of $0.7 million of non-cash income and $36.8 million of non-cash expense, respectively, was recorded as other income (expense) in the Company's consolidated statement of comprehensive loss.

At September 30, 2012 and December 31, 2011, the Company had warrants outstanding to purchase 4,378,940 and 5,725,227 shares of common stock, respectively, from the Company's March 2011 stock offering. The fair value of these warrants on September 30, 2012 and December 31, 2011 was determined using a Black Scholes valuation model with the following level 3 inputs:

	September 30, 2012	December 31, 2011
Risk-free interest rate	0.62%	0.60%
Expected life (in years)	3.46	4.21
Dividend yield	—	—
Volatility	99%	102%
Exercise price	$ 2.46	$ 2.46
Stock price	$ 7.24	$ 1.22

During the three and nine months ended September 30, 2012, the change in fair value related to the March 2011 warrants of $1.7 million of non-cash income and $29.8 million of non-cash expense, respectively, was recorded as other income (expense) in the Company's consolidated statement of comprehensive loss.

The following table sets forth the Company's financial liabilities, related to warrants issued in the August 2008, October 2009 and March 2011 offerings, subject to fair value measurements as of September 30, 2012 and December 31, 2011:

(in thousands)	Fair Value as of September 30, 2012	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
August 2008 warrants	$ 17,099	$ —	$ —	$ 17,099
October 2009 warrants	24,570	—	—	24,570
March 2011 warrants	25,704	—	—	25,704
Total common stock warrants	$ 67,373	$ —	$ —	$ 67,373

(in thousands)	Fair Value as of December 31, 2011	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
August 2008 warrants	$ 1,292	$ —	$ —	$ 1,292
October 2009 warrants	3,738	—	—	3,738
March 2011 warrants	4,179	—	—	4,179
Total common stock warrants	$ 9,209	$ —	$ —	$ 9,209

The following table is a reconciliation of the warrant liability measured at fair value using level 3 inputs (in thousands):

	Warrant Liability
Balance at December 31, 2011	$ 9,209
Change in fair value of common stock warrants during nine months ended September 30, 2012	85,572
Exercise of warrants during nine months ended September 30, 2012	(27,408)
Balance at September 30, 2012	$ 67,373

NOTE 5 — STOCK BASED COMPENSATION

The Company recognizes stock-based compensation in accordance with ASC 718, *"Compensation—Stock Compensation."* Stock-based compensation expense recognized in the unaudited condensed consolidated statement of comprehensive loss related to stock options and ESPP was $0.9 million and $2.1 million for the three and nine months ended September 30, 2012, respectively, and was $0.3 million and $0.7 million for the three and nine months ended September 30, 2011, respectively.

Valuation Assumptions

The Company estimated the fair value of stock options granted using the Black-Scholes option-pricing formula and a single option award approach. This fair value is being amortized on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period. The fair value of employee stock options and employee purchase rights under the Company's ESPP was estimated using the following weighted-average assumptions for the three and nine months ended September 30, 2012 and 2011:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Employee Stock Options				
Risk-free interest rate	1.03%	—	1.13%	1.93%
Expected term (in years)	6.08	—	5.99	5.97
Dividend yield	—	—	—	—
Volatility	98%	—	106%	91%
Weighted-average fair value of stock options granted	$ 5.87	$ —	$ 5.12	$ 1.23

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Employee Stock Purchase Plan (ESPP):				
Risk-free interest rate	0.21%	0.13%	0.21%	0.15%
Expected term (in years)	1.25	1.25	1.25	1.25
Dividend yield	—	—	—	—
Volatility	111%	80%	111%	80%
Weighted-average fair value of ESPP purchase rights	$ 4.62	$ 0.66	$ 3.46	$ 0.66

To determine the expected term of the Company's employee stock options granted, the Company utilized the simplified approach as defined by SEC Staff Accounting Bulletin No. 107, *"Share-Based Payment"*. To determine the risk-free interest rate, the Company utilized an average interest rate based on U.S. Treasury instruments with a term consistent with the expected term of the Company's stock based awards. To determine the expected stock price volatility for the Company's stock based awards, the Company examined historical volatilities for industry peers as well as the Company and utilized a blend of the historical volatilities of the Company and its industry peers. The fair value of all the Company's stock based awards assumes no dividends as the Company does not anticipate paying cash dividends on its common stock.

Employee Stock-based Compensation Expense

As required by ASC 718, the Company recognized $0.8 million and $1.9 million of stock-based compensation expense related to stock options and purchase rights granted after the Company's initial public offering in February 2005, under the Company's stock option plans and ESPP, for the three and nine months ended September 30, 2012, respectively and $0.3 million and $0.7 million of stock based compensation for

the three and nine months ended September 30, 2011, respectively. As of September 30, 2012, the total unrecognized compensation cost related to unvested stock-based awards granted to employees under the Company's stock option plans was approximately $9.4 million before forfeitures. This cost will be recorded as compensation expense on a straight-line basis over the remaining weighted average requisite service period of approximately 2.8 years.

Non-employee Stock-based Compensation Expense

The Company accounts for equity instruments issued to non-employees in accordance with ASC 505,*"Equity."* The equity instruments consisting of stock options are valued using the Black-Scholes option pricing model. The values attributable to these options are amortized over the service period and the unvested portion of these options is remeasured at each vesting date. In connection with the grant of stock options to non-employees, the Company recorded stock-based compensation of approximately $0.1 million and $0.2 million for the three and nine months ended September 30, 2012, respectively, and $20,000 and $51,000 for the three and nine months ended September 30, 2011, respectively.

Stock-based compensation expense, which consists of the compensation cost for employee stock options and ESPP, and the value of options issued to non-employees for services rendered, was allocated to research and development and general and administrative as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Amortization of stock-based compensation:				
Research and development	$ 471	$ 141	$ 1,082	$ 328
General and administrative	473	151	1,005	415
	$ 944	$ 292	$ 2,087	$ 743

Equity Incentive Plans

2004 Equity Incentive Plan On January 1, 2012, an additional 1,250,000 shares was authorized for issuance under the 2004 Equity Incentive Plan ("2004 Incentive Plan"), pursuant to the annual automatic increase to the authorized shares under the 2004 Incentive Plan. At September 30, 2012, 540,784 shares were authorized and available for issuance under the 2004 Equity Incentive Plan.

The following table summarizes stock option activity under the Company's 2004 Equity Incentive Plan:

Options	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2011	3,672,179	$ 1.45	—	—
Granted	1,787,000	$ 6.28	—	—
Exercised	(330,352)	$ 1.36	—	—
Forfeitures	—	$ —	—	—
Outstanding at September 30, 2012	5,128,827	$ 3.14	8.24	$21,102,085
Vested and expected to vest September 30, 2012	5,068,823	$ 3.12	8.23	$20,964,921
Exercisable at September 30, 2012	2,089,451	$ 1.78	7.24	$11,398,737

The total intrinsic value of stock options exercised during the nine months ended September 30, 2012 and 2011 were $1.4 million and $6,000, respectively, as determined at the date of the option exercise. Cash received from stock option exercises was $0.4 million and $14,000 for each of the nine months ended September 30, 2012 and 2011, respectively. The Company issues new shares of common stock upon exercise of options. In connection with these exercises, there was no tax benefit realized by the Company due to the Company's current loss position.

2004 Employee Stock Purchase Plan On January 1, 2012, an additional 100,000 shares was authorized for issuance under the 2004 Employee Stock Purchase Plan ("2004 Purchase Plan") pursuant to the annual automatic increase to the authorized shares under the 2004 Purchase Plan. For the nine months ended September 30, 2012, plan participants had purchased 150,677 shares at an average purchase price of $1.18. At September 30, 2012, plan participants had $0.1 million withheld to purchase stock on February 14, 2013, which is included in accrued liabilities on the accompanying unaudited condensed consolidated balance sheet. At September 30, 2012, 303,141 shares were authorized and available for issuance under the ESPP.

NOTE 6 — FAIR VALUE MEASUREMENTS AND MARKETABLE SECURITIES

The Company accounts for its marketable securities in accordance with ASC 820*"Fair Value Measurements and Disclosures."* ASC 820 defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 - Quoted prices in active markets for identical assets or liabilities.

Level 2 - Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company's short-term investments primarily utilize broker quotes in a non-active market for valuation of these securities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company utilizes the market approach to measure fair value for its financial assets and liabilities. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities. The following table sets forth the Company's financial assets (cash equivalents and marketable securities) at fair value on a recurring basis as of September 30, 2012 and December 31, 2011:

(in thousands)	Fair Value as of September 30, 2012	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	$ 3,861	$ 3,861	$ —	$ —
Certificate of Deposits	485	—	485	—
Corporate bonds	20,160	—	20,160	—
U.S. Government securities	29,004	—	29,004	—
Commercial paper	12,315	—	12,315	—
Total cash equivalents and marketable securities	$ 65,825	$ 3,861	$ 61,964	$ —

(in thousands)	Fair Value as of December 31, 2011	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	$ 4,050	$ 4,050	$ —	$ —
Corporate bonds	4,690	—	4,690	—
Government securities	5,970	—	5,970	—
Commercial paper	5,548	—	5,548	—
Total cash equivalents and marketable securities	$ 20,258	$ 4,050	$ 16,208	$ —

The Company invests in highly-liquid, investment-grade securities. The following is a summary of the Company's available-for-sale securities at September 30, 2012 and December 31, 2011:

As of September 30, 2012 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 3,861	$ —	$ —	$ 3,861
Certificate of Deposits	485	—	—	485
Corporate bonds	20,157	11	(8)	20,160
U.S. Government securities	28,994	10	—	29,004
Commercial paper	12,315	0	—	12,315
	65,812	21	(8)	65,825
Less cash equivalents	(8,634)	—	—	(8,634)
Total marketable securities	$ 57,178	$ 21	$ (8)	$ 57,191

As of December 31, 2011 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 4,050	$ —	$ —	$ 4,050
Corporate bonds	4,693	—	(3)	4,690
U.S. Government securities	5,968	2	—	5,970
Commercial paper	5,548	—	—	5,548
	20,259	2	(3)	20,258
Less cash equivalents	(5,850)	—	—	(5,850)
Total marketable securities	$14,409	$ 2	$ (3)	$14,408

There were no realized gains or losses in the three and nine months ended September 30, 2012 and 2011.

As of September 30, 2012, weighted average days to maturity for the Company's available for sale securities was 157 days, with the longest maturity being December 2013.

The following table provides the breakdown of the marketable securities with unrealized losses at September 30, 2012 (in thousands):

As of September 30, 2012 (in thousands):	In loss position for less than twelve months	
	Fair Value	Unrealized Loss
Corporate bonds	$ 5,302	$ (8)

The Company determined the fair value of the liability associated with its warrants to purchase 11.7 million shares of outstanding common stock using a Black-Scholes Model. See detailed discussion in Note 4 — Stockholders' Equity.

NOTE 7 — COMMITMENTS AND CONTINGENCIES

The Company leases certain of its facilities under noncancelable leases, which qualify for operating lease accounting treatment under ASC 840,*"Leases,"* and, as such, these facilities are not included on its unaudited condensed consolidated balance sheets. The future rental payments required by the Company for all of its facilities under noncancelable operating leases are as follows (in thousands):

Years Ending December 31,	
2012	$ 154
2013	624
2014	641
2015	663
2016	691
2017	234
Total	$3,007

Indemnification

The Company enters into indemnification provisions under its agreements with other companies in the ordinary course of business, including business partners, contractors and parties performing its clinical trials. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party as a result of the Company's activities. The duration of these indemnification agreements is generally perpetual. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of these agreements is minimal. The Company maintains commercial general liability insurance and products liability insurance to offset certain of its potential liabilities under these indemnification provisions. Accordingly, the Company has not recognized any liabilities relating to these agreements as of September 30, 2012.

The Company's bylaws provide that it is required to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of a culpable nature, to the fullest extent permissible by applicable law; and to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the "Risk Factors" section of this Quarterly Report on Form 10-Q. Other than statements of historical fact, statements made in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of Section 21E of the Exchange Act, and Section 27A of the Act . When used in this report or elsewhere by management from time to time, the words "believe," "anticipate," "intend," "plan," "estimate," "expect," and similar expressions are forward-looking statements. Such forward-looking statements are based on current expectations. Forward-looking statements made in this report include, for example, statements about:

- the progress of our clinical programs, including estimated milestones;
- estimates of future performance, capital requirements and needs for financing;
- uncertainties associated with obtaining and enforcing patents and other intellectual property rights; and
- the costs and timing of obtaining drug supply for our pre-clinical and clinical activities.

Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors. For a more detailed discussion of the potential risks and uncertainties that may impact their accuracy, see the "Overview" section of this Management's Discussion and Analysis of Financial Condition and Results of Operations and the "Risk Factors" section in Part II of this quarterly report on Form 10-Q. Forward-looking statements reflect our view only as of the date of this report. We undertake no obligation to update any forward-looking statements. You should also review carefully the cautionary statements and risk factors listed in our Annual Report on Form 10-K for the year ended December 31, 2011, and in our other filings with the SEC, including our Forms 10-Q and 8-K and our Annual Report to Shareholders.

Overview

We are a biotechnology company focused on the discovery and development of drugs targeting the microenvironment of solid tumors and the bone marrows of patients with some hematologic malignancies (blood cancers) as novel treatments for patients living with cancer. The microenvironment of these tissues is characterized by, among other things, hypoxia or lack of oxygen. This hypoxic environment is known to be resistant to standard chemotherapy and radiation. It is thought to be responsible for the poor prognosis of patients with solid tumors and hematological malignancies, and treating the hypoxic environment is currently believed to be a significant unmet medical need. Our hypoxia activated prodrug ("HAP") product candidates, including TH-302, are designed to specifically target the hypoxic microenvironment of tumors by selective activation of the prodrug to release a potent cytotoxin. Our focus is on product candidates for the treatment of patients with cancer. Our clinical development efforts are currently focused on TH-302, for which we entered a license and co-development agreement with Merck KGaA for worldwide development and commercialization. TH-302, which we discovered, is a novel drug candidate that is activated under severe hypoxic conditions and was designed to specifically target the severe hypoxic regions that are believed to be present in all solid tumors and the bone marrows of patients with some hematologic malignancies.

TH-302 is currently in Phase 1, Phase 2 and Phase 3 clinical trials. The development plan for TH-302 is designed to investigate the efficacy and safety across a broad range of solid tumors and hematologic malignancies. We reported updated top-line results from the initial Phase 1 monotherapy trial of TH-302 (401 trial) including indication specific data in patients with metastatic melanoma and small-cell lung cancer (SCLC). We have also reported results from each of four Phase 1/2 combination therapy investigations of a chemotherapy agent plus TH-302 in solid tumors involving combining TH-302 with doxorubicin, gemcitabine, docetaxel and pemetrexed. We have also reported results from our clinical study of TH-302 in patients with advanced leukemias (407 trial) and initiated a clinical study of TH-302 in patients with multiple myeloma (408 trial). In addition, investigations have been initiated to explore the combination of TH-302 with anti-angiogenic therapies including a Phase 1/2 dose escalation clinical trial of TH-302 in combination with sunitinib (Sutent ®) in patients with advanced renal cell carcinoma or gastrointestinal stromal tumors (410 trial) and physician initiated clinical trial of TH-302 administered either in combination with bevacizumab (Avastin ®) in patients with recurrent high grade astrocytoma including glioblastoma or in combination with pazopanib (Votrient ®) in patients with solid tumors. In September 2012, European Society for Medical Oncology (ESMO) 2012 Congress in Vienna, Austria we announced preliminary data from the physician initiated clinical trial of TH-302 in combination with bevacizumab in patients with recurrent glioblastoma

In February of 2012 we reported top-line results from the randomized and controlled Phase 2 trial of TH-302 plus gemcitabine in patients with pancreatic cancer (404 trial). The median progression-free survival (PFS) was 5.6 months for patients treated with gemcitabine in combination with TH-302 at 240 mg/m2 and 340 mg/m2 compared to 3.6 months for patients treated with gemcitabine alone. The PFS hazard ratio comparing the TH-302 combination to gemcitabine alone was 0.61 (95% confidence interval: 0.43—0.87) which was highly statistically significant ($p = 0.005$) and represented a 63% improvement in PFS. The response rate in the combination arms was 22% compared to 12% in the gemcitabine alone group. Results also demonstrated greater efficacy in the higher TH-302 dose group compared to the lower dose group. The combination was well tolerated with a safety profile that was consistent with our prior study of this combination regimen. As in that study, skin and mucosal toxicities related to TH-302 were dose dependent but not dose limiting. In April 2012, we provided detailed results from our 404 trial at the American Association of Cancer Research (AACR) annual meeting including results for each of the 240 mg/m2 and 340 mg/m2 TH-302 combination arms. The median PFS was 6.0 months in the 340 mg/m2 group. The response rate was 27% in the 340 mg/m2 group. A similar dose dependency was reported in serum CA19-9 levels. There was greater drug exposure in the combination groups with a median of 4 cycles received with gemcitabine alone compared with 5 cycles in the 240 mg/m2 group and 6 cycles in the 340 mg/m2 group. The combination safety profile was consistent with the prior study of this combination regimen. As in that study, skin and mucosal toxicities and were less than what has been seen at

the single-agent maximum tolerated dose of TH-302, which was previously established at 575 mg/m2. The incidence of grade 3/4 thrombocytopenia and grade 3/4 neutropenia was significantly higher in the combination arms and highest in the 340 mg/m2 group. Discontinuations for adverse events were lowest in the 340 mg/m2 group. In September 2012, at ESMO 2012 Congress, we presented new findings on overall survival, which was a secondary endpoint of the study, indicating that patients treated with gemcitabine alone had a median overall survival of 6.9 months compared with 9.2 months for patients treated with 340 mg/m2 TH-302 plus gemcitabine (HR: 0.955, 95% CI: 0.67-1.37, p=0.800) and 8.7 months for patients treated with 240 mg/m2 TH-302 plus gemcitabine (HR: 0.960, 95% CI: 0.67-1.38, p=0.827). While not statistically significant, the improvement in median overall survival is consistent with the improvement in median PFS reported previously. The trial was not designed to detect a statistically significant improvement in overall survival and included a cross-over component. Patients receiving gemcitabine alone who crossed over to receive gemcitabine plus TH-302 upon disease progression did contribute to an increase in survival of the control arm. TH-302 continues to demonstrate a safety profile consistent with what has been previously reported at AACR. The most common adverse events were fatigue, nausea, constipation and peripheral edema, and were similar across groups. Skin and mucosal toxicities and myelosuppression were the most common adverse events related to TH-302, were mostly Grade 1 and 2, and did not result in increases in treatment discontinuation. Adverse events leading to discontinuation of study treatment as well as serious adverse events were balanced across all treatment arms. Grade 3/4/5 adverse events were generally below 10%. We expect the Merck to initiate a planned Phase 3 trial of TH-302 plus gemcitabine in patients with pancreatic cancer.

During 2011, we presented updated top-line results from our Phase 1/2 combination therapy in patients with soft tissue sarcoma treated with doxorubicin plus TH-302 at the maximum tolerated dose of 300 mg/m 2 (403 trial). In February 2011, we reached agreement with the FDA on the design and planned analysis of a pivotal Phase 3 trial in patients with soft tissue sarcoma (406 trial). As part of the Special Protocol Assessment (SPA) submission, the FDA agreed that the design and planned analysis of the proposed Phase 3 trial adequately addresses the objectives necessary to support a regulatory submission. We initiated the pivotal Phase 3 trial in September of 2011 and expect to provide an update on the interim analysis which will be conducted by an Independent Data Monitoring Committee (IDMC) in the first half of 2013.

We are working to broaden the applicability of TH-302 to other cancers and in combination with other approved anti-cancer drugs as well as to discover additional hypoxia activated prodrugs that will selectively target cancer cells.

We were incorporated in October 2001. We have devoted substantially all of our resources to research and development of our product candidates. We have not generated any revenue from the commercial sales of our product candidates, and prior to our initial public offering in February 2005, we funded our operations through the private placement of equity securities. During the nine months ended September 30, 2012, we sold 2,022,144 shares of common stock under our at market issuance sales facility for net proceeds of $12.3 million, and we received approximately $8.5 million from the exercise of warrants to purchase common stock. On February 3, 2012, we entered into an agreement with Merck KGaA, which provided for an upfront payment of $25 million. We also earned an additional $42.5 million in milestone payments, $20 million of which we have received during the quarter ended June 30, 2012 and the remaining $22.5 million is expected during the fourth quarter of 2012. We could also receive an additional $42.5 million in potential milestone payments in the near term. As of September 30, 2012 we had cash, cash equivalents and marketable securities of $65.8 million. For the nine months ended September 30, 2012, we had an operating loss of $14.0 million and a net loss of $99.5 million, including $85.6 million in non-cash expense related to the change in the fair value of outstanding warrants. Our cumulative net loss since our inception through September 30, 2012 was $351.7 million.

We expect to continue to devote substantial resources to research and development in future periods as we complete our current clinical trials, start additional clinical trials and continue our discovery efforts. Research and development expenses, excluding reimbursements of Merck's 70% share of total development expenses, are expected to increase in 2012 compared to 2011 due to the continued execution of existing clinical trials and beginning of new clinical trials. We expect research and development expenses net of the reimbursements from Merck, to decrease in 2012 compared to 2011. We believe that our cash, cash equivalents and marketable securities will be sufficient to fund our projected operating requirements for at least the next twelve months based upon current operating plans, milestone payment forecasts and spending assumptions. We expect that we will need to raise additional capital to support new in-house development programs or to in-license or otherwise acquire and develop additional products or programs. We intend to seek funds through additional arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently. Research and development expenses may fluctuate significantly from period to period as a result of the progress and results of our clinical trials.

Results of Operations

Revenue. We recognized a total of $1.8 million and $3.8 million during the three and nine months ended September 30, 2012, respectively, from the amortization of the $25 million upfront payment received and $32.5 million milestone payments earned, including a $20 million milestone payment based on positive results from its randomized Phase 2 trial in pancreatic cancer, from our collaboration with Merck. Subsequent to September 30, 2012, we earned an additional $10 million milestone payment. We are amortizing the upfront payment and milestones earned over the period of performance (product development period). We will periodically review and, if necessary, revise the estimated periods of performance of our collaboration. No revenue was recognized for the three and nine months ended September 30, 2011.

Research and Development. Research and development expenses were $4.0 million for the three months ended September 30, 2012 compared to $6.5 million for the three months ended September 30, 2011. The $2.5 million decrease in expenses is due primarily to a $4.8 million reimbursement for Merck's 70% share of total development expenses for TH-302 and a $0.3 million decrease in consulting expenses, partially offset by $1.9 million increase in clinical development expenses and an increase of $0.7 million in employee related expenses. Research and development expenses were $12.6 million for the nine months ended September 30, 2012 compared to $17.6 million for the nine months ended

September 30, 2011. The $5.0 million decrease in expenses is due primarily to a $9.6 million reimbursement for Merck's 70% share of total development expenses for TH-302 and $0.2 million decrease in consulting expenses, partially offset by $2.9 million increase in clinical development expenses and $1.9 million in employee related expenses.

Research and development expenses by project (in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
TH-302	$3,136	$ 5,501	$ 9,752	$14,815
Discovery research	903	980	2,871	2,831
Total research and development expenses	$4,039	$ 6,481	$12,623	$17,646

Research and development expenses associated with our internally discovered compound TH-302 were $3.1 million for the three months ended September 30, 2012, which includes the $4.8 million reimbursement for Merck's 70% share of total development expenses for TH-302, compared to $5.5 million for the three months ended September 30, 2011. Research and development expenses associated with TH-302 were $9.8 million for the nine months ended September 30, 2012 which includes the $9.6 million reimbursement for Merck's 70% share of total development expenses for TH-302, compared to $14.8 million for the nine months ended September 30, 2011. TH-302 continues to progress through the 406 trial, the 404 trial, and the 403 trial. We reported top-line results for the 404 trial in February 2012 and detailed results in April 2012. We also provided additional overall survival data on the 404 trial in September of 2012.

Discovery research and development expenses were $0.9 million for the three months ended September 30, 2012 compared to $1.0 million for the three months ended September 30, 2011, and were $2.9 million for the nine months ended September 30, 2012 compared to $2.8 million for the nine months ended September 30, 2011. We continue to focus our efforts towards discovering and developing new drug candidates from our hypoxia activated prodrug platform.

We did not track research and development expenses by project prior to 2003, and therefore we cannot provide cumulative project expenses to date. Due to the risks and uncertainties involved in discovering and developing product candidates, such as clinical trial results, regulatory approval requirements, dependence on third parties and market acceptance, which are described in the "Risk Factors" section in Part II of this Quarterly Report on Form 10-Q, we cannot reasonably estimate the costs and timing of completion of each project or when any project will result in net cash inflows.

We expect to continue to devote substantial resources to research and development in future periods as we complete our current clinical trials, start additional clinical trials and continue our discovery efforts under our collaboration with Merck as well as on our own. Research and development expenses, excluding reimbursements of Merck's 70% share of development expenses, are expected to increase in 2012 compared to 2011 due to the continued execution of existing clinical trials and start of new clinical trials. Including the reimbursements from Merck we expect research and development expenses to decrease in 2012 compared to 2011.

General and Administrative. General and administrative expenses were $1.7 million for the three months ended September 30, 2012, compared to $1.3 million for the three months ended September 30, 2011. The $0.4 million increase in expenses is due primarily to an increase in employee related expenses. General and administrative expenses were $5.2 million for the nine months ended September 30, 2012, compared to $4.3 million for the nine months ended September 30, 2011. The increase of $0.9 million was due to $0.6 million in consulting expenses and $0.3 million in employee related expenses to support our collaboration with Merck KGaA. We currently expect our general and administrative expenses to increase in 2012 compared to 2011 due to increased staffing and consulting expenses to support our collaboration with Merck KGaA and the continued development of TH-302.

Interest Income (Expense), Net

Interest income (expense), net for the three months ended September 30, 2012 was $25,000 compared to $5,000 of interest income for 2011. Interest income (expense), net for the nine months ended September 30, 2012 was $55,000 of interest income compared to $20,000 of interest income for 2011.

Other Income (Expense)

Other income (expense) for the three months ended September 30, 2012 was non-cash income of $3.0 million compared to non-cash income of $3.7 million for the three months ended September 30, 2011. Other income (expense) for the nine months ended September 30, 2012 was non-cash expense of $85.6 million compared to non-cash income of $1.5 million for the nine months ended September 30, 2011. The change in non-cash income (expense) was due to a change in the fair value of outstanding warrants to purchase common stock as well as warrants exercised during the three and nine months ended September 30, 2012 as result of a change in the underlying market price of common stock of the Company. ASC 815 *"Derivatives and Hedging"* requires that stock warrants with certain terms need to be accounted for as a liability with changes to their fair value recognized in the consolidated statement of comprehensive loss.

Liquidity and Capital Resources

We have not generated and do not expect to generate revenue from sales of product candidates in the near term. Since our inception we funded our operations primarily through private placements and public offerings of equity securities. During the nine months ended September 30, 2012, we sold an aggregate of 2,022,144 shares of common stock under our at market issuance sales facility for net proceeds of $12.3 million, and we received approximately $8.5 million from the exercise of warrants to purchase approximately 4.6 million shares of common stock.

On February 3, 2012, we entered into an agreement with Merck KGaA and received an upfront payment of $25 million. We also earned $42.5 million in milestone payments, $20 million of which we received during the quarter ended June 30, 2012 and the remaining $22.5 million is expected during the fourth quarter of 2012. We could also receive an additional $42.5 million in potential milestone payments in the near term. We had cash, cash equivalents and marketable securities of $65.8 million and $20.3 million at September 30, 2012 and December 31, 2011, respectively, available to fund operations.

Net cash provided by operating activities for the nine months ended September 30, 2012 was $24.9 million compared to $19.1 million in net cash used in operating activities for the nine months ended September 30, 2011. The increase of $44.0 million in cash provided by operations was primarily attributable to $50.0 million of cash received from the Merck collaboration during the nine months ended September 30, 2012 partially offset by an increase in operating expenses and payments of accrued expenses.

Net cash used in investing activities for the nine months ended September 30, 2012 was $43.6 million compared with net cash used in investing activities of $13.7 million for the nine months ended September 30, 2011. The $29.9 million increase in cash used by investing activities was due primarily due to the excess of proceeds invested in the purchase of marketable securities over proceeds from the sales and maturities of marketable securities.

Net cash provided by financing activities for the nine months ended September 30, 2012 and 2011 was $21.4 million and $30.2 million, respectively. The $8.8 million decrease in cash provided by financing activities was primarily due to the approximately $27.8 million of net proceeds from our March 2011 registered direct offering as compared to the $20.8 million received during 2012 primarily as a result of our issuance of common stock under the at the market sales facility and the exercise of warrants to purchase shares of common stock.

Obligations and Commitments

We lease certain of our facilities under noncancelable leases, which qualify for operating lease accounting treatment under ASC 840,*"Leases,"* and, as such, these facilities are not included on our unaudited condensed consolidated balance sheets.

During the nine months ended September 30, 2012, there have been no significant changes in our payments due under contractual obligations and commitments, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011, which we filed with Securities and Exchange Commission ("SEC") on March 15, 2012.

At Market Sales Facility

On October 29, 2010, we entered into an at market issuance sales agreement, or sales agreement, with MLV & Co., LLC, formerly McNicoll, Lewis & Vlak LLC ("MLV"), pursuant to which we were able to issue and sell shares of our common stock having an aggregate offering price of up to $15.0 million from time to time through MLV as our sales agent. Sales of our common stock through MLV will be made on The NASDAQ Capital Market, on any other existing trading market for our common stock, to or through a market maker or as otherwise agreed by MLV and us. Subject to the terms and conditions of the sales agreement, MLV will use commercially reasonable efforts to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay MLV an aggregate commission rate of 3.0% of the gross proceeds of the sales price per share of any common stock sold under the sales agreement. Under certain circumstances, sales of the stock under the at market issuances sales agreement could result in an adjustment to the exercise price of certain of our outstanding warrants. The number of shares we are able to sell under this arrangement will be limited in practice based on the trading volume of our common stock. As of December 31, 2010 we had not sold any stock pursuant to the sales agreement. For the year ended December 31, 2011, we sold an aggregate of 971,037 shares of our common stock at an average price of $2.66 pursuant to the sales agreement. Net proceeds from the sale of stock in 2011 were $2.3 million. The sales of the stock did not result in an adjustment to the exercise price of certain of our outstanding warrants. Pursuant to an amendment to the at the market issuance sales agreement and a prospectus supplement we filed on January 20, 2012 and pursuant to a new registration statement filed with the Securities and Exchange Commission, we may sell shares of our common stock having an aggregate offering price of up to $15.0 million from time to time through MLV as our sales agent on the terms and conditions described above. During the three months ended March 31, 2012, we sold 2,022,144 shares of our common stock at an average price of $6.29 pursuant to the sales agreement. Net proceeds from the sale of stock were $12.3 million. The sale of stock did not result in an adjustment to the exercise price of certain of our outstanding warrants. During the quarter ended September 30, 2012, there were no sales of common stock pursuant to the at market issuance sales agreement.

We believe that our cash, cash equivalents and marketable securities will be sufficient to fund our projected operating requirements for at least the next twelve months based upon current operating plans, milestone payment forecasts and spending assumptions. We may need to raise additional capital to in-license or otherwise acquire and develop additional products or programs.

We may seek to raise capital through a variety of sources, including:

- the public equity market;
- private equity financing;
- collaborative arrangements;
- licensing arrangements; and/or
- public or private debt.

Our ability to raise additional funds will depend on our clinical and regulatory events, our ability to identify promising new in-house development programs or in-licensing opportunities, and factors related to financial, economic, and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on satisfactory terms. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to our existing stockholders.

In addition, our ability to raise additional capital may be dependent upon our stock being quoted on the NASDAQ Capital Market. If we are unable to secure additional financing on a timely basis or on terms favorable to us, we may be required to cease or reduce certain research and development projects, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. Insufficient funds may require us to delay, scale back, or eliminate some or all of our activities, and if we are unable to obtain additional funding, there is uncertainty regarding our continued existence.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses based on historical experience and on various assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. For further information on our critical accounting policies, see the discussion of critical accounting policies in our Annual Report on Form 10-K for the year ended December 31, 2011, which we filed with the SEC on March 15, 2012. There has been one material revision to the critical accounting policies as discussed in our Annual Report on Form 10-K for the year ended December 31, 2011 for the adoption of revenue recognition as a result of our entering into the collaboration with Merck in February 2012.

Revenue Recognition

We recognize revenue in accordance with ASC 605 “Revenue Recognition”, subtopic ASC 605-25 “Revenue with Multiple Element Arrangements” and subtopic ASC 605-28 “Revenue Recognition-Milestone Method”, which provides accounting guidance for revenue recognition for arrangements with multiple deliverables and guidance on defining the milestone and determining when the use of the milestone method of revenue recognition for research and development transactions is appropriate, respectively.

Our revenues are related to our collaboration arrangement with Merck KGaA, which was entered into in February 2012. Our collaboration with Merck provides for various types of payments to us, including non-refundable upfront license, milestone and royalty payments. We recognize revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. We will also receive reimbursement for Merck’s 70% share for eligible worldwide development expenses for TH-302. Such reimbursement would be reflected as a reduction of operating expenses and not as revenue.

For multiple-element arrangements, each deliverable within a multiple deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. The deliverables under the Merck agreement have been determined to be a single unit of accounting and as such the revenue relating to this unit of accounting will be recorded as deferred revenue and recognized ratably over the term of its estimated performance period under the agreement, which is the product development period. We determine the estimated performance period, and it will be periodically reviewed based on the progress of the related product development plan. The effect of a change made to an estimated performance period and therefore revenue recognized ratably would occur on a prospective basis in the period that the change was made.

Deferred revenue associated with a non-refundable payment received under a collaborative agreement for which the performance obligations are terminated will result in an immediate recognition of any remaining deferred revenue in the period that termination occurred provided that all performance obligations have been satisfied.

We recognize revenue from milestone payments when: (i) the milestone event is substantive and its achievability has substantive uncertainty at the inception of the agreement, and (ii) we do not have ongoing performance obligations related to the achievement of the milestone earned. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either our performance subsequent to the inception of the arrangement to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from our performance subsequent to the inception of the arrangement to achieve the milestone,

(b) relates solely to past performance, and (c) is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement. See Note 3, “Collaboration Arrangements,” in the Notes to the Consolidated Financial Statements included in part I, , Item 1. “Financial Information “ on this Quarterly Report on Form 10-Q, for analysis of each milestone event deemed to be substantive or non-substantive.

Determining whether and when some of these revenue recognition criteria have been satisfied often involves assumptions and judgments that can have a significant impact on the timing and amount of revenue we report. Changes in assumptions or judgments or changes to the elements in an arrangement could cause a material increase or decrease in the amount of revenue that we report in a particular period.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk . Our exposure to market risk for changes in interest rates relates to our cash equivalents on deposit in highly liquid money market funds and investments in short-term marketable securities. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. We invest in high-quality financial instruments, which currently have weighted average maturity of less than one year. We do not use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations. Our investment portfolio is subject to interest rate risk and will fall in value if market interest rates rise. Nevertheless, due to the short duration of our investment portfolio, we believe an increase in the interest rates of one percentage point would not be material to our financial condition or results of operations.

In addition, we do not have any material exposure to foreign currency rate fluctuations as we operate primarily in the United States. Although we conduct some clinical trials and safety studies, and manufacture some active pharmaceutical product with vendors outside the United States, most of our transactions are denominated in U.S. dollars.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Based on their evaluation as of September 30, 2012, our chief executive officer and vice president, finance and controller have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) of the Securities Exchange Act of 1934, as amended) were effective at the reasonable assurance level to ensure that the information required to be disclosed by us in reports we are required to file under the Exchange Act was recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and Form 10-Q and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.

Changes in internal controls over financial reporting.

There were no changes in our internal control over financial reporting during the nine months ended September 30, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls.

Our management, including our chief executive officer and vice president, finance and controller, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Threshold Pharmaceuticals, Inc. have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control.

The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and we cannot be certain that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our chief executive officer and vice president, finance and controller have concluded, based on their evaluation, that our disclosure controls and procedures were sufficiently effective as of September 30, 2012 to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None

ITEM 1A. RISK FACTORS

Risks Related to Drug Discovery, Development and Commercialization

We are substantially dependent upon the success of TH-302.

We have focused our development activities on TH-302, and we do not presently have other compounds in clinical development. The failure of TH-302 to achieve successful clinical trial endpoints, delays in clinical or development of TH-302, unanticipated adverse side effects related to TH-302 or any other adverse developments or information related to TH-302 would significantly harm our business and the value of our common stock.

We are dependent upon our collaborative relationship with Merck KGaA to further develop, manufacture and commercializeTH-302.

Our success in developing, manufacturing and commercializing TH-302 will depend on our relationship with Merck KGaA. On February 2, 2012, we entered into a global license and co-development agreement with Merck KGaA to co-develop and commercialize TH-302. In the United States, we have primary responsibility for development of TH-302 in the soft tissue sarcoma indication. Threshold and Merck KGaA will jointly develop TH-302 in all other cancer indications being pursued, with Merck having primary responsibility. Threshold has rights to co-promote TH-302 in the United States, which it can exercise by giving notice during specified periods, and has the right to co-commercialize TH-302 if certain development or sales milestones are achieved.

We are subject to a number of risks associated with our dependence on our collaborative relationship with Merck, including:

- our ability, together with Merck, to achieve developmental and commercial milestones that will trigger payments to Threshold under the agreement;
- our ability to fund thirty percent (30%) of the global development expenses of TH-302;
- decisions by Merck regarding the amount and timing of resource expenditures for the development and commercialization of TH-302;
- possible disagreements with Merck as to development plans, clinical trials, regulatory marketing or sales;
- our need to develop a sales force to co-promote or co-commercialize TH-302 in the United States if we chose to do so, or our reliance on Merck to promote TH-302 in the United States;
- our inability to co-promote or co-commercialize TH-302 in any country outside the United States, which makes us solely dependent on Merck to promote and commercialize TH-302 in foreign countries;
- Merck's right to terminate the collaboration agreement on limited notice after the attainment of certain milestones or in certain circumstances involving our insolvency or material breach of the agreement;
- loss of significant rights if we fail to meet our obligations under the collaboration agreement;
- adverse regulatory or legal action against Merck resulting from failure to meet healthcare industry compliance requirements in the promotion and sale of TH-302, including federal and state reporting requirements;
- changes in key management personnel at Merck, including Merck's representatives on the joint steering committee or other committees that are administering the agreement; and
- possible disagreements with Merck regarding interpretation or enforcement of the agreement.

We have limited ability to direct Merck in its development of TH-302 and we may be unable to obtain any remedy against Merck if they fail to do so, or do so in a manner that we think is inadequate. Merck may not have sufficient expertise to develop, promote or obtain reimbursement for oncology products in the United States and may fail to devote appropriate resources to this task. Merck's development plans may be slower than or different from our plans were, when we were developing TH-302 on our own, leading to changes and delays in development and in the achievement of milestones that would impact payments to us under our agreement with Merck. In addition, Merck may establish a sales and marketing infrastructure for TH-302 that is not appropriate for the sales opportunity or establish this infrastructure too early or late in view of the ultimate timing of potential regulatory approvals. We are at risk with respect to the success or failure of Merck's development and commercial decisions related to TH-302 as well as the extent to which Merck succeeds in the execution of its strategy. Merck's development of other products may affect its incentives to develop and commercialize TH-302 and cause it to take actions that may be different from those we would take.

Under the terms of the agreement, we and Merck must agree on the development plan for TH-302. If we and Merck cannot agree, clinical trial progress could be significantly delayed. Further, if we cease funding development of TH-302 under the collaboration agreement, then we will be entitled to receive a royalty, but will lose our right to co-commercialize TH-302 and share in profits.

Merck has the right to terminate the agreement after certain milestones have been met on ninety (90) days prior written notice, or following our uncured material breach. If Merck terminates the agreement, then we shall become responsible for the costs of development and commercialization of TH-302, and there can be no assurance we would be able to do so, or to find another collaborator for the continued development and commercialization of TH-302.

If we are unable to maintain our collaborative relationship with Merck, we may be unable to continue development, manufacturing and marketing activities at our own expense. If we were able to do so on our own, this would significantly increase our capital and infrastructure requirements, would necessarily impose delays on development programs, may limit the indications we are able to pursue and could prevent us from effectively developing and commercializing TH-302.

Disputes with Merck may delay or prevent us from further developing, manufacturing or commercializingTH-302, and could lead to litigation against Merck, which could be time consuming and expensive.

Delays in our clinical trials could result in us not achieving anticipated developmental milestones when expected, increased costs and delay our ability to obtain regulatory approval and commercialize our product candidates.

Delays in our clinical trial enrollment or in the progression of our clinical trials could result in us not meeting previously announced clinical milestones and could materially impact our product development costs and milestone revenue and delay regulatory approval of our product candidates. We do not know whether planned clinical trials will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including:

- adverse safety events experienced during our clinical trials;
- a lower than expected frequency of clinical trial events;
- delays in obtaining clinical materials;
- slower than expected patient recruitment to participate in clinical trials;
- delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval,
- delays in obtaining regulatory approval to commence new trials; and
- disagreements with Merck KGaA on development plans.

If we do not successfully complete our clinical trials on schedule, the price of our common stock may decline.

Although we obtained a special protocol assessment for TH-302 for soft tissue sarcoma, a special protocol assessment does not guarantee any particular outcome from regulatory review, including any regulatory approval.

We have obtained an agreement with the Food and Drug Administration, or FDA, following a special protocol assessment, or SPA, for the registration trial for TH-302 for the treatment of soft tissue sarcoma in the United States. The SPA process allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a new drug application, or NDA, and provides a product sponsor with an agreement confirming that the design and size of a trial will be appropriate to form the primary basis of an efficacy claim for an NDA if the trial is performed according to the SPA. Even if we believe that the data from a clinical trial are supportive, an SPA is not a guarantee of approval, and we cannot be certain that the design of, or data collected from, a trial will be adequate to demonstrate safety and efficacy, or otherwise be sufficient to support regulatory approval. There can be no assurance that the terms of an SPA will ultimately be binding on the FDA, and the FDA is not obligated to approve an NDA, if any, even if the clinical outcome is positive. The FDA retains significant latitude and discretion in interpreting the terms of an SPA and the data and results from a clinical trial, and can require trial design changes or additional studies if issues arise essential to determining safety or efficacy. Data may subsequently become available that causes the FDA to reconsider the previously agreed upon scope of review and the FDA may have subsequent safety or efficacy concerns that override an SPA, and we can give no assurance that as clinical trials proceed or as part of an NDA review process, if any, the FDA will determine that a previously approved SPA is still valid.

Additionally, an SPA may be changed only with written agreement of the FDA and sponsor, and any further changes we may propose to the protocol will remain subject to the FDA's approval. The FDA may not agree to any such amendment and, even if they agree, they may request other amendments to the trial design that could require additional cost and time, as well as increase the degree of difficulty in reaching clinical endpoints. As a result, even with an SPA, we cannot be certain that the trial results will be found to be adequate to support an efficacy claim and product approval.

Pre-clinical studies and Phase 1 or 2 clinical trials of TH-302 may not predict the results of subsequent human clinical trials.

Pre-clinical studies, including studies of our product candidates in animal models of disease, may not accurately predict the result of human clinical trials of those product candidates. In particular, promising animal studies suggesting the efficacy of TH-302 for the treatment of different types of cancer may not accurately predict the ability of TH-302 to treat cancer effectively in humans. TH-302 may be found not to be efficacious in treating cancer, alone or in combination with other agents, when studied in human clinical trials. In addition, we will not be able to commercialize our drug candidates until we obtain FDA approval in the United States or approval by comparable regulatory agencies in Europe and other countries.

To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in early clinical trials, including Phase 2 trials, does not ensure that later clinical trials will be successful. Our initial results from clinical trials of TH-302 in Phase 1 and Phase 2 clinical trials also may not be confirmed by later analysis or subsequent larger clinical trials. In particular, positive results for progression-free survival in the

Phase 2b trial of TH-302 in pancreatic cancer may not predict the results of overall survival for patients in the same study or subsequent studies. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

Our product candidates must undergo rigorous clinical testing, the results of which are uncertain and could substantially delay or prevent us from bringing them to market.

Before we can obtain regulatory approval for a product candidate, we must undertake extensive clinical testing in humans to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory agencies. Clinical trials of new drug candidates sufficient to obtain regulatory marketing approval are expensive and take years to complete.

We cannot be certain of successfully completing clinical testing within the time frame we have planned, or at all. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our product candidates, including the following:

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing or to abandon programs;
- the results obtained in earlier stage clinical testing may not be indicative of results in future clinical trials;
- clinical trial results may not meet the level of statistical significance required by the FDA or other regulatory agencies;
- enrollment in our clinical trials for our product candidates may be slower than we anticipate, resulting in significant delays and additional expense;
- we, or regulators, may suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks; and
- the effects of our product candidates on patients may not be the desired effects or may include undesirable side effects or other characteristics that may delay or preclude regulatory approval or limit their commercial use, if approved.

Completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients, which is a function of many factors, including:

- the therapeutic endpoints chosen for evaluation;
- the eligibility criteria defined in the protocol;
- the perceived benefit of the investigational drug under study;
- the size of the patient population required for analysis of the clinical trial's therapeutic endpoints;
- our ability to recruit clinical trial investigators and sites with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- competition for patients by clinical trial programs for other treatments.

We may experience difficulties in enrolling patients in our clinical trials, which could increase the costs or affect the timing or outcome of these clinical trials. This is particularly true with respect to diseases with relatively small patient populations.

We are subject to significant regulatory approval requirements, which could delay, prevent or limit our ability to market our product candidates.

Our research and development activities, preclinical studies, clinical trials and the anticipated manufacturing and marketing of our product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in Europe and elsewhere. We require the approval of the relevant regulatory authorities before we may commence commercial sales of our product candidates in a given market. The regulatory approval process is expensive and time-consuming, and the timing of receipt of regulatory approval is difficult to predict. Our product candidates could require a significantly longer time to gain regulatory approval than expected, or may never gain approval. We cannot be certain that, even after expending substantial time and financial resources, we will obtain regulatory approval for any of our product candidates. A delay or denial of regulatory approval could delay or prevent our ability to generate product revenues and to achieve profitability.

Changes in regulatory approval policies during the development period of any of our product candidates, changes in, or the enactment of, additional regulations or statutes, or changes in regulatory review practices for a submitted product application may cause a delay in obtaining approval or result in the rejection of an application for regulatory approval.

Regulatory approval, if obtained, may be made subject to limitations on the indicated uses for which we may market a product. These limitations could adversely affect our potential product revenues. Regulatory approval may also require costly post-marketing follow-up studies. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping related to the product will be

subject to extensive ongoing regulatory requirements. Furthermore, for any marketed product, its manufacturer and its manufacturing facilities will be subject to continual review and periodic inspections by the FDA or other regulatory authorities. Failure to comply with applicable regulatory requirements may, among other things, result in fines, suspensions of regulatory approvals, product recalls, product seizures, operating restrictions and criminal prosecution.

Our product candidates are based on targeting the microenvironment of solid tumors and hematological malignancies, which currently is an unproven approach to therapeutic intervention.

Our product candidates are designed to target the microenvironment of solid tumors and hematological malignancies by, in the case of TH-302, harnessing hypoxia for selective toxin activation. We have not, nor to our knowledge has any other company, received regulatory approval for a drug based on this approach. We cannot be certain that our approach will lead to the development of approvable or marketable drugs.

In addition, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of drugs based on these targeting approaches, which could lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates.

Our product candidates may have undesirable side effects that prevent or delay their regulatory approval or limit their use if approved.

Anti-tumor drugs being developed by us, including TH-302, are expected to have undesirable side effects. For example, in clinical trials of TH-302, some patients have exhibited skin and/or mucosal toxicities that have in some cases caused patients to stop or delay therapy. The extent, severity and clinical significance of these or other undesirable side effects may not be apparent initially and may be discovered or become more significant during drug development or even post-approval. These expected side effects or other side effects identified in the course of our clinical trials or that may otherwise be associated with our product candidates may outweigh the benefits of our product candidates. Side effects may prevent or delay regulatory approval or limit market acceptance if our products are approved.

We have not yet gained sufficient experience with a commercial formulation of TH-302.

The formulation of TH-302 that we are using in our clinical trials was recently changed to address issues with a prior formulation that was subject to storage and handling requirements that were not be suitable for commercial product. The new formulation of TH-302 may be suitable for commercial product, but additional data will be required to verify this. There can be no assurance that it will be. If we are not able to develop a commercial formulation, we may delay registration of TH-302.

Orphan drug exclusivity affords us limited protection, and if another party obtains orphan drug exclusivity for the drugs and indications we are targeting, we may be precluded from commercializing our product candidates in those indications.

For those drugs that meet the eligible requirements, we intend to seek orphan drug designation for the cancer indications that our drug candidates are intended to treat. Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is defined by the FDA as a disease or condition that affects fewer than 200,000 individuals in the United States. The company that obtains the first FDA approval for a designated orphan drug indication receives marketing exclusivity for use of that drug for that indication for a period of seven years. Orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective, or if the manufacturer is unable to assure sufficient quantity of the drug. Orphan drug designation does not shorten the development or regulatory review time of a drug.

Orphan drug exclusivity may not prevent other market entrants. A different drug, or, under limited circumstances, the same drug may be approved by the FDA for the same orphan indication. The limited circumstances include an inability to supply the drug in sufficient quantities or where a new formulation of the drug has shown superior safety or efficacy. As a result, if our product were to be approved and receive orphan drug status, the FDA could still approve other drugs for use in treating the same indication covered by our product, which could create a more competitive market for us.

Moreover, due to the uncertainties associated with developing pharmaceutical products, we may not be the first to obtain marketing approval for any orphan drug indication. Even if we obtain orphan drug designation, if a competitor obtains regulatory approval for TH-302 for the same indication we are targeting before we do, we would be blocked from obtaining approval for that indication for seven years, unless our product is a new formulation of the drug that has shown superior safety or efficacy, or the competitor is unable to supply sufficient quantities.

Even if we obtain regulatory approval, our marketed drugs will be subject to ongoing regulatory review. If we or Merck KGaA fail to comply with continuing United States and foreign regulations, we or they could lose our approvals to market drugs and our business would be seriously harmed.

Following initial regulatory approval of any drugs we may develop, we and Merck KGaA will be subject to continuing regulatory review, including review of adverse drug experiences and clinical results that are reported after our drug products become commercially available. This would include results from any post-marketing tests or vigilance required as a condition of approval. The manufacturer and manufacturing facilities used to make any of our drug candidates will also be subject to periodic review and inspection by the FDA. If a previously unknown problem or problems with a product or a manufacturing and laboratory facility used by us is discovered, the FDA or foreign regulatory agency may impose restrictions on that product or on the manufacturing facility, including requiring us to withdraw the product from the market. Any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified,

can be marketed. Manufacturers of our products, if approved, will be subject to ongoing FDA requirements for submission of safety and other post-market information. If such manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw our regulatory approval;
- suspend or terminate any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on our operations;
- close the facilities of our contract manufacturers;
- seize or detain products or require a product recall, or
- revise or restrict labeling and promotion.

The FDA and foreign regulatory authorities may impose significant restrictions on the indicated uses and marketing of pharmaceutical products.

FDA rules for pharmaceutical promotion require that a company not promote an unapproved drug or an approved drug for an unapproved use. In addition to FDA requirements, regulatory and law enforcement agencies, such as the United States Department of Health and Human Services' Office of Inspector General and the United States Department of Justice, monitor and investigate pharmaceutical sales, marketing and other practices. For example, sales, marketing and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, as amended, and similar state laws. In recent years, actions by companies' sales forces and marketing departments have been scrutinized intensely to ensure, among other things, that actions by such groups do not qualify as "kickbacks" to healthcare professionals. A "kickback" refers to the provision of any item of value to a healthcare professional or other person in exchange for purchasing, recommending, or referring an individual for an item or service reimbursable by a federal healthcare program. These kickbacks increase the expenses of the federal healthcare program and may result in civil penalties, criminal prosecutions, and exclusion from participation in government programs, any of which would adversely affect our financial condition and business operations. In addition, even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Comparable laws also exist at the state level.

We are, and in the future may be, subject to new federal and state requirements to submit information on our open and completed clinical trials to public registries and databases.

In 1997, a public registry of open clinical trials involving drugs intended to treat serious or life-threatening diseases or conditions was established under the Food and Drug Administration Modernization Act, or FDMA, in order to promote public awareness of and access to these clinical trials. Under FDMA, pharmaceutical manufacturers and other clinical trial sponsors are required to post the general purpose of these clinical trials, as well as the eligibility criteria, location and contact information of the clinical trials. Since the establishment of this registry, there has been significant public debate focused on broadening the types of clinical trials included in this or other registries, as well as providing for public access to clinical trial results. A voluntary coalition of medical journal editors has adopted a resolution to publish results only from those clinical trials that have been registered with a no-cost, publicly accessible database, such as http://www.clinicaltrials.gov. The Pharmaceuticals and Research Manufacturers of America has also issued voluntary principles for its members to make results from certain clinical trials publicly available and has established a website for this purpose. Other groups have adopted or are considering similar proposals for clinical trial registration and the posting of clinical trial results. The state of Maine has enacted legislation, with penalty provisions, requiring the disclosure of results from clinical trials involving drugs marketed in the state, and similar legislation has been introduced in other states. Federal legislation was introduced in the fall of 2004 to expand http://www.clinicaltrials.gov and to require the inclusion of clinical trial results in this registry. In some states, such as New York, prosecutors have alleged that a lack of disclosure of clinical trial information constitutes fraud, and these allegations have resulted in settlements with pharmaceutical companies that include agreements to post clinical trial results. Our failure to comply with any clinical trial posting requirements could expose us to negative publicity, fines, and other penalties, all of which could materially harm our business.

We do not have a sales force and may not develop an effective one.

Our license and co-development agreement with Merck KGaA gives us the right, under certain circumstances, to co-promote or co-commercialize TH-302. We have no sales experience, and developing a sales force will require substantial expenditures. We may not be able to effectively recruit, train or retain sales personnel. We may not be able to effectively sell TH-302, if approved, and if we exercise our rights to do so, which could materially harm our business.

Risks Related to Our Financial Performance and Operations

We have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and our future profitability is uncertain.

We have incurred losses in each year since our inception in 2001, and we expect to incur losses for the foreseeable future. We have devoted, and will continue to devote for the foreseeable future, substantially all of our resources to research and development of our product candidates. For the nine months ended September 30, 2012, we had an operating loss of $14.0 million and a net loss of $99.5 million, including $85.6 million in non-cash expense related to the change in the fair value of outstanding warrants. Our cumulative net loss since our inception through September 30, 2012 was $351.7 million. Clinical trials and activities associated with discovery research are costly. We do not expect to generate any revenue from the commercial sales of our product candidates in the near term, and we expect to continue to have significant losses for the foreseeable future.

To attain ongoing profitability, we will need to develop products successfully and market and sell them effectively, or rely on other parties, such as Merck KGaA, to do so. We cannot predict when we will achieve ongoing profitability, if at all. We have never generated revenue from the commercial sales of our product candidates, and there is no guarantee that we will be able to do so in the future. If we fail to become profitable, or if we are unable to fund our continuing losses, we would be unable to continue our research and development programs.

Our financial results are likely to fluctuate from period to period, making it difficult to evaluate our stock based on financial performance.

Our quarterly and annual results of operations are likely to fluctuate based on the timing of milestones and payments under our license and development agreement with Merck KGaA. We believe that period-to-period comparisons of our operating results should not be relied upon as predictive of future performance. Our prospects must be considered in light of the risks, expenses and difficulties encountered by companies with no approved pharmaceutical products, and with products that are undergoing clinical development.

We are likely to require substantial additional funding and may be unable to raise capital when needed, which could force us to delay, reduce or eliminate our drug discovery, product development and commercialization activities.

Developing drugs, conducting clinical trials, and commercializing products is expensive. Our future funding requirements will depend on many factors, including:

- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;
- the progress and cost of our clinical trials and other research and development activities;
- the costs and timing of obtaining regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights;
- the cost and timing of securing manufacturing capabilities for our clinical product candidates and commercial products, if any; and
- the costs of lawsuits involving us or our product candidates.

We believe that our cash, cash equivalents and marketable securities will be sufficient to fund the Company's projected operating requirements for at least the next twelve months based upon current operating plans, milestone payment forecasts and spending assumptions. We expect that we will need to raise additional capital to support new in-house development programs or to in-license or otherwise acquire and develop additional products or programs. We intend to seek funds through additional arrangements with collaborators or others that may require us to relinquish rights to the products candidates that we might otherwise seek to develop or commercialize independently. We cannot be certain that we will be able to enter into any such arrangements on reasonable terms, if at all.

We may seek to raise capital through a variety of sources, including:

- the public equity market;
- private equity financing;
- collaborative arrangements;
- licensing arrangements; and/or
- public or private debt.

Our ability to raise additional funds will depend, in part on the outcome of our clinical trials and other clinical and regulatory events, as well as factors related to financial, economic, and market conditions, collaboration or license agreement with others and factors related to financial, economic and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on satisfactory terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through additional arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail or eliminate some or all of our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. In addition, we may have to delay, reduce the scope of or eliminate some of our research and development, which could delay the time to market for any of our product candidates, if adequate funds are not available.

If we are unable to secure additional financing on a timely basis or on terms favorable to us, we may be required to cease or reduce certain research and development projects, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. Insufficient funds may require us to delay, scale back, or eliminate some or all of our activities, and if we are unable to obtain additional funding, there is uncertainty regarding our continued existence.

Our success depends in part on retaining and motivating key personnel and, if we fail to do so, it may be more difficult for us to execute our business strategy. As a small organization we are dependent on key employees and may need to hire additional personnel to execute our business strategy successfully.

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management and scientific staff, particularly our Chief Executive Officer, Dr. Harold E. Selick, and Senior Vice President of Discovery Research, Dr. Mark G. Matteucci. We do not have an employment agreement with Drs. Selick or Matteucci. The loss of the services of Drs. Selick or Matteucci or one or more of our other key employees could delay or have an impact on the successful completion of our clinical trials or the development of additional product candidates.

As of September 30, 2012, we had 48 employees. Our success will depend on our ability to retain and motivate remaining personnel and hire additional qualified personnel when required. Competition for qualified personnel in the biotechnology field is intense. We face competition for personnel from other biotechnology and pharmaceutical companies, universities, public and private research institutions and other organizations. We may not be able to attract and retain qualified personnel on acceptable terms given the competition for such personnel. If we are unsuccessful in our retention, motivation and recruitment efforts, we may be unable to execute our business strategy.

Our facilities in California are located near an earthquake fault, and an earthquake or other natural disaster or resource shortage could disrupt our operations.

Important documents and records, such as hard copies of our laboratory books and records for our product candidates, are located in our corporate headquarters at a single location in South San Francisco, California, near active earthquake zones. In the event of a natural disaster, such as an earthquake, drought or flood, or localized extended outages of critical utilities or transportation systems, we do not have a formal business continuity or disaster recovery plan, and could therefore experience a significant business interruption. In addition, California from time to time has experienced shortages of water, electric power and natural gas. Future shortages and conservation measures could disrupt our operations and could result in additional expense. Although we maintain business interruption insurance coverage, the policy specifically excludes coverage for earthquake and flood.

Risks Related to Our Dependence on Third Parties

We rely on third parties to manufacture TH-302. If these parties do not manufacture the active pharmaceutical ingredients or finished drug products of satisfactory quality, in a timely manner, in sufficient quantities or at an acceptable cost, clinical development and commercialization of our product candidates could be delayed.

Under our license and co-development agreement with Merck KGaA, we are dependent on Merck for clinical and commercial supply of TH-302, except for clinical trials for United States approval of TH-302 for soft tissue sarcoma and for any other clinical trials for which we are responsible. In the latter case, we can obtain clinical supply directly from existing or new suppliers. Neither we nor Merck, have entered into any long term manufacturing or supply agreement for TH-302 or for any of our other product candidates. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our ability to develop and commercialize any product candidates on a timely and competitive basis.

We need to have sufficient TH-302 API and drug product to meet the clinical supply demands of our clinical trials. Additional clinical trial material continues to be manufactured as required. We have ordered additional API and drug product; however, we have experienced delays in the receipt of satisfactory drug product, and any additional delays we may experience in the receipt of satisfactory API or drug product could cause delays in our clinical trials, which would harm our business. In addition, we will need to obtain additional supplies of TH-302 API and drug product to complete our ongoing studies and any other additional trials. The need for additional supplies and preparation for registration may require scaling up and manufacturing process improvements in TH-302 API and drug product. The scaling up of the manufacturing processes for the TH-302 API may require facilities upgrades at our suppliers, which may lead to delays or disruption in supply, or delays in regulatory approval of TH-302. Changes to the formulation of TH-302 for our clinical trials may also require bridging studies to demonstrate the comparability of the new formulation with the old. These studies may delay our clinical trials and may not be successful. If we are not successful in procuring sufficient TH-302 clinical trial material, we may experience a significant delay in our TH-302 clinical program.

Merck will need to enter into additional agreements for additional supplies of TH-302 to complete clinical development and/or commercialize it or develop such capability itself. We cannot be certain that Merck can do so on favorable terms, if at all. The products will need to satisfy all current good manufacturing practice, or cGMP, regulations, including passing specifications. Merck’s inability to satisfy these requirements could delay our clinical programs.

If TH-302 or any of our other product candidates is approved by the FDA or other regulatory agencies for commercial sale, we or Merck as applicable, will need to have it manufactured in commercial quantities. It may not be possible to increase the manufacturing capacity for TH-302 or any of our other product candidates in a timely or economic manner successfully or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA and other regulatory agencies must review and approve. If Merck with respect to TH-302, or we with respect to our other product candidates, are unable to successfully increase the manufacturing capacity for such product candidate, the regulatory approval or commercial launch of that product candidate may be delayed, or there may be a shortage of supply which could limit sales.

In addition, if the facility or the equipment in the facility that produces our product candidates is significantly damaged or destroyed, or if the facility is located in another country and trade or commerce with such country is interrupted, we may be unable to replace the manufacturing capacity quickly or inexpensively. The inability to obtain manufacturing agreements, the damage or destruction of a facility on which we rely for manufacturing or any other delays in obtaining supply would delay or prevent us from completing our clinical trials and commercializing our current product candidates.

We have no control over our manufacturers' and suppliers' compliance with manufacturing regulations, and their failure to comply could result in an interruption in the supply of our product candidates.

The facilities used by our contract manufacturers must undergo an inspection by the FDA for compliance with cGMP regulations, before the respective product candidates can be approved. In the event these facilities do not receive a satisfactory cGMP inspection for the manufacture of our product candidates, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for such product candidate. In addition, our contract manufacturers, and any alternative contract manufacturer we may utilize, will be subject to ongoing periodic inspection by the FDA and corresponding state and foreign agencies for compliance with cGMP regulations, similar foreign regulations and other regulatory standards. We do not have control over our contract manufacturers' compliance with these regulations and standards. Any failure by our third-party manufacturers or suppliers to comply with applicable regulations could result in sanctions being imposed on them (including fines, injunctions and civil penalties), failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecution.

We rely on third parties to conduct some of our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates.

We may use clinical research organizations to assist in conduct of our clinical trials. There are numerous alternative sources to provide these services. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. This risk is heightened for clinical trials conducted outside of the United States, where it may be more difficult to ensure that clinical trials are conducted in compliance with FDA requirements. Any third-party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials and in our plans to file NDAs, the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented.

We are dependent on Eleison to develop and commercialize glufosfamide

We are dependent upon Eleison Pharmaceuticals, Inc., to whom we exclusively licensed glufosfamide in October 2009, to develop and commercialize glufosfamide. Any profit sharing or other payments to us under the Eleison license depend almost entirely upon the efforts of Eleison, which may not be able to raise sufficient funds to commence clinical development activities with glufosfamide. Even if Eleison is successful at raising initial funding, it may not be successful in developing and commercializing glufosfamide or raising sufficient funds for development and commercialization. We may also be asked to provide technical assistance related to the development of glufosfamide, which may divert our resources from other activities. If the Eleison license terminates in such a way that glufosfamide reverts to us and we seek alternative arrangements with one or more other parties to develop and commercialize glufosfamide, we may not be able to enter into such an agreement with another suitable third party or third parties on acceptable terms or at all.

Risks Related to Our Intellectual Property

Hypoxia activated prodrug technology is not a platform technology broadly protected by patents, and others may be able to develop competitive drugs using this approach.

Although we have US and foreign issued patents that cover certain hypoxia-targeted prodrugs, including TH-302, we have no issued patents or pending patent applications that would prevent others from taking advantage of hypoxia activated prodrug technology generally to discover and develop new therapies for cancer or other diseases. Consequently, our competitors may seek to discover and develop potential therapeutics that operate by mechanisms of action that are the same or similar to the mechanisms of action of our hypoxia activated prodrug product candidates.

We are dependent on patents and proprietary technology. If we fail to adequately protect this intellectual property or if we otherwise do not have exclusivity for the marketing of our products, our ability to commercialize products could suffer.

Our commercial success will depend in part on our ability to obtain and maintain patent protection sufficient to prevent others from marketing our product candidates, as well as to defend and enforce these patents against infringement and to operate without infringing the proprietary rights of others. We will only be able to protect our product candidates from unauthorized use by third parties to the extent that valid and enforceable patents cover our product candidates or their manufacture or use or if they are effectively protected by trade secrets. If our patent applications do not result in issued patents, or if our patents are found to be invalid, we will lose the ability to exclude others from making, using or selling the inventions claimed therein. We have a limited number of patents and pending patent applications.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States. The laws of many countries may not protect intellectual property rights to the same extent as United States laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We do not know whether any of our patent applications will result in the issuance of any patents and we cannot predict the breadth of claims that may be allowed in our patent applications or in the patent applications we may license from others.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents, and we may have to participate in expensive and protracted interference proceedings to determine priority of invention;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop identical, similar or alternative product candidates to any of our product candidates;
- our pending patent applications may not result in issued patents;
- our issued patents may not provide a basis for commercially viable products or may not provide us with any competitive advantages or may be challenged by third parties;
- others may design around our patent claims to produce competitive products that fall outside the scope of our patents;
- we may not develop additional patentable proprietary technologies related to our product candidates; or
- the patents of others may prevent us from marketing one or more of our product candidates for one or more indications that may be valuable to our business strategy.

Moreover, an issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing the same or related product candidates or could limit the length of the term of patent protection of our product candidates. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. Patent term extensions may not be available for these patents.

We rely on trade secrets and other forms of non-patent intellectual property protection. If we are unable to protect our trade secrets, other companies may be able to compete more effectively against us.

We rely on trade secrets to protect certain aspects of our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory approval process. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secret information is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to or may not protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we are sued for infringing intellectual property rights of third parties or if we are forced to engage in an interference proceeding, it will be costly and time consuming, and an unfavorable outcome in that litigation or interference would have a material adverse effect on our business.

Our ability to commercialize our product candidates depends on our ability to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign patents and patent applications, which are owned by third parties, exist in the general field of cancer therapies or in fields that otherwise may relate to our product candidates. If we are shown to infringe, we could be enjoined from use or sale of the claimed invention if we are unable to prove that the patent is invalid. In addition, because patent applications can take many years to issue, there may be currently pending patent applications, unknown to us, which may later result in issued patents that our product candidates may infringe, or which may trigger an interference proceeding regarding one of our owned or licensed patents or applications. There could also be existing patents of which we are not aware that our product candidates may inadvertently infringe or which may become involved in an interference proceeding.

The biotechnology and pharmaceutical industries are characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. For so long as our product candidates are in clinical trials, we believe our clinical activities fall within

the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our clinical investigational drug product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. While we attempt to ensure that our active clinical investigational drugs and the methods we employ to manufacture them, as well as the methods for their use we intend to promote, do not infringe other parties' patents and other proprietary rights, we cannot be certain they do not, and competitors or other parties may assert that we infringe their proprietary rights in any event.

We may be exposed to future litigation based on claims that our product candidates, or the methods we employ to manufacture them, or the uses for which we intend to promote them, infringe the intellectual property rights of others. Our ability to manufacture and commercialize our product candidates may depend on our ability to demonstrate that the manufacturing processes we employ and the use of our product candidates do not infringe third-party patents. If third-party patents were found to cover our product candidates or their use or manufacture, we could be required to pay damages or be enjoined and therefore unable to commercialize our product candidates, unless we obtained a license. A license may not be available to us on acceptable terms, if at all.

Risks Related To Our Industry

If our competitors are able to develop and market products that are more effective, safer or more affordable than ours, or obtain marketing approval before we do, our commercial opportunities may be limited.

Competition in the biotechnology and pharmaceutical industries is intense and continues to increase, particularly in the area of cancer treatment. Most major pharmaceutical companies and many biotechnology companies are aggressively pursuing oncology development programs, including traditional therapies and therapies with novel mechanisms of action. Our cancer product candidates face competition from established biotechnology and pharmaceutical companies, including Sanofi, AstraZeneca PLC, Genentech (a member of the Roche Group), Bayer Corporation, Celgene Corporation, Eli Lilly and Company and Pfizer, Inc. and from generic pharmaceutical manufacturers. In particular, our drug candidate for pancreatic cancer will compete with Gemzar®, marketed by Eli Lilly and Company, Tarceva®, cisplatin, paclitaxel, ifosfamide, and 5-flurouracil, or 5-FU, a generic product which is sold by many manufacturers. Several drugs marketed for different indications, such as Camptosar ®, marketed by Pfizer, Inc., Erbitux ®, marketed by Imclone Systems Inc. and Bristol-Myers Squibb Company, Taxotere®, marketed by Sanofi, DTIC-Dome ®, marketed by Bayer Pharmaceuticals Corporation, Xeloda ®, marketed by Hoffmann-LaRoche, Inc., Avastin®, marketed by Genentech (a member of the Roche Group), Nexavar®, marketed by Onyx Pharmaceuticals, Inc. and Bayer AG, and Alimta ®, marketed by Eli Lilly and Company, are under investigation or have completed investigation as combination therapies or monotherapy for pancreatic, prostate, ovarian, non small cell lung and small cell lung cancers, melanoma and soft tissue sarcoma. In addition, Proacta Inc. has a compound under clinical investigation that targets the hypoxic zones of tumors, as our TH-302 clinical product candidate is intended to do. Celgene Corporation is conducting clinical trials of Abraxene ® as a combination therapy for first-line treatment of pancreatic cancer and Clovis Oncology is developing CO-101 for first-line treatment of pancreatic cancer. ZIOPHARM Oncology Inc. is conducting clinical trials of a compound as a combination therapy for first-line treatment of advanced soft tissue sarcoma.

We also face potential competition from academic institutions, government agencies and private and public research institutions engaged in the discovery and development of drugs and therapies. Many of our competitors have significantly greater financial resources and expertise in research and development, preclinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing, sales and marketing than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies.

Our competitors may succeed in developing products that are more effective, have fewer side effects and are safer or more affordable than our product candidates, which would render our product candidates less competitive or noncompetitive. These competitors also compete with us to recruit and retain qualified scientific and management personnel, establish clinical trial sites and patient registration for clinical trials, as well as to acquire technologies and technology licenses complementary to our programs or advantageous to our business. Moreover, competitors that are able to achieve patent protection obtain regulatory approvals and commence commercial sales of their products before we do, and competitors that have already done so, may enjoy a significant competitive advantage.

There is a substantial risk of product liability claims in our business. If we do not obtain sufficient liability insurance, a product liability claim could result in substantial liabilities.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of human therapeutic products. Regardless of merit or eventual outcome, product liability claims may result in:

- delay or failure to complete our clinical trials;
- withdrawal of clinical trial participants;
- decreased demand for our product candidates;
- injury to our reputation;
- litigation costs;
- substantial monetary awards against us; and
- diversion of management or other resources from key aspects of our operations.

If we succeed in marketing products, product liability claims could result in an FDA investigation of the safety or efficacy of our products, our manufacturing processes and facilities or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, or limitations on the indications, for which they may be used, or suspension or withdrawal of approval.

We have product liability insurance that covers our clinical trials up to a $5 million annual aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates or any other compound that we may develop. However, insurance coverage is expensive and we may not be able to maintain insurance coverage at a reasonable cost or at all, and the insurance coverage that we obtain may not be adequate to cover potential claims or losses.

Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our product candidates upon their commercial introduction, which would negatively affect our ability to achieve profitability.

Our product candidates may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any approved products will depend on a number of factors, including:

- the effectiveness of the product;
- the prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the price of the product, both in absolute terms and relative to alternative treatments; and
- sufficient third-party coverage or reimbursement.

If our product candidates receive regulatory approval but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate product revenues sufficient to attain profitability.

If third-party payors do not adequately reimburse patients for any of our product candidates, if approved for marketing, we may not be successful in selling them.

Our ability to commercialize any products successfully will depend in part on the extent to which reimbursement will be available from governmental and other third-party payors, both in the United States and in foreign markets. Even if we succeed in bringing one or more products to the market, the amount reimbursed for our products may be insufficient to allow us to compete effectively and could adversely affect our profitability.

Reimbursement by a governmental and other third-party payor may depend upon a number of factors, including a governmental or other third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a product from each third-party and governmental payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to obtain reimbursement.

Eligibility for coverage does not imply that any drug product will be reimbursed in all cases or at a rate that allows us to make a profit. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not become permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost drugs that are already reimbursed, may be incorporated into existing payments for other products or services and may reflect budgetary constraints and/or Medicare or Medicaid data used to calculate these rates. Net prices for products also may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

The health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products. The Medicare Prescription Drug, Improvement and Modernization Act of 2003, or MMA, became law in November 2003 and created a broader prescription drug benefit for Medicare beneficiaries. The MMA also contains provisions intended to reduce or eliminate delays in the introduction of generic drug competition at the end of patent or nonpatent market exclusivity. The impact of the MMA on drug prices and new drug utilization over the next several years is unknown. The MMA also made adjustments to the physician fee schedule and the measure by which prescription

drugs are presently paid, changing from Average Wholesale Price to Average Sales Price. The effects of these changes are unknown but may include decreased utilization of new medicines in physician prescribing patterns, and further pressure on drug company sponsors to provide discount programs and reimbursement support programs. There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect reimbursement levels for our future products. In addition, the Centers for Medicare & Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our profitability will be negatively affected.

We may incur significant costs complying with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

Our research and development activities use biological and hazardous materials that are dangerous to human health and safety or the environment. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes resulting from these materials. We are also subject to regulation by the Occupational Safety and Health Administration, or OSHA, the California and federal environmental protection agencies and to regulation under the Toxic Substances Control Act. OSHA or the California or federal Environmental Protection Agency, or EPA, may adopt regulations that may affect our research and development programs. We are unable to predict whether any agency will adopt any regulations that could have a material adverse effect on our operations. We have incurred, and will continue to incur, capital and operating expenditures and other costs in the ordinary course of our business in complying with these laws and regulations.

Although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could significantly exceed our insurance coverage.

Risks Related To Our Common Stock

A significant number of shares of our common stock are subject to issuance upon exercise of outstanding warrants, which upon such exercise would result in dilution to our security holders.

On March 16, 2011, we issued warrants to purchase an aggregate of 5,725,227 shares of our common stock, at an exercise price of $2.46 per share. On October 5, 2009, we issued warrants to purchase an aggregate of 7,329,819 shares of our common stock, at an exercise price of $2.23 per share, which exercise price was subsequently reduced to $2.05 per share on March 16, 2011 under the anti-dilution provisions of the warrants as a result of our March 2011 registered offering of common stock and warrants. In addition, on August 29, 2008, we issued warrants to purchase an aggregate of 3,588,221 shares of our common stock, at an exercise price of $2.34 per share, which exercise price was subsequently reduced to $1.86 per share on October 5, 2009 under the anti-dilution provisions of the warrants as a result of our October 2009 private placement. As of September 30, 2012, warrants to purchase 1,346,287 shares of common stock issued in March 2011, warrants to purchase 3,041,879 shares of common stock issued in October 2009 and warrants to purchase 529,410 shares of common stock issued in August 2008 had been exercised. The exercise price and/or the number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances, including certain issuances of securities at a price equal to less than the then current exercise price (which could result from, for example, sales under our at market issuance sales agreement dated October 29, 2010 as amended), subdivisions and stock splits, stock dividends, combinations, reorganizations, reclassifications, consolidations, mergers or sales of properties and assets and upon the issuance of certain assets or securities to holders of our common stock, as applicable. Although we cannot determine at this time which of these warrants will ultimately be exercised, it is reasonable to assume that such warrants will be exercised only if the exercise price is below the market price of our common stock. To the extent the warrants are exercised, additional shares of our common stock will be issued that will be eligible for resale in the public market, which will result in dilution to our security holders. The issuance of additional securities could also have an adverse effect on the market price of our common stock.

The price of our common stock has been and may continue to be volatile.

The stock markets in general, the markets for biotechnology stocks and, in particular, the stock price of our common stock, have experienced extreme volatility.

Price declines in our common stock could result from general market and economic conditions and a variety of other factors, including:

- adverse results or delays in our clinical trials;
- announcements of FDA non-approval of our product candidates, or delays in the FDA or other foreign regulatory agency review process;

- our or Merck's failure to meet milestones that would have given rise to payments under our agreement with Merck;
- announcements by Merck related to the development of TH-302 or announcements related to our agreement with Merck;
- adverse actions taken by regulatory agencies with respect to our product candidates, clinical trials, manufacturing processes or sales and marketing activities;
- announcements of technological innovations, patents or new products by our competitors;
- regulatory developments in the United States and foreign countries;
- any lawsuit involving us or our product candidates;
- announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;
- developments concerning any strategic alliances or acquisitions we may enter into;
- actual or anticipated variations in our operating results;
- changes in recommendations by securities analysts or lack of analyst coverage;
- deviations in our operating results from the estimates of analysts;
- sales of our common stock by our executive officers, directors and five percent stockholders or sales of substantial amounts of common stock; and
- loss of any of our key scientific or management personnel.

In the past, following periods of volatility in the market price of a particular company's securities, litigation has often been brought against that company. Any such lawsuit could consume resources and management time and attention, which could adversely affect our business.

If our officers, directors and largest stockholders choose to act together, they may be able to control our management and operations, acting in their best interests and not necessarily those of other stockholders.

As of December 31, 2011, our officers, directors and other affiliates beneficially owned approximately 15.9% of our outstanding common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of Delaware law, where we are incorporated, our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include:

- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders;
- providing for a classified board of directors with staggered terms;
- requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws;
- eliminating the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

In addition, in August 2006, our board of directors adopted a preferred shares rights agreement, the provisions of which could make it more difficult for a potential acquirer to consummate a transaction without the approval of our board of directors.

We have never paid dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

We may not maintain the listing of our common stock on the NASDAQ Capital Market.

Our ability to raise additional capital may be dependent upon our stock being quoted on the NASDAQ Capital Market. Previously, we had fallen out of compliance with continued listing requirements because our common stock did not comply with the $1.00 minimum bid price requirement for continued listing set forth in NASDAQ Marketplace Rule 5450(a)(1) (formerly Rule 4450(a)(5)). To regain compliance, effective August 20, 2008, we implemented a 1-for-6 reverse stock split of our common stock. After that date, our common stock traded above the minimum $1.00 bid price for at least ten consecutive business days and on September 5, 2008, the NASDAQ Stock Market notified us that we had regained compliance with the minimum bid price requirements. Even though we regained compliance with the minimum bid price, we cannot assure that we will be able to maintain compliance with the minimum bid price requirement or other listing requirements in the future, and our failure to do so could result in the delisting of our shares from the NASDAQ Capital Market.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibits

The exhibits listed on the accompanying index to exhibits are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.

Exhibit Number	Description
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a) of Harold E. Selick.
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a) of Joel A. Fernandes.
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Harold E. Selick.
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Joel A. Fernandes.
101.INS	XBRL Instance Document++
101.SCH	XBRL Taxonomy Extension Schema Document++
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document++
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document++
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document++
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document++

++ These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

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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.

Date: November 2, 2012

/s/ Harold E. Selick

Harold E. Selick., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 2, 2012

/s/ Joel A. Fernandes

Joel A. Fernandes
Vice President, Finance and Controller
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

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Exhibit 31.1

CERTIFICATION

I, Harold E. Selick, certify that:

1. I have reviewed this Form 10-Q of Threshold Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2012

/s/ Harold E. Selick
Harold E. Selick, Ph.D.
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Joel A. Fernandes, certify that:

1. I have reviewed this Form 10-Q of Threshold Pharmaceuticals, Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2012

/s/ Joel A. Fernandes
Joel A. Fernandes
Vice President, Finance and Controller
(Principal Financial and Accounting Officer)

Exhibit 32.1

THRESHOLD PHARMACEUTICALS, INC.

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Threshold Pharmaceuticals, Inc (the "Company") on Form 10-Q for the quarter ended September 30, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Harold E. Selick, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 2, 2012

/s/ Harold E. Selick
Harold E. Selick, Ph.D.
Chief Executive Officer

Exhibit 32.2

THRESHOLD PHARMACEUTICALS, INC.

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Threshold Pharmaceuticals, Inc (the "Company") on Form 10-Q for the quarter ended September 30, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joel A. Fernandes, Senior Director, Finance and Controller of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 2, 2012

/s/ Joel A. Fernandes
Joel A. Fernandes
Vice President, Finance and Controller

(Principal Financial and Accounting Officer)