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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, 2009

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.)**

1300 Seaport Boulevard, Suite 500
Redwood City, CA 94063
(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, 2009, there were 33,562,448 shares of common stock, par value $0.001 per share, of Threshold Pharmaceuticals, Inc. outstanding.

Threshold Pharmaceuticals, Inc.

FORM 10-Q
THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2009

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

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PART I. FINANCIAL INFORMATION

ITEM I. FINANCIAL STATEMENTS

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

	September 30, 2009	December 31, 2008 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,205	$ 15,466
Marketable securities	4,284	6,871
Prepaid expenses and other current assets (Note 7)	11,135	518
Total current assets	19,624	22,855
Property and equipment, net	647	1,168
Restricted cash and other assets	609	508
Total assets	$ 20,880	$ 24,531
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 517	$ 840
Accrued clinical and development expenses	1,274	544
Accrued liabilities (Note 7)	11,439	842
Notes payable, current portion	—	337
Total current liabilities	13,230	2,563
Warrant liability	3,576	—
Deferred rent	505	554
Total liabilities	17,311	3,117
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 2,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value, shares authorized: 50,000,000 shares; issued and outstanding: 15,231,362 shares at September 30, 2009 and 15,214,044 shares at December 31, 2008	15	15
Additional paid-in capital	206,612	204,999
Deferred stock-based compensation	—	(6)
Accumulated other comprehensive income	2	19
Deficit accumulated during the development stage	(203,060)	(183,613)
Total stockholders' equity	3,569	21,414
Total liabilities and stockholders' equity	$ 20,880	$ 24,531

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

Threshold Pharmaceuticals, Inc.
(A DEVELOPMENT STAGE ENTERPRISE)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine months Ended September 30,		Cumulative Period from October 17, 2001 (date of inception) to September 30,
	2009	2008	2009	2008	2009
Revenue	$ —	$ 362	$ —	$ 1,080	$ 5,027
Operating expenses:					
Research and development	3,973	3,672	11,719	9,873	155,585
General and administrative	1,235	1,344	4,115	5,067	57,161
Total operating expenses	5,208	5,016	15,834	14,940	212,746
Loss from operations	(5,208)	(4,654)	(15,834)	(13,860)	(207,719)
Interest income, net	12	109	73	414	8,840
Interest and other expense	(957)	(13)	(3,154)	(52)	(3,649)
Net loss	(6,153)	(4,558)	(18,915)	(13,498)	(202,528)
Dividend related to beneficial conversion feature of redeemable convertible preferred stock	—	—	—	—	(40,862)
Net loss attributable to common stockholders	$ (6,153)	$(4,558)	$(18,915)	$(13,498)	$ (243,390)
Net loss per common share, basic and diluted	$ (0.40)	$ (0.49)	$ (1.24)	$ (1.86)	
Weighted average number of shares used in per common share calculations: basic and diluted	15,227	9,392	15,223	7,276	

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

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

	Nine Months Ended September 30,		Cumulative Period from October 17, 2001 (date of inception) to September 30,
	2009	2008	2009
Cash flows from operating activities:			
Net loss	$(18,915)	$(13,498)	$ (202,528)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	521	725	4,251
Stock-based compensation expense	1,601	2,566	37,395
Change in common stock warrant value	3,044	—	3,044
Amortization of debt issuance costs	—	—	44
Loss on sale of investments, property and equipment	—	—	(27)
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(10,636)	(11)	(11,179)
Accounts payable	(323)	(667)	517
Accrued clinical and development expenses	730	(244)	1,274
Accrued liabilities	10,515	(60)	11,357
Deferred rent	(49)	(5)	505
Deferred revenue	—	(1,078)	—
Net cash used in operating activities	(13,512)	(12,272)	(155,347)
Cash flows from investing activities:			
Acquisition of property and equipment	(23)	(30)	(4,989)
Acquisition of marketable securities	(7,622)	(4,825)	(153,231)
Proceeds from sales and maturities of marketable securities	10,215	12,500	149,067
Restricted cash	—	—	(483)
Net cash provided by (used in) investing activities	2,570	7,645	(9,636)
Cash flows from financing activities:			
Proceeds from redeemable convertible preferred stock, net	—	—	49,839
Proceeds from issuance of common stock and warrants, net of offering expenses	18	16,845	119,349
Proceeds from issuance of notes payable	—	—	3,616
Repayment of notes payable	(337)	(675)	(3,616)
Net cash (used in) provided by financing activities	(319)	16,170	169,188
Net increase (decrease) in cash and cash equivalents	(11,261)	11,543	4,205
Cash and cash equivalents, beginning of period	15,466	11,404	—
Cash and cash equivalents, end of period	$ 4,205	$ 22,947	$ 4,205
Supplemental schedule of non-cash investing and financing activities			
Deferred stock-based compensation	$ —	$ —	$ 19,511
Cumulative effect of change in accounting principle — Reclassification of common stock warrants to liability upon adoption of EITF 07-5	$ 532	$ —	$ 532
Change in unrealized gain (loss) on marketable securities	$ (17)	$ (16)	$ 2
Conversion of redeemable preferred stock	$ —	$ —	$ 49,839
Dividend related to beneficial conversion feature of redeemable convertible preferred stock.	$ —	$ —	$ 40,862

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

Threshold Pharmaceuticals, Inc.
(A DEVELOPMENT STAGE ENTERPRISE)
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company

Threshold Pharmaceuticals, Inc. (the "Company") is a biotechnology company focused on the discovery and development of drugs targeting the microenvironment of solid tumors. 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.

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, 2008 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, 2008 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 13, 2009.

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. In connection with the preparation of the condensed consolidated financial statements and in accordance with ASC 855, *"Subsequent Events",* the Company evaluated subsequent events after the balance sheet date of September 30, 2009 through November 5, 2009, which is the date that the financial statements were issued.

Liquidity

The Company has product candidates in various stages of development as well as discovery and, since inception, has devoted substantially all of its time and efforts to performing research and development, raising capital and recruiting personnel. The accompanying consolidated financial statements of the Company were prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred significant losses since its inception. At September 30, 2009, the Company had an accumulated deficit of $203.1 million. On October 5, 2009, the Company sold to certain investors an aggregate of 18,324,599 shares of its common stock for a purchase price equal to $1.86 per share and, for a purchase price equal $0.05, warrants exercisable for a total of 7,329,819 shares of its common stock with an exercise price equal to $2.23 per share (subject to adjustment). The Company received aggregate gross proceeds equal to $35.0 million in connection with the offering. Net proceeds generated from the offering are expected to be approximately $33.1 million. See further discussion of the offering in Note 9 – Subsequent Events.

The Company expects to need to raise additional capital or incur indebtedness to continue to fund its future operations. The Company 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.

The Company's ability to raise additional funds will depend on its clinical and regulatory events, its ability to identify promising 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. If adequate funds are not available, the Company may be required to significantly reduce or refocus its operations or to obtain funds through arrangements that may require the Company to relinquish rights to certain of its products, technologies or potential markets, any of which could delay or require that the Company curtail its development programs or otherwise have a material adverse effect on its business, financial condition and results of operations. In addition, the Company may have to delay, reduce the scope or eliminate some of its research and development, which could delay the time to market for any of its product candidates, if such adequate funds are not available. 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.

Recent Accounting Pronouncements

In October 2009, the FASB issued Accounting Standards Update, 2009-13, Revenue Recognition (Topic 605):*Multiple Deliverable Revenue Arrangements – A Consensus of the FASB Emerging Issues Task Force."* This update provides application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. The Company will be required to apply this guidance prospectively for revenue arrangements entered into or materially modified after January 1, 2011; however, earlier application is permitted. The Company has not determined the impact that this update may have on its financial statements.

On July 1, 2009, the Financial Accounting Standards Board ("FASB") issued guidance now codified as FASB Accounting Standards Codification ("ASC") 105-10, "*Generally Accepted Accounting Principles*" ("ASC 105-10") (the "Codification"). ASC 105-10 establishes the exclusive authoritative reference for U.S. GAAP for use in financial statements, except for SEC rules and interpretive releases, which are also authoritative GAAP for SEC registrants. The Codification superseded all existing non-SEC accounting and reporting standards. The Company has included the references to the Codification, as appropriate, in these consolidated financial statements.

In April 2009, the FASB issued guidance now codified as ASC 820,*"Fair Value Measurements and Disclosures,"* ASC 320, *"Investments – Debt and Equity Securities" and* ASC 825, *"Financial Instruments,"* that was intended to provide additional application guidance and enhance disclosures about fair value measurements and impairments of securities. ASC 820 clarifies the objective and method of fair value measurement even when there has been a significant decrease in market activity for the asset being measured. ASC 320 establishes a new model for measuring other-than-temporary impairments for debt securities, including establishing criteria for when to recognize a write-down through earnings versus other comprehensive income. ASC 825 expands the fair value disclosures required for all financial instruments to interim periods. The new guidance in these three ASC topics was effective for interim and annual reporting periods ending after June 15, 2009. The implementation did not have a material impact on the Company's financial statements.

NOTE 2 — NET LOSS PER COMMON SHARE

Basic net loss per common share is computed by dividing net loss per share by the weighted-average number of vested 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, warrants and common stock subject to repurchase. 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,	
	2009	2008	2009	2008
Numerator:				
Net loss	$ (6,153)	$(4,558)	$(18,915)	$(13,498)
Denominator:				
Weighted average common shares outstanding	15,227	9,394	15,223	7,287
Less: Weighted average unvested common shares subject to repurchase	—	(2)	—	(11)
Denominator for basic and diluted calculations	15,227	9,392	15,223	7,276
Basic and diluted net loss per share	$ (0.40)	$ (0.49)	$ (1.24)	$ (1.86)

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

	As of September 30,	
	2009	2008
Shares issuable upon exercise of warrants	3,588	3,588
Shares issuable upon exercise of stock options	940	640
Shares issuable related to the ESPP	31	7
Common shares subject to repurchase	—	1

NOTE 3 — STOCKHOLDERS' EQUITY

Common Stock Warrants

On August 29, 2008, the Company sold to certain investors an aggregate of 8,970,574 shares of its common stock for a purchase price equal to $2.04 per share for aggregate gross proceeds equal to $18.3 million in connection with the offering. Net proceeds generated from the offering were $16.8 million. As part of the sale of common stock, the Company also issued warrants exercisable for a total of 3,588,221 shares of its common stock to the investors. The warrants have a five-year term and an exercise price equal to $2.34 per share of common stock. 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, 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. The common stock and warrants were previously recorded in stockholders equity in accordance with ASC 815, *"Derivatives and Hedging"* and ASC 825, *"Financial instruments."*

In June 2008, the FASB issued new 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 new guidance in ASC 815 was effective for financial statements issued for fiscal years beginning after December 15, 2008. The adoption of the new guidance on January 1, 2009, resulted in the reclassification of the Company's outstanding warrants from stockholders' equity to liabilities, which requires the warrants to be fair valued at each reporting period, with the changes in fair value recognized as interest and other expense in the Company's consolidated statement of operations.

At January 1, 2009 and September 30, 2009, the Company had warrants outstanding to purchase 3,588,221 shares of common stock. The Company determined the fair value of the warrants using a Black Scholes valuation model. The fair value of these warrants on the date of adoption of January 1, 2009 and on September 30, 2009 was determined using a Black Scholes valuation model with the following assumptions:

	January 1, 2009	September 30, 2009
Risk-free interest rate	1.72%	1.88%
Expected life (in years)	4.66	3.92
Dividend yield	—	—
Volatility	70%	83%
Stock price	$ 0.57	$ 1.81

On January 1, 2009, Company recorded a cumulative effect of change in accounting principle adjustment to its deficit accumulated during development stage of $0.5 million and a corresponding reclassification of the Company's outstanding warrants from stockholder's equity to warrant liability. In addition, the change in fair value of the warrants resulted in a $1.0 million and a $3.0 million change to interest and other expense in the consolidated statement of operations and a corresponding increase to the warrant liability for the three and nine months ended September 30, 2009, respectively.

Reverse Stock Split

On August 13, 2008, the Company's Board of Directors approved a 1-for-6 reverse split of its common stock, following approval by the Company's stockholders on May 13, 2008. The reverse stock split was effective August 20, 2008. All common share and per share amounts contained in the accompanying condensed consolidated financial statements have been retroactively adjusted to reflect the reverse stock split.

NOTE 4 — STOCK BASED COMPENSATION

The Company recognizes stock-based compensation in accordance with ASC 815, *"Compensation – Stock Compensation,"* using the modified prospective transition method, except for options granted prior to the Company's initial public offering in February 2005, for which the fair value was determined for disclosure purposes using the minimum value method. Under this transition method, stock-based compensation cost recognized for the three and nine months ended September 30, 2009 and 2008 includes:

- compensation cost for all unvested stock-based awards as of January 1, 2006 that were granted subsequent to the Company's initial public offering in February 2005, and prior to January 1, 2006, that were earned during the three and nine months ended September 30, 2009 and 2008, based on the recognition of the grant date fair value estimated in accordance with ASC 815 over the service period, which is generally the vesting period.
- compensation cost for all stock-based awards granted or modified subsequent to January 1, 2006, that were earned during the three and nine months ended September 30, 2009 and 2008, based on the recognition of the grant date fair value estimated in accordance with ASC 815 over the service period, which is generally the vesting period; and
- compensation cost for options granted prior to the Company's initial public offering in February 2005 that were earned during the three and nine months ended September 30, 2009 and 2008, based on the grant date intrinsic value over the service period, which is generally the vesting period, in accordance with ASC 815.

In addition, ASC 815 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of the new guidance on January 1, 2006, the Company accounted for forfeitures upon occurrence.

Stock-based compensation expense recognized in the unaudited condensed consolidated statement of operations related to stock options and ESPP was $0.5 million and $1.6 million for the three and nine months ended September 30, 2009, respectively, and was $0.7 million and $2.6 million for the three and nine months ended September 30, 2008, respectively. Stock-based compensation expense related to options granted prior to the initial public offering that were valued using the intrinsic value method in accordance with the provisions of APB 25 was $6,000 for the three and nine months ended September 30, 2009, respectively, and was $0.1 million and $0.8 million for the three and nine months ended September 30, 2008, 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, 2009 and 2008:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Employee Stock Options				
Risk-free interest rate	1.70%	2.93%	1.70%	3.12%
Expected term (in years)	5.17	6.08	5.17	5.97
Dividend yield	—	—	—	—
Volatility	84%	83%	84%	83%
Weighted-average fair value of stock options granted	$ —	$ 1.28	$ 0.50	$ 2.14
Employee Stock Purchase Plan (ESPP):				
Risk-free interest rate	0.71%	2.27%	0.71%	2.14%
Expected term (in years)	1.25	1.25	1.25	1.25
Dividend yield	—	—	—	—
Volatility	67%	67%	67%	67%
Weighed-average fair value of ESPP purchase rights	$ 0.51	$ 0.82	$ 0.52	$ 0.94

To determine the expected term of the Company's employee stock options granted during the three and nine months ended September 30, 2009 and 2008, the Company utilized the simplified approach as defined by SEC Staff Accounting Bulletin No. 107, *"Share-Based Payment"* ("SAB 107"). 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 awards. To determine the expected stock price volatility for the Company's stock options for the three and nine months ended September 30, 2009 and 2008, the Company examined historical volatilities for industry peers as the Company did not have sufficient trading history for its common stock and utilized a median of the historical volatilities of the Company's industry peers. The Company will continue to analyze the expected stock price volatility and expected term assumption as more historical data for the Company's common stock becomes available. The expected stock price volatility for the Company's ESPP for the three and nine months and ended September 30, 2009 and 2008 was based on expected stock price volatilities of the Company's industry peers, as well as the historical volatility of the Company's common stock as the Company had trading history for its common stock in excess of the expected term of the stock purchase rights under the ESPP. The fair value of all the Company's stock based award assumes no dividends as the Company does not anticipate paying cash dividends on its common stock.

Employee Stock-based Compensation Expense

Deferred stock-based compensation Prior to the initial public offering, the Company issued options to certain employees with exercise prices below the fair market value of the Company's common stock at the date of grant, determined with hindsight. In accordance with the requirements of ASC 815, the Company recorded deferred stock-based compensation aggregating $19.5 million, net of forfeitures for the difference between the exercise price of the stock option and the fair market value of the Company's stock at the date of grant. This deferred stock-based compensation was being amortized on a straight-line basis over the period during which the Company's right to repurchase the stock lapsed or the options vested, generally four years. Through March 31, 2009, the Company had amortized all $19.5 million of such compensation expense, net of forfeitures, with approximately $6,000 being amortized in the nine months ended September 30, 2009 and $0.1 million and $0.8 million being amortized in the three and nine months ended September 30, 2008, respectively.

Stock-based compensation expense As required by ASC 815 the Company recognized $0.5 million and $1.6 million of stock-based compensation expense related to stock options and purchase rights granted subsequent to 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, 2009, respectively, and $0.7 million and $2.6 million of stock based compensation for the three and nine months ended September 30, 2008, respectively, in addition to the amortization of deferred compensation above. As of September 30, 2009, the total unrecognized

compensation cost related to unvested stock-based awards granted to employees under the Company's stock option plans was approximately $1.4 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 2.1 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 $8,000 and $18,000 for the three and nine months ended September 30, 2009, respectively, and $5,000 and $25,000 for the three and nine months ended September 30, 2008, respectively.

Stock-based compensation expense, which consists of the compensation cost for employee stock options, 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,	
	2009	2008	2009	2008
Research and development	$ 204	$ 323	$ 715	$ 1,157
General and administrative	279	341	886	1,409
	$ 483	$ 664	$ 1,601	$ 2,566

Equity Incentive Plans

2004 Equity Incentive Plan During the nine months ended September 30, 2009, the Company granted stock options to purchase 390,600 shares at an average exercise price of $0.97 per share under the 2004 Equity Incentive Plan. At September 30, 2009, 146,505 shares were authorized and available for issuance under the stock option plan.

On February 13, 2009, the Company cancelled 559,665 options of 37 eligible employees, consultants and directors that had a weighted average exercise price of $8.08 and re-granted 559,665 options at an exercise price of $1.30, which was the Company's closing price on February 17, 2009. As a result of the repricing of options of eligible employees and directors, the Company will incur an incremental stock-based compensation expense of approximately $0.2 million over the weighted average vesting period of the repriced options of 2.2 years. The incremental compensation cost was measured as the fair value of the new stock option award over the fair value of the original stock option award based on the closing price on the date of re-grant. The incremental expense related to the repricing recorded for the three months and nine months ended September 30, 2009 was not significant.

The following table summarizes stock option activity under the Company's stock option plans:

Options	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2008	617,098	$ 8.41	—	—
Granted	952,265	$ 1.17	—	—
Exercised	(1,055)	$ 0.96	—	—
Forfeitures	(627,939)	$ 8.28	—	—
Outstanding at September 30, 2009	940,369	$ 1.17	8.33	$616,646
Vested and expected to vest September 30, 2009	930,232	$ 1.17	8.33	$608,897
Exercisable at September 30, 2009	310,528	$ 1.21	7.94	$192,617

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company's common stock for options that were in-the-money at September 30, 2009. The total intrinsic value of stock options exercised during the nine months ended September 30, 2009 and 2008 was each less than $1,000, determined at the date of the option exercise. Cash received from stock option exercises was $1,000 for each of the nine months ended September 30, 2009 and 2008. 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 For the nine months ended September 30, 2009, plan participants had purchased 16,263 shares at an average purchase price of $1.04. At September 30, 2009, plan participants had $33,000 withheld to purchase stock on February 14, 2010, which is included in accrued liabilities on the accompanying unaudited condensed consolidated balance sheet. At September 30, 2009, 402,902 shares were authorized and available for issuance under the ESPP.

NOTE 5 — FAIR VALUE MEASUREMENTS AND MARKETABLE SECURITIES

In September 2006, the FASB issued new guidance now codified as ASC 820, *"Fair Value Measurements and Disclosures."* The new guidance defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements and was adopted by the Company in the first quarter of 2008. In February 2008, the FASB issued new guidance now codified in ASC 820 which delays the effective date for non-financial assets and liabilities that are not measured or disclosed on a recurring basis to fiscal years beginning after November 15, 2008 and was adopted by the Company in the first quarter of 2009.

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, 2009 and December 31, 2008:

(in thousands)	Fair Value as of September 30, 2009	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	$ 4,037	$ 4,037	$ —	$ —
Certificates of deposit	1,831	—	1,831	—
U.S. Government securities	2,103	—	2,103	—
Commercial paper	350	—	350	—
Total cash equivalents and marketable securities	$ 8,321	$ 4,037	$ 4,284	$ —

(in thousands)	Fair Value as of December 31, 2008	Basis of Fair Value Measurements Level 1	Level 2	Level 3
Money market funds	$ 11,995	$ 11,995	$ —	$ —
Corporate bonds	1,228	—	1,228	—
U.S. Government securities	5,846	—	5,846	—
Commercial paper	3,047	—	3,047	—
Total cash equivalents and marketable securities	$ 22,116	$ 11,995	$ 10,121	$ —

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, 2009 and December 31, 2008:

As of September 30, 2009 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 4,037	$ —	$ —	$ 4,037
Certificates of deposit	1,830	1	—	1,831
U.S. Government securities	2,101	2	—	2,103
Commercial paper	350	—	—	350
	8,318	3	—	8,321
Less cash equivalents	(4,037)	—	—	(4,037)
Total marketable securities	$ 4,281	$ 3	$ —	$ 4,284

As of December 31, 2008 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 11,995	$ —	$ —	$ 11,995
Corporate bonds	1,229	—	(1)	1,228
U.S. Government securities	5,827	19	—	5,846
Commercial paper	3,042	5	—	3,047
	22,093	24	(1)	22,116
Less cash equivalents	(15,241)	(4)	—	(15,245)
Total marketable securities	$ 6,852	$ 20	$ (1)	$ 6,871

There were no realized gains or losses in the three and nine months ended September 30, 2009 and 2008.

As of September 30, 2009, weighted average days to maturity for the Company's available for sale securities was 29 days, with the longest maturity being February 2010.

There were no marketable securities with unrealized losses at September 30, 2009.

The Company determined the fair value of the liability associated with its 3.6 million outstanding common stock warrants using a Black-Scholes Model. See detailed discussion in Note 3 — Common Stockholders' Equity.

NOTE 6 — NOTES PAYABLE

In April 2006, the Company amended the existing loan and security agreement to borrow up to an additional $4.0 million for working capital and equipment purchases. The interest rate for borrowings under this facility was determined based on the 36-month U.S. Treasury note plus 2.25% on the date of borrowing. The Company borrowed $2.6 million under this facility, which was repaid over a 36-month period from the date of borrowing. The interest rate on these borrowings was approximately 7.2% per annum. Borrowings under the equipment line of credit are collateralized by the related equipment. At June 30, 2009, amounts under the amended loan and security agreement were paid in full.

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. In February 2006, the Company entered into a new lease for an additional 34,205 square feet of space and an increase in the lease term for the existing space located at the Company's headquarters in Redwood City, California to September 30, 2011. The lease is for a period of 66 months, beginning on April 1, 2006 with respect to the additional square footage and will begin on March 1, 2010 with respect to the existing square footage. The lease will expire, unless otherwise terminated under the terms of the lease, on September 30, 2011. The aggregate rent for the term of the lease is approximately $4.8 million. In addition, the lease requires the Company to pay certain taxes, assessments, fees and other costs and expenses associated with the premises in amounts yet to be determined as well as a customary management fee. The Company will also be responsible for the costs of certain tenant improvements associated with the leased space. In connection with the lease, the Company furnished a letter of credit to the landlord for approximately $0.3 million.

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,	
2009 (remaining three months)	$ 389
2010	1,462
2011	1,129
Total	$2,980

The Company's purchase commitments at September 30, 2009 were $2.2 million.

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.

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.

Legal proceedings

On July 5 and July 18, 2007, purported shareholder class action complaints alleging violations of the federal securities laws were filed against the Company, its Chief Executive Officer Harold E. Selick and its former Chief Financial Officer Janet I. Swearson in the United States District Court for the Southern District of New York. On September 14, 2007, these lawsuits, which have been consolidated by the Court into a single proceeding, were ordered transferred to the United States District Court for the Northern District of California. On January 15, 2008, Plaintiffs filed a first consolidated amended complaint. On July 11, 2008, the Court granted Defendants' motions to dismiss that complaint but afforded Plaintiffs leave to file a further amended complaint. On September 19, 2008, Plaintiffs filed a second consolidated amended complaint, which, on behalf of an alleged class of purchasers of the Company's common stock from the date of its initial public offering of securities on February 4, 2005 through July 14, 2006, purports to allege claims arising under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended (the "Securities Act"), and under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Plaintiffs allege generally that the defendants violated the federal securities laws by, among other things, making material misstatements or omissions concerning our Phase 2 and Phase 3 clinical trials of Lonidamine (TH-070). On November 14, 2008, Defendants moved to dismiss the second consolidated amended complaint. On April 3, 2009, the Court granted in part and denied in part the motions to dismiss,

dismissing with prejudice all claims arising under the Securities Act and all claims against Ms. Swearson, while narrowing the remaining claims. On October 30, 2009, the parties entered into a stipulation of settlement to resolve the lawsuit. The settlement provides for a payment of $10 million to the plaintiff class solely by the Company's insurers. The settlement is subject to preliminary and, following notice to class members, final approval by the Court. The defendants, including the Company, have denied and continue to deny all of plaintiffs' allegations of wrongdoing. There can be no assurance at this time that the settlement process will result in final Court approval. To the extent the case does not finally resolve through settlement, the defendants to the lawsuit, including the Company, continue to believe that Plaintiffs' claims are without merit and intend to defend against the actions vigorously.

As of September 30, 2009, in accordance with provisions of the settlement, the Company recorded $10 million in accrued liabilities, which represents the amount of the settlement costs to be paid to the plaintiffs, and $10 million in prepaid expenses and other assets, which represents the amount the Company's insurers will pay towards the settlement costs.

NOTE 8 — COMPREHENSIVE LOSS

Comprehensive loss is comprised of net loss and other comprehensive loss, which consists of unrealized losses on the Company's available-for-sale securities. The components of comprehensive loss are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net loss	$(6,153)	$(4,558)	$(18,915)	$(13,498)
Other comprehensive loss:				
Unrealized loss on marketable securities	—	(8)	(17)	(16)
Total comprehensive loss	$(6,153)	$(4,566)	$(18,932)	$(13,514)

NOTE 9 — SUBSEQUENT EVENTS

On October 5, 2009, the Company sold to certain investors an aggregate of 18,324,599 shares of its common stock for a purchase price equal to $1.86 per and, for a purchase price of $0.05 per share, warrants exercisable for a total of 7,329,819 shares of its common stock for aggregate gross proceeds equal to $35.0 million in connection with the offering. Net proceeds generated from the offering are expected to be approximately $33.1 million. The warrants have a five-year term and an exercise price equal to $2.23 per share of common stock. The exercise price 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. In addition, the number of shares issuable upon exercise of the warrants and the exercise price are subject to adjustment for 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.

The Company's offering of common stock and warrants, on October 5, 2009, included 1,570,980 shares of common stock and warrants exercisable for a total of 628,264 shares of common stock sold to entities affiliated with Sutter Hill Ventures ("Sutter Hill"), and 1,047,120 shares of common stock and warrants exercisable for a total of 418,847 shares of common stock sold to entities affiliated with Three Arch Management III, L.L.C. ("Three Arch"). Jeffrey W. Bird and Wilfred E. Jaeger, members of the Company's board of directors, are managing members of Sutter Hill and Three Arch, respectively. Also as part of this offering, certain members of the Company's management team purchased 248,690 shares and received warrants to purchase 99,475 shares of common stock.

Effective September 29, 2009, the Company entered into an amendment (the "Second Amendment") to that certain Preferred Shares Rights Agreement, dated as of August 8, 2006, by and between the Company and Mellon Investor Services LLC (the "Rights Agreement"), and the amendment to the Rights Agreement dated July 10, 2008. The Second Amendment amended certain terms in the Rights Agreement so that the Company could announce and consummate the offering described above without triggering the Rights Agreement.

In addition, as result of the above offering, on October 5, 2009, the exercise price of the warrants exercisable for a total of 3,588,221 shares of common stock sold to investors in August 2008 that had an original exercise price of $2.34 per share, was subsequently reduced to $1.86 per share pursuant to the terms of such warrants.

On October 14, 2009, we entered into an exclusive licensing agreement with Eleison Pharmaceuticals, Inc. ("Eleison"). Pursuant to the agreement we granted Eleison exclusive worldwide rights to develop and commercialize glufosfamide for the treatment of cancer in humans and animals, and certain other uses. Under the agreement, Eleison is responsible for the development, manufacturing and marketing of glufosfamide. Eleison and Threshold will share equally in the profits of commercialization, if the

further clinical development of glufosfamide leads to regulatory approval and marketing. Eleison intends to secure funding for the clinical development of glufosfamide. The agreement between Threshold and Eleison contemplates that Eleison, to satisfy its diligence obligations, will raise sufficient funds to commence clinical development activities with glufosfamide.

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, 2008, 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 as novel treatments for patients living with cancer. The microenvironment of solid tumors is characterized by, among other things, hypoxia or lack of oxygen, disordered blood vessel growth, and the upregulation of glucose transport. This hypoxic environment is known to be resistant to standard chemotherapy and radiation. It is thought to be responsible for the poor prognosis of many solid tumors and treating the hypoxic environment is currently believed to be a significant unmet medical need. Our product candidates are designed to selectively target the hypoxic microenvironment of tumors either by selective toxin activation in the case of our hypoxia activated prodrug (HAP) program, including TH-302, or potentially utilizing the consequences of increased uptake of glucose in cancer cells relative to most normal cells. Our product candidates glufosfamide and 2DG share certain structural characteristics with glucose but act instead as chemotherapeutic toxins when taken up by a cell.

On October 14, 2009, we entered into an exclusive licensing agreement with Eleison Pharmaceuticals, Inc. ("Eleison"). Pursuant to the agreement we granted Eleison exclusive worldwide rights to develop and commercialize glufosfamide for the treatment of cancer in humans and animals, and certain other uses. Under the agreement, Eleison is responsible for the development, manufacturing and marketing of glufosfamide. Eleison and Threshold will share equally in the profits of commercialization, if the further clinical development of glufosfamide leads to regulatory approval and marketing. Eleison intends to secure funding for the clinical development of glufosfamide. The agreement between Threshold and Eleison contemplates that Eleison, to satisfy its diligence obligations, will raise sufficient funds to commence clinical development activities with glufosfamide.

Our focus is on product candidates for the treatment of patients with cancer. We have two product candidates for which we have exclusive worldwide marketing rights:

- TH-302, which we discovered, is our lead product candidate for the potential treatment of patients with cancer. It is a novel drug candidate that is activated under the severe hypoxic conditions of most solid tumors. TH-302 is currently in Phase 1 and Phase 1/2 clinical trials, as discussed below. As further discussed below, in May 2009, we reported results from the dose escalation component of the Phase 1 trial and interim results from the Phase 1/2 trials. We expect to present top-line results from the Phase 1 monotherapy and Phase 1/2 combination therapy trials in the first quarter of 2010. We also expect to complete enrollment in the Phase 1/2 monotherapy and Phase 1/2 combination therapy trials in the fourth quarter of 2009. We expect to initiate at least one controlled clinical trial with TH-302 in the first half of 2010.

- 2DG is our product candidate for the potential treatment of patients with cancer and has been evaluated in a Phase 1 clinical trial alone and in combination with docetaxel as a combination therapy. This clinical trial began in the first quarter of 2004 and we completed enrollment in the first half of 2008. We presented top-line results for this clinical trial in August 2008. We are not currently planning or conducting any additional clinical trials of 2DG.

We are working to discover additional hypoxia activated prodrugs that will selectively target cancer cells.

In July 2007, we initiated a Phase 1 clinical trial evaluating the safety of TH-302 in patients with advanced solid tumors. In the first quarter of 2009, we expanded enrollment of this trial, also known as the 401 trial, to explore potentially higher dosing of TH-302 every three weeks as well as to further investigate single-agent anti-tumor activity in specific tumor types. In August 2008, we initiated a multi-armed Phase 1/2 clinical trial of TH-302 which includes three separate treatment arms, with each arm combining TH-302 with a different chemotherapeutic agent for the treatment of patients with solid tumors. This trial, also known as the 402 trial, is expected to enroll up to 120 patients and will include a dose escalation phase followed by expansion at the maximum tolerated dose (MTD) of TH-302 within four specific indications with 12 patients treated in each indication. In September 2008, we also initiated a Phase 1/2 clinical trial of TH-302 in combination with doxorubicin in patients with advanced soft tissue sarcoma. This trial, also known as the 403 trial, will include up to 36 patients (12-24 in the dose escalation arm).

In May 2009, at the American Society for Clinical Oncology (ASCO) 2009 annual meeting and as part of a company presentation concurrent with the meeting, we presented results from thirty-one patients in the dose escalation component of the Phase 1 clinical trial evaluating the safety and preliminary efficacy of TH-302 as a monotherapy in patients with advanced solid tumors. Partial responses were documented in two patients enrolled in this Phase 1 trial. One patient with refractory small cell lung cancer metastatic to the liver had a partial response (PR), as judged by RECIST (Response Evaluation Criteria In Solid Tumors), at their initial response assessment. The patient had received two cycles of TH-302 at 480 mg/m2 and discontinued from the trial after treatment delay, unrelated to therapy, and disease progression. An additional patient with melanoma metastatic to the lung and liver had a RECIST PR after two cycles of TH-302 at 670 mg/m2. Fifty-eight percent of the 31 patients, who had previously failed a median of 3 prior therapies, achieved stable disease (SD) or better.

The first dose limiting toxicities for TH-302 as a monotherapy were reported in the 670 mg/m2 cohort: one patient developed grade 3 perianal and rectal ulcers and a second patient developed grade 3 oral mucositis associated with dehydration. An intermediate dose of 575 mg/m2 was evaluated and determined to be the MTD. Since nausea and vomiting increased at higher doses of TH-302, standard anti-emetic prophylaxis was recommended at doses that exceed 240 mg/m2. Skin and mucosal adverse events increased with dose and in some patients required dose delays or dose reductions at higher doses. Adverse events of grade 3 or higher were reported in 17 (55%) of 31 patients. Adverse events of grade 3 or higher considered related to study drug were reported in three (10%) patients. Hematologic toxicity was minimal with no grade 3 or grade 4 neutropenia or thrombocytopenia and grade 2 neutropenia reported in two patients (6%), grade 2 thrombocytopenia reported in one (3%) patient, and worsening anemia and lymphopenia in fourteen (45%) and twenty (65%) patients, respectively.

As we reported at the ASCO meeting, in the expansion phase of the Phase 1 monotherapy clinical trial, which included weekly doses of TH-302 at the MTD of 575 mg/m2, the drug continued to be tolerated. There were no new unexpected adverse events, with one of the nine additional patients treated at the MTD of 575 mg/m2 having a dose limiting toxicity (DLT) of grade 3 cheilitis (inflammation of the lips). The initial activity seen in small cell lung cancer and malignant melanoma was further supported by an additional PR in each indication in the initial patients treated in the dose expansion. As reported at the ASCO meeting, two of five patients with small cell lung cancer and two of two patients with metastatic melanoma in the monotherapy trial had achieved a RECIST criteria PR. Dosing once every three weeks is also being evaluated in this trial and dose escalation is ongoing. There was one case of pancytopenia (a reduction in the number of red and white blood cells, as well as platelets) at 670 mg/m2 and one DLT of grade 3 fatigue in the initial patient dosed at 940 mg/m2.

In addition, at the ASCO meeting, we reported interim results from the 402 and 403 Phase 1/2 combination therapy clinical trials. In the 402 trial, 30 patients in the dose-escalation phase had been assessed for response in the trial's three separate treatment arms. In the TH-302 plus gemcitabine arm, eleven patients had tumor assessments, three of whom had a PR in the following cancers: ovarian, esophageal and pancreatic. The ovarian response was confirmed, meaning that the RECIST criteria PR was maintained through a subsequent assessment at least 28 days later; the esophageal and pancreatic PRs were unconfirmed. There were six patients

with SD, five of whom had ongoing SD lasting for three to eight cycles of chemotherapy. In the TH-302 plus docetaxel arm, nine patients had tumor assessments, two of whom had a PR in non-small cell lung cancer and anal cancer with both confirmed and ongoing at the time of the presentation. There were five patients with SD, three of whom had ongoing SD lasting for four to five cycles. In the TH-302 plus pemetrexed arm, ten patients had tumor assessments, two of whom had a PR, both in non small cell lung cancer with both confirmed and ongoing after over six months on treatment. There were five patients with SD, three of whom had ongoing SD lasting for five to nine cycles. In the 403 trial, three patients had tumor assessments, two of whom had a confirmed PR. The third patient has ongoing SD for four cycles.

As reported at the ASCO meeting, hematologic toxicity after administering TH-302 in combination with chemotherapy was higher than might be expected if chemotherapy was administered by itself, but was generally well tolerated and not dose limiting. Skin and mucosal toxicities were TH-302 dose dependent with a trend for increased frequency and greater severity at higher doses. Although these skin and mucosal toxicities have been bothersome in some patients and resulted in dose reductions or delays in therapy, these events have been reversible with an improvement in symptoms between cycles and following dose reductions. Investigations have been initiated to better understand and treat, or prevent, these toxicities.

On August 4, 2009, TH-302 clinical trial results were presented at the World Congress on Lung Cancer Meeting. The presentation summarized results from the 401 and 402 trials of TH-302. Data from these trials were previously discussed at the ASCO Meeting in May 2009. Results from thirteen patients with relapsed/refractory lung cancer across the two clinical trials were presented. Partial responses were observed in three patients, one patient receiving docetaxel and TH-302 and two patients receiving pemetrexed and TH-302. Eight of twelve (67%) evaluable patients with relapsed or refractory NSCLC achieved stable disease or better. Eight patients with small cell lung cancer (SCLC) who received TH-302 as a monotherapy were assessed for tumor response. Partial responses were observed in two patients. Six of eight (75%) patients achieved stable disease or better.

In September 2009, results from the 402 clinical trial were presented at the 15th Congress of the European CanCer Organisation (ECCO) and 34th Congress of the European Society for Medical Oncology (ESMO). In the 402 trial, 45 patients in the dose-escalation phase had been assessed for response in the trial's three separate treatment arms. In the TH-302 plus gemcitabine arm, fifteen patients had tumor assessments, six of whom had a PR in the following cancers: pancreatic (2), ovarian, esophageal, squamous non-small cell lung cancer and thyroid. The ovarian response was confirmed, meaning that the RECIST criteria PR was maintained through a subsequent assessment at least 28 days later; the esophageal and pancreatic PRs were unconfirmed. There were seven patients with SD. Of the four patients with first-line pancreatic cancer assessed for response, two achieved PRs and two have had SD. In the TH-302 plus docetaxel arm, eleven patients had tumor assessments, two of whom had a PR in non-small cell lung cancer and anal cancer with both confirmed and ongoing at the time of the presentation. There were six patients with SD. In the TH-302 plus pemetrexed arm, nineteen patients have had tumor assessments, four of whom had a PR, two in non small cell lung cancer and two in transitional cell carcinoma. There were nine patients with SD. Of the eight patients with relapsed or refractory NSCLC treated with TH-302 in combination with either docetaxel or pemetrexed, three patients achieved PRs and four patients achieved stable disease.

On October 8, 2009, TH-302 clinical trial results were presented at the Perspectives in Melanoma XIII Conference. The presentation summarized results from the 401 trial of TH-302 in those patients with metastatic melanoma. Data from these trials were previously discussed at the ASCO Meeting in May 2009. Eight of nine patients with metastatic melanoma were assessed for response. Six of eight (75%) evaluable melanoma patients had SD or better, including three (38%) patients with a PR (one confirmed, one un-confirmed who discontinued treatment after their first tumor assessment due to seizures related to brain metastases, one on study yet to receive a second tumor assessment) as measured by RECIST (Response Evaluation Criteria In Solid Tumors). Four of the eight patients continue to receive TH-302 after receiving TH-302 for 2.6 to 6.2 months.

We are a development stage company 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 sale 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. In February 2005, we completed our initial public offering that raised net proceeds of $38.1 million, and in October 2005, we completed an offering of common stock that raised net proceeds of $62.4 million. In August 2008, we completed an offering of common stock and warrants that raised net proceeds of $16.8 million. As of September 30, 2009 we had cash, cash equivalents and marketable securities of $8.5 million. Our net loss for the nine months ended September 30, 2009 was $18.9 million and our cumulative net loss since our inception through September 30, 2009 was $203.1 million. In October 2009, we completed an offering of common stock and warrants that raised aggregate gross proceeds of $35.0 million and net proceeds are expected to be approximately $33.1million.

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 are expected to increase in 2009 compared to 2008 due to the continued execution of existing clinical trials and beginning of new clinical trials. We expect that our cash, cash equivalents and marketable securities as of September 30, 2009 along with the net proceeds from our October 2009 private placement of shares of common stock and warrants to purchase shares of common stock, will be sufficient to fund our projected operating requirements through the second quarter of 2011, including completing our current ongoing clinical trials and conducting research and discovery efforts toward additional product candidates, working capital and general corporate purposes. 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. No revenue was recognized for the three and nine months ended September 30, 2009. For the three months and nine ended September 30, 2008, we recognized revenue of $0.4 million and $1.1 million, respectively, related to the $5.0 million upfront payment received in connection with a 2004 agreement with MediBIC Co. Ltd for the development of glufosfamide in Japan and several other Asian countries. Revenue was fully recognized on a straight-line basis over the estimated development period through 2008. We have no further responsibilities for development activities under this agreement.

Research and Development. Research and development expenses were $4.0 million for the three months ended September 30, 2009 compared to $3.7 million for the three months ended September 30, 2008. The $0.3 million increase in expenses is due primarily to an increase in consulting and personnel related expenses. Research and development expenses were $11.7 million for the nine months ended September 30, 2009 compared to $9.9 million for the nine months ended September 30, 2008. The $1.8 million increase in expenses is due primarily to a $1.4 million increase in clinical and development expenses and a $0.8 million increase in consulting and personnel related expenses, offset by a $0.4 million decrease in stock based compensation.

	Three months ended September 30,		Nine months ended September 30,	
Research and development expenses by project (in thousands)	2009	2008	2009	2008
TH-302	$ 2,928	$ 2,052	$ 8,075	$4,743
Glufosfamide	81	627	232	1,840
2DG	23	92	162	307
Discovery research	941	901	3,250	2,983
Total research and development expenses	$ 3,973	$ 3,672	$11,719	$9,873

Research and development expenses associated with our internally discovered compound TH-302 were $2.9 million for the three months ended September 30, 2009 and $2.1 million for the three months ended September 30, 2008. Research and development expenses associated with TH-302 were $8.l million for the nine months ended September 30, 2009 and $4.7 million for the nine months ended September 30, 2008. TH-302 continues to progress through the Phase 1 monotherapy clinical trial initiated in July 2007, for which in the first quarter of 2009, we expanded enrollment to explore activity in specific indications. In addition, in the third quarter of 2008, we initiated a Phase 1/2 combination therapy clinical trial of TH-302 which includes three separate treatment arms and a Phase 1/2 clinical trial of TH-302 in combination with doxorubicin in patients with advanced soft tissue sarcoma.

Research and development expenses associated with glufosfamide were $0.1 million for the three months ended September 30, 2009 and $0.6 million for the three months ended September 30, 2008. Research and development expenses associated with glufosfamide were $0.2 million for the nine months ended September 30, 2009 and $1.8 million for the nine months ended September 30, 2008. This decline in expenses was due to the completion and announcement of results for our Phase 2 trials in pancreatic cancer and soft-tissue sarcoma in 2007 and discontinuation of our Phase 2 trials in recurrent sensitive small cell lung cancer and platinum-resistant ovarian cancer in October 2007 and January 2008, respectively. In October 2009, we exclusively licensed development and commercialization of glufosfamide to Eleison and as a result, we do not expect to incur research and development expenses associated with glufosfamide in the future.

Research and development expenses associated with 2DG were $23,000 for the three months ended September 30, 2009 and $0.1 million for the three months ended September 30, 2008, and were $0.2 million for the nine months ended September 30, 2009 and $0.3 million for the nine months ended September 30, 2008, as we completed enrollment of the 2DG Phase 1 trial in the second quarter of 2008, and announced results in third quarter of 2008. We are not currently planning or conducting further additional

clinical trials of 2DG.

Discovery research and development expenses were $0.9 million for the three months ended September 30, 2009 compared to $0.9 million for the three months ended September 30, 2008, and were $3.3 million for the nine months ended September 30, 2009 compared to $3.0 million for the nine months ended September 30, 2008 as 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. Research and development expenses are expected to increase in 2009 compared to 2008 due to the continued execution and expansion of our existing trials.

General and Administrative. General and administrative expenses were $1.2 million for the three months ended September 30, 2009, compared to $1.3 million for the three months ended September 30, 2008. The decrease of $0.1 million is due to lower staffing and facilities expenses and stock based compensation.

General and administrative expenses were $4.1 million for the nine months ended September 30, 2009, compared to $5.1 million for the nine months ended September 30, 2008. The decrease of $1.0 million is due to $0.5 million of decrease in stock-based compensation expenses and $0.5 million in lower consulting expenses and staffing and facilities expenses.

General and administrative expenses are expected to remain approximately the same in 2009 compared to 2008.

Interest Income, Net. Interest income for the three months ended September 30, 2009 was $12,000 compared to $0.1 million for the three months ended September 30, 2008. Interest income for nine months ended September 30, 2009 was $0.1 million compared to $0.4 million for the nine months ended September 30, 2008. The decrease was primarily due to lower invested cash balances and, lower interest rates during the three months ended September 30, 2009 compared to the prior year.

Interest and Other Expense. Interest and other expense was $1.0 million and $3.2 million, for the three and nine months ended September 30, 2009, respectively, compared to $13,000 and $0.1 million for the three and nine months ended September 30, 2008, respectively. The increase was primarily due to the $1.0 million and $3.0 million non cash charge for the three and nine months ended September 30, 2009, respectively, related to the change in fair value of the common stock warrants recorded in interest and other expense as a result of our adoption of new guidance codified in ASC 815, *"Derivatives and Hedging"* as of January 1, 2009. In accordance with ASC 815, stock warrants with certain terms that were previously accounted for as equity must now be accounted for as a liability with changes to their fair value recognized in the consolidated statement of operations.

Liquidity and Capital Resources

We have incurred net losses of $203.1 million since inception through September 30, 2009. We have not generated and do not expect to generate revenue from sales of product candidates in the near term. From inception until our initial public offering in February 2005, we funded our operations primarily through private placements of our preferred stock. In February 2005, we completed our initial public offering of 1,018,768 shares of common stock, raising net proceeds of $38.1 million. In October 2005, we completed a public offering of 1,066,537 shares of our common stock for net proceeds of $62.4 million. On August 29, 2008, we sold to certain investors an aggregate of 8,970,574 shares of our common stock for a purchase price equal to $2.04 per share and warrants exercisable for a total of 3,588,221 shares of our common stock with an exercise price equal to $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 the private placement that was completed on that date and discussed below. Net proceeds generated from the offering were $16.8 million. In August 2008, our Board of Directors approved a 1-for-6 reverse split of its common stock, effective August 20, 2008. Accordingly, all references to common shares of stock have been retroactively adjusted to reflect the reverse split. We had cash, cash equivalents and marketable securities of $8.5 million and $22.3 million at September 30, 2009 and December 31, 2008, respectively, available to fund operations.

On October 5, 2009, we sold to certain investors an aggregate of 18,324,599 shares of our common stock for a purchase price equal to $1.86 per share and, for a purchase price equal to $0.05 per share, warrants exercisable for a total of 7,329,819 shares of our common stock for aggregate gross proceeds equal to $35.0 million in connection with the offering. Net proceeds generated from the offering are expected to be approximately $33.1 million. The warrants have a five-year term and an exercise price equal to $2.23 per share of common stock. The exercise price 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. In addition, the number of shares issuable upon exercise of the warrants and the exercise price are subject to adjustment for 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.

Pursuant to the terms of the October 2009 offering we have filed a registration statement with the SEC to register for resale the common stock and the common stock to be issued upon exercise of the warrants from the transaction and may be required to file additional registration statements under certain circumstances. If the registration statement is not declared effective within a certain time period or we fail to register the shares pursuant to additional registration statements filed with the SEC, subject to certain terms and conditions, we may be required to pay certain liquidated damages, plus interest for any late payments.

Net cash used in operating activities for the nine months ended September 30, 2009 and 2008 was $13.5 million and $12.3 million, respectively. The increase of $1.2 million in cash used in operations was primarily attributable to a higher net loss in 2009, partially offset by higher non-cash expenses in 2009.

Net cash provided by investing activities for the nine months ended September 30, 2009 and 2008 was $2.6 million and $7.6 million, respectively. The $5.0 million decrease in cash provided by investing activities was due primarily to a decrease in proceeds from sales and maturities of marketable securities and an increase in the purchase of marketable securities.

Net cash used in financing activities for the nine months ended September 30, 2009 was $0.3 million, compared to net cash provided by financing activities for the nine months ended September 30, 2008 of $16.2 million. The cash provided by financing activities in the nine months ended September 30, 2008 reflects the $16.8 million net proceeds from the sale of our common stock and warrants in August 2008.

Obligations and Commitments

In April 2006, we amended the existing loan and security agreement to borrow up to an additional $4.0 million for working capital and equipment purchases. The interest rate for borrowings under this facility was determined based on the 36-month U.S. Treasury note plus 2.25% on the date of borrowing. We borrowed $2.6 million under this facility, which was repaid over a 36-month period from the date of borrowing. The interest rate on these borrowings was approximately 7.2% per annum. As of June 30, 2009, the total amount due under this facility was fully paid.

In August 2004, we entered into a noncancelable facilities sublease agreement that expires on February 28, 2010 for our headquarters in Redwood City, California. On April 1, 2005, we entered into a noncancelable facilities lease agreement that expires on February 28, 2010 for additional laboratory space in Redwood City, California.

In February 2006, we entered into a lease for an additional 34,205 square feet of space and increased the lease term for the existing space located at our headquarters in Redwood City, California to September 30, 2011. The lease is for a period of 66 months, beginning on April 1, 2006 with respect to the additional square footage and will begin on March 1, 2010 with respect to the existing square footage. The lease will expire, unless otherwise terminated under the terms of the lease, on September 30, 2011. The aggregate rent for the term of the lease is approximately $4.8 million.

In addition, the lease requires us to pay certain taxes, assessments, fees and other costs and expenses associated with the premises as well as a customary management fee. We are also responsible for the costs of certain tenant improvements associated with the leased space. In connection with the lease, we furnished a letter of credit to the landlord for approximately $0.3 million.

Our major outstanding contractual obligations consist of amounts due under our operating lease agreements and purchase commitments under contract research, development and clinical supply agreements. Contractual obligations and related scheduled payments as of September 30, 2009, are as follows (in thousands):

	Remainder of current year (2009)	One to three years (2010 to 2012)	Four to five years (2013 to 2014)	After five Years	Total
Facilities leases	$ 389	$ 2,591	$ —	$ —	$2,980
Purchase commitments	2,284	—	—	—	2,284
Total	$ 2,673	$ 2,591	$ —	$ —	$5,264

We expect 2009 cash requirements to be in the range of $19 million to $21 million. We believe that our cash, cash equivalents and marketable securities as of September 30, 2009 along with the net proceeds from our private placement of shares of common stock and warrants to purchase shares of common stock completed on October 5, 2009, will be sufficient to fund our projected operating requirements through the second quarter of 2011, including completing our current trials, conducting research and discovery efforts towards additional product candidates, working capital and general corporate purposes. We intend to seek funds through 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.

We expect to need to raise additional capital or incur indebtedness to continue to fund our future operations. 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 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. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through 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 our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. 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. 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 4450(a)(5). On August 13, 2008 our Board of Directors implemented a one for six reverse stock split, effective August 20, 2008, to regain compliance with the minimum bid price requirement. On September 5, 2008, the NASDAQ Stock Market notified us that we had regained compliance with the minimum bid price. Even though we regained compliance with the minimum bid price requirement, we cannot be assured that we will be able to maintain compliance with the minimum bid price requirement in the future, and our failure to do so could result in the delisting of our shares from the NASDAQ Capital Market. To maintain our listing on the NASDAQ Capital Market, we are also required, among other things, to either maintain stockholders' equity of at least $2.5 million or a market value of at least $35 million. While we currently satisfy the stockholders' equity requirement, we may not continue to do so. On October 16, 2008, the NASDAQ Stock Market suspended the enforcement of the minimum bid price and market value requirements through January 16, 2009. The suspension period was subsequently extended to July 31, 2009. NASDAQ's enforcement of these rules resumed on August 3, 2009 and NASDAQ does not expect any further extensions of the suspension.

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 2008 Annual Report on Form 10-K, which we filed with the Securities and Exchange Commission on March 13, 2009.

There have been no material revisions to the critical accounting policies as discussed in our Annual Report on Form 10-K for the year ended December 31, 2008 except as discussed below:

Prior to January 1, 2009, common stock warrants were recorded in stockholders equity in accordance with ASC 815,*"Derivatives and Hedging"* and ASC 825, *"Financial instruments."* However in June 2008, the FASB issued new 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 a liability. The new guidance was effective for financial statements issued for fiscal years beginning after December 15, 2008. The adoption of the new guidance on January 1, 2009, resulted in the reclassification of our outstanding warrants from stockholders' equity to liability and a cumulative effect of change in accounting principle on our deficit accumulated during development stage of $0.5 million. In addition, the stock warrants are required to be fair valued at each reporting period, with the changes in fair value recognized in the Company's consolidated statement of operations. We fair value the warrants using a Black Scholes valuation model. Since the outstanding common stock warrants are fair valued at end of each reporting period, any change in the underlying assumptions to the Black Scholes valuation model may have a significant impact on our consolidated financial statements.

Recent Accounting Pronouncements

In October 2009, the FASB issued Accounting Standards Update, 2009-13, Revenue Recognition (Topic 605):*Multiple Deliverable Revenue Arrangements – A Consensus of the FASB Emerging Issues Task Force."* This update provides application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. We will be required to apply this guidance prospectively for revenue arrangements entered into or materially modified after January 1, 2011; however, earlier application is permitted. We have not determined the impact that this update may have on our financial statements.

On July 1, 2009, the Financial Accounting Standards Board ("FASB") issued guidance now codified as FASB Accounting Standards Codification ("ASC") 105-10, "*Generally Accepted Accounting Principles*" ("ASC 105-10") (the "Codification"). ASC 105-10 establishes the exclusive authoritative reference for U.S. GAAP for use in financial statements, except for SEC rules and interpretive releases, which are also authoritative GAAP for SEC registrants. The Codification superseded all existing non-SEC accounting and reporting standards. We have included the references to the Codification, as appropriate, in these consolidated financial statements.

In April 2009, the FASB issued guidance now codified as ASC 820,*"Fair Value Measurements and Disclosures,"* ASC 320, *"Investments – Debt and Equity Securities" and* ASC 825, *"Financial Instruments,"* that was intended to provide additional application guidance and enhance disclosures about fair value measurements and impairments of securities. ASC 820 clarifies the objective and method of fair value measurement even when there has been a significant decrease in market activity for the asset being measured. ASC 320 establishes a new model for measuring other-than-temporary impairments for debt securities, including establishing criteria for when to recognize a write-down through earnings versus other comprehensive income. ASC 825 expands the fair value disclosures required for all financial instruments to interim periods. The new guidance in these three ASC topics was effective for interim and annual reporting periods ending after June 15, 2009. The implementation did not have a material impact on our financial statements.

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, 2009, our chief executive officer and senior director, finance and controller have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(f) of the Securities Exchange Act of 1934, as amended) were sufficiently effective 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 three months ended September 30, 2009 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 senior director, 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 principal financial and accounting officer have concluded, based on their evaluation, that our disclosure controls and procedures were sufficiently effective as of September 30, 2009 to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On July 5 and July 18, 2007, purported shareholder class action complaints alleging violations of the federal securities laws were filed against us, our Chief Executive Officer Harold E. Selick and our former Chief Financial Officer Janet I. Swearson in the United States District Court for the Southern District of New York. On September 14, 2007, these lawsuits, which have been consolidated by the Court into a single proceeding, were ordered transferred to the United States District Court for the Northern District of California. On January 15, 2008, the plaintiffs filed a first consolidated amended complaint. On July 11, 2008, the Court granted Defendants' motions to dismiss that complaint but afforded the plaintiffs leave to file a further amended complaint. On September 19, 2008, the plaintiffs filed a second consolidated amended complaint, which, on behalf of an alleged class of purchasers of our common stock from the date of our initial public offering of securities on February 4, 2005 through July 14, 2006, purports to allege claims arising under Sections 11, 12(a)(2) and 15 of the Securities Act, and under Sections 10(b) and 20(a) of the Exchange

Act. Plaintiffs allege generally that the defendants violated the federal securities laws by, among other things, making material misstatements or omissions concerning our Phase 2 and Phase 3 clinical trials of Lonidamine (TH-070). On November 14, 2008, Defendants moved to dismiss the second consolidated amended complaint. On April 3, 2009, the Court granted in part and denied in part the motions to dismiss, dismissing with prejudice all claims arising under the Securities Act and all claims against Ms. Swearson, while narrowing the remaining claims. On October 30, 2009, the parties entered into a stipulation of settlement to resolve the lawsuit. The settlement provides for a payment of $10 million to the plaintiff class solely by our insurers. The settlement is subject to preliminary and, following notice to class members, final approval by the Court. The defendants, including us, have denied and continue to deny all of plaintiffs' allegations of wrongdoing. There can be no assurance at this time that the settlement process will result in final Court approval. To the extent the case does not finally resolve through settlement, the defendants to the lawsuit, including us, continue to believe that the plaintiffs' claims are without merit and intend to defend against the actions vigorously.

ITEM 1A. RISK FACTORS

RISKS RELATED TO OUR BUSINESS

Risks Related to Drug Discovery, Development and Commercialization

We are substantially dependent upon the success of TH-302 and our other product candidates. Clinical trials may not demonstrate efficacy or lead to regulatory approval and preliminary results may not be confirmed.

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 preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. Our preliminary results from clinical trials of TH-302 in a small number of patients may not be confirmed by later analysis or subsequent larger clinical trials. 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;
- 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.

Pre-clinical studies of our product candidates may not predict the results of their 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.

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, which currently are unproven approaches to therapeutic intervention.

Our product candidates are designed to target the microenvironment of solid tumors either by harnessing hypoxia for selective toxin activation in the case of TH-302 and our HAP program or potentially utilizing the increased uptake of glucose in cancer cells relative to most normal cells. Our product candidate 2DG shares certain structural characteristics with glucose but acts instead as poison when taken up by a cancer cell. We have not, nor to our knowledge has any other company, received regulatory approval for a drug based on either of these approaches. We cannot be certain that our approaches 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.

Certain anti-tumor drugs being developed by us, such as TH-302 and 2DG, are expected to have undesirable side effects. The extent, severity and clinical significance of these effects may not be apparent initially and may be discovered 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.

Delays in clinical testing could result in increased costs to us and delay our ability to obtain regulatory approval and commercialize our product candidates.

Significant delays in clinical testing could materially impact our product development costs and delay regulatory approval of our product candidates. We do not know whether planned clinical trials will need to be redesigned or 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 and delays in:

- obtaining regulatory approval to commence a clinical trial;
- obtaining clinical materials;
- reaching agreement on acceptable clinical trial agreement terms with prospective sites;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site; and
- recruiting patients to participate in a clinical trial.

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 is approved and receives orphan drug status, the FDA can 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 or 2DG 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 fail to comply with continuing United States and foreign regulations, we 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 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 we use 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. We and our contract manufacturers will be subject to ongoing FDA requirements for submission of safety and other post-market information. If we and our contract 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; or
- seize or detain products or require a product recall.

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.

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 are a development stage company with a limited operating history and no current source of revenue from the sale of our product candidates. 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, 2009, we had a net loss of $18.9 million and our cumulative net loss since our inception through September 30, 2009 was $203.1 million. Clinical trials are costly. We do not expect to generate any revenue from the sale of our product candidates in the near term, and we expect to continue to have significant losses for the foreseeable future.

To attain profitability, we will need to develop products successfully and market and sell them effectively. We cannot predict when we will become profitable, if at all. We have never generated revenue from the sale 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.

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 existing cash, cash equivalents and marketable securities as of September 30, 2009 along with the net proceeds from our private placement of shares of common stock and warrants to purchase shares of common stock completed on October 5, 2009, will be sufficient to fund our projected operating requirements through the second quarter of 2011, including prosecuting our current clinical trials, conducting research and discovery efforts towards additional product candidates, working capital and general corporate purposes. Additional funds will be required to in-license or otherwise acquire and develop additional products or programs. We expect to seek funds through arrangements with collaborators or others that may require us to relinquish rights to certain 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 expect to need to raise additional capital or incur indebtedness to continue to fund our future operations. 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 our clinical and regulatory events, our ability to identify promising 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, 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 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.

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.

If we do not timely file any registration statements required under the terms of the October 2009 private placement, or if any required registration statements are not declared effective within certain time periods, we will be required to pay liquidated damages.

Pursuant to the terms of the October 2009 private placement, we have filed a registration statement with the SEC to register for resale the shares of common stock and the common stock to be issued upon exercise of the warrants from the October 2009 private placement. Under certain circumstances, we may be required to file additional registration statements for the resale of the foregoing shares of common stock. If the initial registration statement is not declared effective within a specified period, or if we fail to file any additional required registration statements or if any such additional registration statements are not declared effective within certain time periods, we will, subject to certain terms and conditions, be required to pay monthly liquidated damages to the investors in the October 2009 private placement equal to 1% of the number of shares of common stock required to be contained in each such additional registration statement multiplied by $1.86 until the required registration statement is filed or declared effective, as applicable, subject to maximum liquidated damages of $4.2 million, plus interest for any late payments.

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, President and Chief Medical Officer, Dr. John M. Curd and Senior Vice President of Discovery Research, Dr. Mark G. Matteucci. We do not have employment agreements with Drs. Selick, Curd or Matteucci. The loss of the services of Drs. Selick, Curd 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, 2009, we had 30 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.

The reduction in our work force may cause difficulties in conducting operations and maintaining an effective work environment.

The reductions in our work force in August 2006 and October 2007 imposed significant added responsibilities on remaining management and other employees, including the need to consolidate job functions and to conduct operation with fewer employees. This required that we increase our use of various third parties in order to continue and conduct some operations. Our ability to manage our operations and outside relationships will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. If we are unable to do this effectively, it may be difficult for us 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 Redwood City, 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 and 2DG. 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.

We do not currently own or operate manufacturing facilities; consequently, we rely and expect to continue to rely on third parties for the production of clinical and commercial quantities of our product candidates. We have not yet entered into any long term manufacturing or supply agreement for any of our 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.

Our contract manufacturers have produced sufficient TH-302 Active Pharmaceutical Ingredient, API, and drug product to meet the clinical supply demands of our ongoing clinical trials. Additional clinical trial material continues to be manufactured as required. We will need to obtain additional supplies of TH-302 API and drug product to complete our Phase 1/2 clinical trials and any other additional trials. The need for additional supplies may require manufacturing process improvements in TH-302 API and drug product. 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.

We rely on contract manufacturers for the manufacturing of 2DG API and drug product. If we seek a partner to continue development of 2DG, we will be dependent on contract manufacturers to produce additional API and drug product. If we are not successful, we may experience problems in seeking a partner or in meeting our obligations under a potential partnership to continue development of 2DG.

We will need to enter into additional agreements for additional supplies of each of our product candidates to complete clinical development and/or commercialize them. We cannot be certain that we can do so on favorable terms, if at all. The products will need to satisfy all cGMP manufacturing requirements, including passing specifications. Our inability to satisfy these requirements could delay our clinical programs.

If any of our product candidates is approved by the FDA or other regulatory agencies for commercial sale, we will need to have it manufactured in commercial quantities. We may not be able to increase the manufacturing capacity for any of our 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 we are unable to successfully increase the manufacturing capacity for a 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 our 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 current good manufacturing practice, or 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 may rely on strategic collaborators to market and sell our products.

We have no sales and marketing experience. We may contract with strategic collaborators to sell and market our products, when and if approved. We may not be successful in entering into collaborative arrangements with third parties for the sale and marketing of any products. Any failure to enter into collaborative arrangements on favorable terms could delay or hinder our ability to develop and commercialize our product candidates and could increase our costs of development and commercialization. Dependence on collaborative arrangements will subject us to a number of risks, including:

- we may not be able to control the amount or timing of resources that our collaborators may devote to the product candidates;
- we may be required to relinquish important rights, including intellectual property, marketing and distribution rights;
- we may have lower revenues than if we were to market and distribute such products ourselves;
- should a collaborator fail to commercialize one of our product candidates successfully, we may not receive future milestone payments or royalties;
- a collaborator could separately move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors;
- our collaborators may experience financial difficulties;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement; and

- our collaborators may operate in countries where their operations could be adversely affected by changes in the local regulatory environment or by political unrest.

We are dependent on Eleison to develop and commercialize glufosfamide

We are dependent upon Eleison Pharmaceuticals, Inc. ("Eleison"), 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. 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 one issued patent that covers a category of hypoxia-activated 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.

2DG is a known compound that is not protected by patents on the composition of the molecule.

2DG is a known compound that is no longer eligible for patent protection on the composition of the molecule. A patent of this nature, known as a compound per se patent, excludes others from making, using or selling the patented compound, regardless of how or for what purpose the compound is formulated or intended to be used. Consequently, this compound and certain of its uses are in the public domain.

We have an issued U.S. patent for the use of orally administered 2DG for the treatment of cancer at certain doses and administration schedules, and we have in-licensed three issued U.S. patents that cover the treatment of certain cancers with 2DG in combination with other specific anti-cancer agents.

Others may develop and market 2DG for the treatment of cancer, however, if they develop treatments using dosing and administration schedules or combination therapies outside the scope of our patents or in contravention of our patent rights.

Metabolic Targeting by targeting the increased uptake of glucose and the increased reliance on glycolysis as an energy source in cancer cells is not protected by patents, and others may be able to develop competitive drugs using this approach.

We have not issued patents or pending patent applications that would prevent others from taking advantage of targeting the increased uptake of glucose and the increased reliance of glycolysis as an energy source in solid tumors 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 product candidates.

We are dependent on patents and proprietary technology, both our own and those licensed from others. If we or our licensors 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 and the ability of our licensors 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 if they are effectively protected by trade secrets. If our patent applications do not result in issued patents, or if our patents, or those patents we have licensed, 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 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 or our licensors might not have been the first to make the inventions covered by each of our or our licensors' pending patent applications and issued patents, and we may have to participate in expensive and protracted interference proceedings to determine priority of invention;
- we or our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative product candidates or duplicate any of our or our licensors' product candidates;
- our or our licensors' pending patent applications may not result in issued patents;
- our or our licensors' 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 or our licensors' patent claims to produce competitive products that fall outside the scope of our or our licensors' patents;
- we may not develop or in-license 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 issued patents and pending 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. We are also aware of a patent that claims certain agents, including 2DG, to inhibit the import of glucose-6-phosphate into the endoplasmic reticulum of a cell. We do not know whether administration of 2DG for our intended uses inhibits such import. If it does, we would be required to license the patent or risk that a claim of infringement could be made. 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 applications, unknown to us, which may later result in issued patents that our product candidates or any other compound that we may develop, 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 biopharmaceutical 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 drugs 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-aventis, AstraZeneca PLC, Genentech, Inc., Bayer Corporation, Eli Lilly and Company and Pfizer, Inc. and from generic pharmaceutical manufacturers. In particular, our drug candidates for pancreatic cancer will compete with Gemzar, marketed by Eli Lilly and Company, doxorubicin, cisplatin, paclitaxel, ifosfamide, and 5-flurouracil, or 5-FU, a generic product which is sold by many manufacturers. In addition, 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-aventis, DTIC-Dome®, marketed by Bayer Pharmaceuticals Corporation, Xeloda®, marketed by Hoffmann-LaRoche, Inc., Avastin®, marketed by Genentech, Inc., 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. Additionally OSI Pharmaceuticals, Inc. and Genentech, Inc. market Tarceva® as a combination therapy with gemcitabine for the first-line treatment of pancreatic cancer. 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.

Novacea has conducted studies on AQ4N and sanofi-aventis recently completed a Phase 3 clinical trial on Tirapazamine, a hypoxically activated prodrug, and while Novacea has stopped current clinical development of AQ4N and sanofi-aventis has released rights to the compound to the innovator SRI, another company may pursue further clinical development of either compound.

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 an $8 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 increasingly expensive. 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.

We may not be able to conduct, or contract with others to conduct, animal testing in the future, which could harm our research and development activities.

Certain laws and regulations relating to drug development require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed.

Risks Related To Our Common Stock

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. On October 16, 2008, the NASDAQ Stock Market suspended the enforcement of the minimum bid price and market value requirements through January 16, 2009. The suspension period was subsequently extended to July 31, 2009 and NASDAQ's enforcement of these rules resumed on Monday, August 3, 2009. NASDAQ does not expect any further extensions of the suspension. Even though we regained compliance with the minimum bid price, we cannot assure you 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.

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 October 5, 2009, we issued outstanding warrants to purchase an aggregate of 7,329,819 shares of our common stock, at an exercise price of $2.23 per share. In addition, on August 29, 2008, we issued outstanding 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 the October 2009 private placement that was completed on that date. 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, 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;
- 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;
- 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. On July 5 and July 18, 2007, purported shareholder class action complaints alleging violations of the federal securities laws were filed against us, our Chief Executive Officer Harold E. Selick and our former Chief Financial Officer Janet I. Swearson in the United States District Court for the Southern District of New York. On September 14, 2007, these lawsuits, which have been consolidated by the Court into a single proceeding, were ordered transferred to the United States District Court for the Northern District of California On January 15, 2008, the plaintiffs filed a first consolidated amended complaint. On July 11, 2008, the Court granted the defendants' motions to dismiss that complaint but afforded the plaintiffs leave to file a further amended complaint. On September 19, 2008, the plaintiffs filed a second consolidated amended complaint, which, on behalf of an alleged class of purchasers of our common stock from the date of our initial public offering of securities on February 4, 2005 through July 14, 2006, purports to allege claims arising under Sections 11, 12(a)(2) and 15 of the Securities Act and under Sections 10(b) and 20(a) of the Exchange Act. The plaintiffs allege generally that the defendants violated the federal securities laws by, among other things, making material misstatements or omissions concerning our Phase 2 and Phase 3 clinical trials of Lonidamine (TH-070). On November 14, 2008, Defendants moved to dismiss the second consolidated amended complaint. On April 3, 2009, the Court granted in part and denied in part the motions to dismiss, dismissing with prejudice all claims arising under the Securities Act and all claims against Ms. Swearson, while narrowing the remaining claims. On October 30, 2009, the parties entered into a stipulation of settlement to resolve the lawsuit. The settlement provides for a payment of $10 million to the plaintiff class solely by our insurers. The settlement is subject to preliminary and, following notice to class members, final approval by the Court. The defendants, including us, have denied and continue to deny all of plaintiffs' allegations of wrongdoing. There can be no assurance at this time that the settlement process will result in final Court approval. To the extent the case does not finally resolve through settlement, the defendants to the lawsuit, including us, continue to believe that plaintiffs' claims are without merit and intend to defend against the actions vigorously. Although we believe our directors and officer's insurance coverage is adequate, if our defense of the suit is unsuccessful, there can be no assurances that the insurance will substantially cover any resulting claim or that the premiums for directors and officers insurance will not be substantially higher in the future.

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 October 15, 2009, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned in excess of 79% of our common stock, assuming the full exercisability of all outstanding warrants. 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 the 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.

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

(c) Issuer Purchases of Equity Securities

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Period	(a) Total number of shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
01/01/2009 to 01/31/2009	—	$ —	—	—
02/01/2009 to 02/28/2009	—	$ —	—	—
03/01/2009 to 03/31/2009	—	$ —	—	—

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

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.

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 5, 2009

/s/ HAROLD E. SELICK

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

Date: November 5, 2009

/s/ JOEL A. FERNANDES

Joel A. Fernandes
Senior Director, Finance and Controller
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

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.

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 function):

   (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 5, 2009

/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 function):

   (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 5, 2009

/s/ Joel A. Fernandes
Joel A. Fernandes
Senior Director, 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, 2009, 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 5, 2009

/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, 2009, 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 5, 2009

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