

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, 2008

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
(State or other jurisdiction of
incorporation or organization)

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

1300 Seaport Boulevard
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 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

Smaller reporting company

(Do not check if a 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, 2008, there were 15,214,044 shares of common stock, par value \$0.001 per share, of Threshold Pharmaceuticals, Inc. outstanding.

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FORM 10-Q
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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, trade names 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, 2008	December 31, 2007 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 22,947	\$ 11,404
Marketable securities	3,602	11,289
Prepaid expenses and other current assets	527	516
Total current assets	27,076	23,209
Property and equipment, net	1,398	2,097
Restricted cash and other assets	508	508
Total assets	<u>\$ 28,982</u>	<u>\$ 25,814</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 355	\$ 1,022
Accrued clinical and development expenses	996	1,240
Accrued liabilities	657	717
Deferred revenue	359	1,437
Notes payable, current portion	571	909
Total current liabilities	2,938	5,325
Notes payable, less current portion	—	337
Deferred rent	560	565
Total liabilities	3,498	6,227
Commitments and contingencies (Note 8)		
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 at September 30, 2008 and 150,000,000 at December 31, 2007; issued and outstanding: 15,214,044 shares at September 30, 2008 and 6,228,056 shares at December 31, 2007	15	6
Additional paid-in capital	204,376	185,733
Deferred stock-based compensation	(75)	(834)
Accumulated other comprehensive (loss) income	(13)	3
Deficit accumulated during the development stage	(178,819)	(165,321)
Total stockholders' equity	25,484	19,587
Total liabilities and stockholders' equity	<u>\$ 28,982</u>	<u>\$ 25,814</u>

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

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

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine months Ended</u> <u>September 30,</u>		<u>Cumulative</u> <u>Period from</u> <u>October 17, 2001</u> <u>(date of inception)</u> <u>to September 30, 2008</u>
	<u>2008</u>	<u>2007</u>	<u>2008</u>	<u>2007</u>	
Revenue	\$ 362	\$ 359	\$ 1,080	\$ 1,077	\$ 4,667
Operating expenses:					
Research and development	3,672	4,896	9,873	18,230	140,299
General and administrative	1,344	2,407	5,067	7,517	51,379
Total operating expenses	<u>5,016</u>	<u>7,303</u>	<u>14,940</u>	<u>25,747</u>	<u>191,678</u>
Loss from operations	(4,654)	(6,944)	(13,860)	(24,670)	(187,011)
Interest income, net	109	415	414	1,524	8,678
Interest expense	(13)	(30)	(52)	(110)	(486)
Net loss	(4,558)	(6,559)	(13,498)	(23,256)	(178,819)
Dividend related to beneficial conversion feature of redeemable convertible preferred stock	—	—	—	—	(40,862)
Net loss attributable to common stockholders	<u>\$ (4,558)</u>	<u>\$ (6,559)</u>	<u>\$ (13,498)</u>	<u>\$ (23,256)</u>	<u>\$ (219,681)</u>
Net loss per common share, basic and diluted	<u>\$ (0.49)</u>	<u>\$ (1.06)</u>	<u>\$ (1.86)</u>	<u>\$ (3.77)</u>	
Weighted average number of shares used in per common share calculations: basic and diluted	<u>9,392</u>	<u>6,180</u>	<u>7,276</u>	<u>6,165</u>	

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 STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE PERIOD
FROM OCTOBER 17, 2001 (DATE OF INCEPTION) TO SEPTEMBER 30, 2008
(in thousands, except share and per share data)
(unaudited)

	Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount					
Issuance of restricted common stock to a founder and member of the Board of Directors in October 2001 for cash at \$0.12 per share	25,300	\$ —	\$ 2	\$ —	\$ —	\$ —	\$ 2
Net loss	—	—	—	—	—	(236)	(236)
Balances, December 31, 2001	25,300	—	2	—	—	(236)	(234)
Issuance of restricted common stock to a member of the Board of Directors for cash at \$0.96 per share in January 2002	3,795	—	4	—	—	—	4
Issuance of common stock pursuant to exercise of stock options for cash at \$0.96 per share	405	—	—	—	—	—	—
Deferred stock-based compensation	—	—	25	(25)	—	—	—
Amortization of deferred stock-based compensation	—	—	—	1	—	—	1
Non-employee stock-based compensation	—	—	21	—	—	—	21
Components of other comprehensive income (loss):							
Unrealized loss on marketable securities	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	(2,458)	(2,458)
Comprehensive loss	—	—	—	—	—	—	(2,459)
Balances, December 31, 2002	29,500	—	52	(24)	(1)	(2,694)	(2,667)
Issuance of common stock pursuant to exercise of stock options for cash at \$0.96 per share	1,285	—	1	—	—	—	1
Issuance of a warrant to purchase Series A redeemable convertible preferred stock	—	—	44	—	—	—	44
Beneficial conversion feature related to issuance of Series B redeemable convertible preferred stock	—	—	40,862	—	—	—	40,862
Deemed dividend related to beneficial conversion feature of Series B redeemable convertible preferred stock	—	—	(40,862)	—	—	—	(40,862)
Deferred stock-based compensation, net of cancellations	—	—	2,332	(2,332)	—	—	—
Amortization of deferred stock-based compensation	—	—	—	810	—	—	810
Non-employee stock-based compensation	—	—	256	—	—	—	256
Components of other comprehensive income (loss):							
Change in unrealized gain (loss) on marketable securities	—	—	—	—	164	—	164
Net loss	—	—	—	—	—	(8,303)	(8,303)
Comprehensive loss	—	—	—	—	—	—	(8,139)
Balances, December 31, 2003	30,785	—	2,685	(1,546)	163	(10,997)	(9,695)
Issuance of common stock pursuant to exercise of stock options for cash	586,384	—	878	—	—	—	878
Deferred stock-based compensation, net of cancellations	—	—	20,385	(20,385)	—	—	—
Amortization of deferred stock-based compensation	—	—	—	5,294	—	—	5,294
Non-employee stock-based compensation	—	—	681	—	—	—	681
Repurchase of unvested common stock	(2,074)	—	(6)	—	—	—	(6)

THRESHOLD PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE ENTERPRISE)
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)—(Continued)
FOR THE PERIOD
FROM OCTOBER 17, 2001 (DATE OF INCEPTION) TO SEPTEMBER 30, 2008
(in thousands, except share and per share data)
(unaudited)

	Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount					
Components of other comprehensive income (loss):							
Change in unrealized gain (loss) on marketable securities	—	—	—	—	(59)	—	(59)
Net loss	—	—	—	—	—	(23,566)	(23,566)
Comprehensive loss							(23,625)
Balances, December 31, 2004	615,095	—	24,623	(16,637)	104	(34,563)	(26,473)
Issuance of common stock in an initial public offering for cash of \$42.00, per share, net of issuance costs of \$4.6 million	1,018,768	1	38,134	—	—	—	38,135
Issuance of common stock for cash of \$62.76 per share, net of issuance costs of \$4.5 million	1,066,537	1	62,394	—	—	—	62,395
Issuance of common stock pursuant to exercise of warrants	3,211	—	—	—	—	—	—
Conversion of convertible preferred stock upon initial public offering	3,425,468	4	49,835	—	—	—	49,839
Issuance of common stock pursuant to stock plans	84,771	—	557	—	—	—	557
Deferred stock-based compensation, net of cancellations	—	—	3,321	(3,321)	—	—	—
Reversal of deferred stock-based compensation related to employee terminations	—	—	(2,862)	2,862	—	—	—
Amortization of deferred stock-based compensation	—	—	(416)	5,740	—	—	5,324
Non-employee stock-based compensation	—	—	4,097	—	—	—	4,097
Repurchase of unvested common stock	(8,588)	—	(18)	—	—	—	(18)
Components of other comprehensive income (loss):							
Change in unrealized gain (loss) on marketable securities	—	—	—	—	(80)	—	(80)
Net loss	—	—	—	—	—	(44,408)	(44,408)
Comprehensive loss							(44,488)
Balances, December 31, 2005	6,205,262	6	179,665	(11,356)	24	(78,971)	89,368
Issuance of common stock pursuant to stock plans	46,129	—	518	—	—	—	518
Reversal of deferred stock-based compensation related to employee terminations	—	—	(2,970)	2,970	—	—	—
Amortization of deferred stock-based compensation	—	—	—	4,411	—	—	4,411
Stock-based compensation	—	—	5,738	—	—	—	5,738
Repurchase of unvested common stock	(27,076)	—	(80)	—	—	—	(80)
Components of other comprehensive income (loss):							
Change in unrealized gain (loss) on marketable securities	—	—	—	—	(31)	—	(31)
Net loss	—	—	—	—	—	(55,686)	(55,686)
Comprehensive loss							(55,717)
Balances, December 31, 2006	6,224,315	\$ 6	\$182,871	\$ (3,975)	\$ (7)	\$ (134,657)	\$ 44,238

THRESHOLD PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE ENTERPRISE)
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)—(Continued)
FOR THE PERIOD
FROM OCTOBER 17, 2001 (DATE OF INCEPTION) TO SEPTEMBER 30, 2008
(in thousands, except share and per share data)
(unaudited)

	Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount					
Issuance of common stock pursuant to stock plans	20,146	—	128	—	—	—	128
Reversal of deferred stock-based compensation related to employee terminations	—	—	(304)	304	—	—	—
Amortization of deferred stock-based compensation	—	—	—	2,837	—	—	2,837
Stock-based compensation	—	—	3,072	—	—	—	3,072
Repurchase of unvested common stock	(16,405)	—	(34)	—	—	—	(34)
Components of other comprehensive income (loss):							
Change in unrealized gain (loss) on marketable securities	—	—	—	—	10	—	10
Net loss	—	—	—	—	—	(30,664)	(30,664)
Comprehensive loss							(30,654)
Balances, December 31, 2007	6,228,056	\$ 6	\$185,733	\$ (834)	\$ 3	\$ (165,321)	\$ 19,587
Issuance of common stock and warrants to certain investors, net of issuance costs of \$1.5 million	8,970,574	9	16,805	—	—	—	16,814
Issuance of common stock pursuant to stock plans	15,458	—	31	—	—	—	31
Amortization of deferred stock-based compensation	—	—	—	759	—	—	759
Stock-based compensation	—	—	1,807	—	—	—	1,807
Repurchase of unvested common stock	(44)	—	—	—	—	—	—
Components of other comprehensive income (loss):							
Change in unrealized gain (loss) on marketable securities	—	—	—	—	(16)	—	(16)
Net loss	—	—	—	—	—	(13,498)	(13,498)
Comprehensive loss							(13,514)
Balances, September 30, 2008	15,214,044	\$ 15	\$204,376	\$ (75)	\$ (13)	\$ (178,819)	\$ 25,484

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, 2008
	2008	2007	
Cash flows from operating activities:			
Net loss	\$(13,498)	\$(23,256)	\$ (178,819)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	725	784	3,520
Stock-based compensation expense	2,566	4,475	35,108
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	(11)	(124)	(552)
Accounts payable	(667)	161	355
Accrued clinical and development expenses	(244)	(2,122)	996
Accrued liabilities	(60)	(1,652)	657
Deferred rent	(5)	83	560
Deferred revenue	(1,078)	(1,077)	359
Net cash used in operating activities	<u>(12,272)</u>	<u>(22,728)</u>	<u>(137,799)</u>
Cash flows from investing activities:			
Acquisition of property and equipment	(30)	(10)	(4,966)
Acquisition of marketable securities	(4,825)	(18,233)	(141,192)
Proceeds from sales and maturities of marketable securities	12,500	29,079	137,652
Restricted cash	—	—	(483)
Net cash provided by (used in) investing activities	<u>7,645</u>	<u>10,836</u>	<u>(8,989)</u>
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	16,845	98	119,325
Proceeds from issuance of notes payable	—	—	3,616
Repayment of notes payable	(675)	(747)	(3,045)
Net cash (used in) provided by financing activities	<u>16,170</u>	<u>(649)</u>	<u>169,735</u>
Net increase (decrease) in cash and cash equivalents	11,543	(12,541)	22,947
Cash and cash equivalents, beginning of period	11,404	28,450	—
Cash and cash equivalents, end of period	<u>\$ 22,947</u>	<u>\$ 15,909</u>	<u>\$ 22,947</u>
Supplemental schedule of non-cash investing and financing activities			
Deferred stock-based compensation	\$ —	\$ (158)	\$ (19,511)
Fair value of redeemable convertible preferred stock warrant	\$ —	\$ —	\$ 44
Change in unrealized gain (loss) on marketable securities	\$ (16)	\$ 9	\$ (13)
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, 2007 has been derived from the audited financial statements at that date but does not include all the information and footnotes required by United States Generally Accepted Accounting Principles (“GAAP”) for complete financial statements. 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, 2007 included in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (“SEC”) on March 12, 2008.

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

Liquidity

The Company has 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 Company has incurred significant losses since its inception. At September 30, 2008, the Company had an accumulated deficit of \$178.8 million. 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 and warrants exercisable for a total of 3,588,221 shares of its common stock with an exercise price equal to \$2.34 per share (subject to adjustment). The Company received aggregate gross proceeds equal to \$18.3 million in connection with the offering. Net proceeds generated from the offering were \$16.8 million.

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;

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- licensing arrangements; and/or
- public or private debt.

The Company believes that its existing cash, cash equivalents and marketable securities as of September 30, 2008 will be sufficient to fund its projected operating requirements through the fourth quarter of 2009, including completing its current 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.

The Company intends to seek funds through arrangements with collaborators or others that may require the Company to relinquish rights to certain product candidates that it might otherwise seek to develop or commercialize independently. Additionally, the Company may need or choose to raise additional capital or incur indebtedness to continue to fund its operations in the future.

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 December 2007, the FASB issued SFAS No. 141 (revised 2007), "*Business Combinations*" ("SFAS No. 141(R)"), which replaces SFAS No. 141. SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree and the goodwill acquired. SFAS No. 141(R) also establishes disclosure requirements which will enable users to evaluate the nature and financial effects of the business combination. SFAS No. 141(R) is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The Company is currently evaluating the impact of the adoption of SFAS No. 141(R) on its consolidated financial statements.

In February 2008, the FASB issued FASB Staff Position No. FAS 157-2, "Effective Date of FASB Statement No. 157" ("FSP 157-2"), to partially defer FASB Statement No. 157, "Fair Value Measurements" ("SFAS 157"). FSP 157-2 defers the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), to fiscal years, and interim periods within those fiscal years, beginning after November 15, 2008. The Company adopted SFAS No. 157 in the first quarter of 2008 and is currently evaluating the impact of adopting the provisions of FSP 157-2 on its consolidated financial statements.

In June 2008, the FASB ratified the consensus reached on EITF Issue No. 07-5, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock" ("EITF 07-5"). EITF 07-5 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. EITF 07-5 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. The adoption of EITF 07-5 may result in the reclassification of the Company's outstanding warrants from stockholders' equity to liability, which would require the warrants to be marked to market at each reporting period, with the changes in market value recorded in the Company's consolidated statement of operations. At September 30, 2008 the Company had warrants outstanding to purchase 3,588,221 shares of common stock at an exercise price of \$2.34 per share. The Company is currently evaluating the impact of the pending adoption of EITF 07-5 on its consolidated financial statements.

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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,	
	2008	2007	2008	2007
Numerator:				
Net loss	<u>\$(4,558)</u>	<u>\$(6,559)</u>	<u>\$(13,498)</u>	<u>\$(23,256)</u>
Denominator:				
Weighted average common shares outstanding	9,394	6,226	7,287	6,235
Less: Weighted average unvested common shares subject to repurchase	<u>(2)</u>	<u>(46)</u>	<u>(11)</u>	<u>(70)</u>
Denominator for basic and diluted calculations	<u>9,392</u>	<u>6,180</u>	<u>7,276</u>	<u>6,165</u>
Basic and diluted net loss per share	<u>\$ (0.49)</u>	<u>\$ (1.06)</u>	<u>\$ (1.86)</u>	<u>\$ (3.77)</u>

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,	
	2008	2007
Shares issuable upon exercise of warrants	3,588	—
Shares issuable upon exercise of stock options	640	470
Shares issuable related to the ESPP	7	5
Common shares subject to repurchase	1	38

NOTE 3 — STOCKHOLDERS' EQUITY

Common Stock

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 have been recorded in stockholders equity in accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" and FSP 00-19-2, "Accounting for Registration Payment Arrangements."

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. The par value of the common stock was not affected by the reverse stock split and remains at \$0.001 per share. Consequently, on the Company's balance sheet, the aggregate par value of the issued common stock was reduced by reclassifying the par value amount of the eliminated shares of common stock to Additional Paid-in Capital. The Company paid cash in lieu of any fractional shares to which a holder of common stock would otherwise be entitled as a result of the reverse stock split, including fractional shares for the in-the-money stock options. In addition, the number of authorized shares of common stock was reduced from 150,000,000 to 50,000,000. 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.

Preferred Share Rights Agreement

Effective July 10, 2008, the Company entered into an amendment (the "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"). The 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.

NOTE 4 — STOCK BASED COMPENSATION

The Company recognizes stock-based compensation in accordance with the fair value provisions of Statement of Financial Accounting Standards No.123(R), "Share-Based Payment" ("SFAS 123(R)") 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, 2008 and 2007 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, 2008 and 2007, based on the recognition of the grant date fair value estimated in accordance with the original provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), as amended by SFAS No. 148, "Accounting for Stock-Based Compensation, Transition and Disclosure." 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, 2008 and 2007, based on the recognition of the grant date fair value estimated in accordance with the provisions of SFAS 123(R) over the service period, which is generally the vesting period; and

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- 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, 2008 and 2007, based on the grant date intrinsic value over the service period, which is generally the vesting period, in accordance with the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25").

In addition, SFAS 123(R) 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 SFAS 123(R), the Company accounted for forfeitures upon occurrence.

Stock-based compensation expense related to stock options and ESPP recognized in the unaudited condensed consolidated statement of operations was \$0.7 million and \$2.6 million for the three and nine months ended September 30, 2008, respectively, and was \$1.5 million and \$4.5 million for the three and nine months ended September 30, 2007, 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 \$0.1 million and \$0.8 million for the three and nine months ended September 30, 2008, respectively, and was \$0.7 million and \$2.2 million for the three and nine months ended September 30, 2007, 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, 2008 and 2007:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Employee Stock Options				
Risk-free interest rate	2.93%	4.70%	3.12%	4.63%
Expected term (in years)	6.08	6.05	5.97	5.97
Dividend yield	—	—	—	—
Volatility	83%	77%	83%	77%
Weighted-average fair value of stock options granted	\$ 1.28	\$ 3.90	\$ 2.14	\$ 9.72
Employee Stock Purchase Plan (ESPP):				
Risk-free interest rate	2.27%	4.53%	2.14%	4.55%
Expected term (in years)	1.25	1.25	1.25	1.25
Dividend yield	—	—	—	—
Volatility	67%	67%	67%	67%
Weighted-average fair value of ESPP purchase rights	\$ 0.82	\$ 2.10	\$ 0.94	\$ 2.34

To determine the expected term of the Company's employee stock options granted during the three and nine months ended September 30, 2008 and 2007, 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, 2008 and 2007, 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 ended September 30, 2008 and 2007 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.

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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 APB 25, 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 is being amortized on a straight-line basis over the period during which the Company's right to repurchase the stock lapses or the options vest, generally four years. Through September 30, 2008, the Company amortized approximately \$19.4 million of such compensation expense, net of forfeitures, with approximately \$0.1 million and \$0.8 million being amortized in the three and nine months ended September 30, 2008, respectively and \$0.7 million \$2.2 million being amortized in the three and nine months ended September 30, 2007, respectively.

Stock-based compensation expense As required by SFAS 123(R) the Company recognized \$0.6 million and \$1.8 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, for the three and nine months ended September 30, 2008, respectively, and \$0.7 million and \$2.2 million of stock-based compensation expense for the three and nine months ended September 30, 2007, respectively, in addition to the amortization of deferred compensation above. As of September 30, 2008, the total unrecognized compensation cost related to unvested stock-based awards granted to employees under the Company's stock option plans was approximately \$3.9 million before forfeitures. This cost will be recorded as compensation expense on a straight-line basis over the remaining weighted average requisite service period of approximately 2.8 years.

Non-employee Stock-based Compensation Expense

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." 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 \$5,000 and \$25,000 for the three months and nine months ended September 30, 2008, respectively, and \$24,000 and \$0.1 million for the three months and nine months ended September 30, 2007, 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		Nine Months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
Stock-based compensation expense:				
Research and development	\$ 323	\$ 602	\$ 1,157	\$ 1,797
General and administrative	341	892	1,409	2,678
	<u>\$ 664</u>	<u>\$ 1,494</u>	<u>\$ 2,566</u>	<u>\$ 4,475</u>

Equity Incentive Plans

2004 Equity Incentive Plan During the nine months ended September 30, 2008, the Company granted stock options to purchase 230,238 shares at an average exercise price of \$2.93 per share under the 2004 Equity Incentive Plan. At September 30, 2008, 245,148 shares were authorized and available for issuance under the stock option plan.

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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 January 1, 2008	497,139	\$ 12.69	—	—
Granted	230,238	\$ 2.93	—	—
Exercised	(727)	\$ 1.56	—	—
Forfeitures	(86,270)	\$ 16.05	—	—
Outstanding at September 30, 2008	<u>640,380</u>	\$ 8.74	8.58	\$ 646
Vested and expected to vest September 30, 2008	630,938	\$ 8.79	8.57	\$ 646
Exercisable at September 30, 2008	<u>220,837</u>	\$ 12.24	7.99	\$ 646

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, 2008. The total intrinsic value of stock options exercised during the nine months ended September 30, 2008 and 2007 was \$400 and \$2,000, respectively, determined at the date of the option exercise. Cash received from stock option exercises was \$1,000 and \$5,000 for the nine months ended September 30, 2008 and 2007, respectively. The Company issues new shares of common stock upon exercise of options. In connection with these exercises, there was no tax benefit realized by the Company due to the Company's current loss position.

2004 Employee Stock Purchase Plan For the nine months ended September 30, 2008, plan participants had purchased 14,756 shares at an average purchase price of \$1.97. At September 30, 2008, plan participants had \$13,000 withheld to purchase stock on February 14, 2009, which is included in accrued liabilities on the accompanying unaudited condensed consolidated balance sheet. At September 30, 2008, 119,165 shares were authorized and available for issuance under the ESPP.

NOTE 5 — FAIR VALUE MEASUREMENTS AND MARKETABLE SECURITIES

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, "*Fair Value Measures*" ("SFAS No. 157"). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. In February 2008, the FASB issued FSP FAS 157-2 "Partial Deferral of the Effective Date of Statement 157" (FSP 157-2). FSP-2 delays the effective date of FAS 157 for non-financial assets and liabilities that are not measured or disclosed on a recurring basis to fiscal years beginning after November 15, 2008. The Company adopted SFAS No. 157 in the first quarter of 2008. The Company is currently in the process of evaluating the impact of adopting this pronouncement for other non-financial assets or liabilities.

SFAS 157 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. SFAS 157 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.

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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, 2008:

(in thousands)	Fair Value as of September 30, 2008	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	\$ 9,088	\$ 9,088	\$ —	\$ —
Corporate bonds	1,519	—	1,519	—
Government securities	2,625	—	2,625	—
Commercial paper	12,557	—	12,557	—
Total cash equivalents and marketable securities	\$ 25,789	\$ 9,088	\$ 16,701	\$ —

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, 2008 and December 31, 2007:

As of September 30, 2008 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	\$ 9,088	\$ —	\$ —	\$ 9,088
Corporate bonds	1,532	—	(13)	1,519
Government securities	2,622	3	—	2,625
Commercial paper	12,565	—	(8)	12,557
	25,807	3	(21)	25,789
Less cash equivalents	(22,192)	(3)	8	(22,187)
Total marketable securities	\$ 3,615	\$ —	\$ (13)	\$ 3,602

As of December 31, 2007 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	\$ 3,386	\$ —	\$ —	\$ 3,386
Corporate bonds	2,353	1	(2)	2,352
Government securities	8,542	3	—	8,545
Commercial paper	7,230	—	—	7,230
Asset-backed securities	793	2	—	795
	22,304	6	(2)	22,308
Less cash equivalents	(11,018)	(1)	—	(11,019)
Total marketable securities	\$ 11,286	\$ 5	\$ (2)	\$ 11,289

NOTE 6 — RESTRUCTURING ACCRUAL

In October 2007, the Company adopted a plan to reduce its operating expenses and refocus its research and development efforts. The plan included a reduction of 12 positions in both research and development and general and administrative areas of the Company. As a result of the staffing reduction, the Company incurred severance benefits of approximately \$1.2 million in the fourth quarter of 2007. The Company made payments on severance benefits of \$0.1 million and \$1.1 million in the quarters ended March 31, 2008 and December 31, 2007, respectively.

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The following table sets forth an analysis of the restructuring accrual at September 30, 2008 (in thousands):

	Severance and benefits
Balance at December 31, 2007	\$ 120
Charges	—
Cash paid	(120)
Balance at September 30, 2008	<u>\$ —</u>

NOTE 7 — 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 will be 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 is being repaid over a 36-month period from the date of borrowing. The interest rate on these borrowings was approximately 7.2% per annum. Under the amended loan and security agreement, the Company is required to maintain the lower of 85% of its total cash and cash equivalents or \$10.0 million with the financial institution. Borrowings under the equipment line of credit are collateralized by the related equipment. At September 30, 2008, the Company was in compliance with all financial covenants in the agreement.

At September 30, 2008, future principal payments under the amended loan and security agreement are as follows (in thousands):

<u>Years Ending December 31,</u>	
2008 (remaining three months)	\$234
2009	<u>337</u>
Total	<u>\$571</u>

NOTE 8 — COMMITMENTS AND CONTINGENCIES

The Company leases certain of its facilities under noncancelable leases, which qualify for operating lease accounting treatment under SFAS No. 13, "Accounting for 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):

<u>Years Ending December 31,</u>	
2008 (remaining three months)	\$ 341
2009	1,398
2010	1,462
2011	<u>1,129</u>
Total	<u>\$4,330</u>

The Company's purchase commitments at September 30, 2008 were \$2.2 million.

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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 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 of 1933, as amended (the "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 II and Phase III clinical trials of Lonidamine (TH-070). Management believes that Plaintiffs' claims are without merit and intends to defend against the actions vigorously. The Company cannot reasonably predict the outcome of this matter at this time.

NOTE 9 — 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		Nine Months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
Net loss	\$ (4,558)	\$ (6,559)	\$ (13,498)	\$ (23,256)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities	(8)	11	(16)	9
Total comprehensive loss	<u>\$ (4,566)</u>	<u>\$ (6,548)</u>	<u>\$ (13,514)</u>	<u>\$ (23,247)</u>

NOTE 10 — RELATED PARTIES

In March 2008, the Company entered into a License Agreement, for the use of 5,500 square feet of its facilities and laboratory space with Ethos Pharmaceuticals (formerly AllChemie, Inc.), a Delaware corporation. Dr. Harold E. Selick, the Company's Chief Executive Officer and a member of the board of directors, is the chairman of the board of directors of Ethos Pharmaceuticals. Ethos Pharmaceuticals will pay the Company a fee in the aggregate of \$193,462 for the one-year initial term of the agreement and, if extended, a fee in the aggregate of \$127,050 for the six-month extension term of the License Agreement. In addition, Ethos Pharmaceuticals will pay for costs incurred relating to agreed upon services provided by the Company.

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The Company's offering of common stock and warrants, on August 29, 2008, included 980,391 shares of common stock and warrants exercisable for a total of 392,156 shares of common stock sold to entities affiliated with Three Arch Management III, L.L.C. ("Three Arch"). Wilfred E. Jaeger, a member of the Company's board of directors, is a managing member of Three Arch. Also as part of this offering, certain members of the Company's management team purchased 245,095 shares and received warrants to purchase 98,038 shares of common stock.

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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, 2007, 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 2-deoxyglucose ("2DG") share certain structural characteristics with glucose but act instead as chemotherapeutic toxins when taken up by a cell.

Our focus is on product candidates for the treatment of patients living with cancer. We have three 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. In May 2007, we announced the filing of an investigational new drug application ("IND") with the FDA for TH-302, and in July 2007, we initiated a Phase 1 clinical trial evaluating the safety of TH-302 in patients with advanced solid tumors. In July 2008, we reported top line results for this clinical trial, which has planned enrollment completion by Q4 2008. In August 2008, we initiated a complete 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. 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.
- Glufosfamide is for the potential treatment of patients with cancer. In the third quarter of 2007, we presented final results including promising tumor response and survival data from the Phase 2 stage of a clinical trial of glufosfamide plus gemcitabine for the first-line treatment of pancreatic cancer. In 2007 we initiated a Phase 2 clinical trial of glufosfamide in soft-tissue sarcoma, platinum-resistant ovarian cancer and recurrent sensitive small cell lung cancer. All studies have been closed to enrollment and top-line results from each study have been reported. In February 2007, we announced that our Phase 3 clinical trial did not reach its primary endpoint of a statistically significant survival benefit for patients with metastatic pancreatic cancer that relapsed following chemotherapy with gemcitabine. We plan to partner or seek external funding for the future development of glufosfamide.

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- 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 planning on conducting any additional clinical trials of 2DG as we are focusing our resources on the development of our hypoxia-activated prodrug, TH-302, and the out-licensing of glufosfamide for the potential treatment of solid tumors.

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

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, 2008 we had cash, cash equivalents and marketable securities of \$26.5 million. The net loss for the three and nine months ended September 30, 2008 was \$4.6 million and \$13.5 million, respectively, and the cumulative net loss since our inception through September 30, 2008 was \$178.8 million.

We expect to continue to incur losses from operations in the future. We expect that expenses will decrease in 2008 compared to 2007 due to a reduced workforce and reduced number of patients in smaller clinical trials, and that our cash, cash equivalents and marketable securities as of September 30, 2008 will be sufficient to fund our projected operating requirements through the fourth quarter of 2009, 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. For each of the three and nine months ended September 30, 2008 and 2007, we recognized revenue of \$0.4 million and \$1.1 million, respectively, related to a \$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 is being recognized on a straight-line basis over the estimated development period, currently estimated to continue through 2008. We are responsible for all development activities under this agreement.

Research and Development. Research and development expenses were \$3.7 million for the three months ended September 30, 2008 compared to \$4.9 million for the three months ended September 30, 2007. The \$1.2 million decrease in expenses is due to a \$0.4 million decrease in clinical and development expenses, \$0.4 million in lower staffing expenses due to a lower headcount compared to the prior year period and \$0.1 million in lower consulting expenses. Stock-based compensation decreased by \$0.3 million primarily due to a reduction in the number of employees and consultants compared to the prior year, as well as a lower valuation for 2008 stock option grants primarily due to a lower stock price. Research and development expenses were \$9.9 million for the nine months ended September 30, 2008 compared to \$18.2 million for the nine months ended September 30, 2007. The \$8.3 million decrease in expenses is due to a \$5.1 million decrease in clinical and development expenses, \$1.7 million in lower staffing expense, \$0.7 million in lower consulting expenses and a \$0.3 million decrease in facilities expenses. Stock-based compensation expense decreased by \$0.7 million primarily due to a reduction in the number of employees and consultants compared to the prior year, as well as a lower valuation for 2008 stock option grants primarily due to a lower stock price.

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Research and development expenses by project (in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
TH-302	\$ 2,052	\$ 846	\$4,743	\$ 3,827
Glufosfamide	627	2,448	1,840	9,804
2DG	92	285	307	931
Discovery research	901	1,317	2,983	3,668
Total research and development expenses	<u>\$ 3,672</u>	<u>\$ 4,896</u>	<u>\$9,873</u>	<u>\$18,230</u>

Research and development expenses associated with our internally discovered compound TH-302 were \$2.1 million for the three months ended September 30, 2008 and \$0.9 million for the three months ended September 30, 2007. TH-302 continues to progress through the Phase 1 monotherapy clinical trial initiated in July 2007, with enrollment expected to be completed in Q4 2008. 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 \$0.6 million for the three months ended September 30, 2008 and \$2.4 million for the three months ended September 30, 2007. This decrease is primarily due to a \$0.8 million decrease in clinical, manufacturing and consulting expenses and a \$0.7 million decrease in employee-related and stock-based compensation expenses. These declines in expenses were due to 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. Research and development expenses associated with 2DG were \$0.1 million for the three months ended September 30, 2008 and \$0.3 million for the three months ended September 30, 2007 as we completed enrollment in our 2DG Phase 1 trial in Q2 2008 and announced results in Q3 2008. Discovery research expenses were \$0.9 million for the three months ended September 30, 2008 and \$1.3 million for the three months ended September 30, 2007. The decrease was primarily due to the allocation of resources towards our TH-302 program and lower staffing and facilities expenses to support our other discovery research programs.

Research and development expenses associated with our internally discovered compound TH-302 were \$4.7 million for the nine months ended September 30, 2008 and \$3.8 million for the nine months ended September 30, 2007. TH-302 continues to progress through the Phase 1 monotherapy clinical trial initiated in July 2007, with enrollment expected to be completed in Q4 2008. In addition, in 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 \$1.8 million for the nine months ended September 30, 2008 and \$9.8 million for the nine months ended September 30, 2007. This decrease is primarily due to a \$4.8 million decrease in clinical and manufacturing expenses and a \$2.6 million decrease in employee-related and stock compensation expenses and a \$0.6 million decrease in outside consulting expenses. These declines in expenses were due to 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. Research and development expenses associated with 2DG were \$0.3 million for the nine months ended September 30, 2008 and \$0.9 million for the nine months ended September 30, 2007, as we completed enrollment of our 2DG Phase 1 trial in Q2 2008 and announced results in Q3 2008. Discovery research expenses were \$3.0 million for the nine months ended September 30, 2008 and \$3.7 million for the nine months ended September 30, 2007. The decrease was primarily due to the allocation of resources towards our TH-302 program and lower staffing and facilities expenses to support our other discovery research programs.

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 decrease in 2008 compared to 2007 due to smaller clinical trials and a reduced workforce.

General and Administrative. General and administrative expenses were \$1.3 million for the three months ended September 30, 2008, compared to \$2.4 million for the three months ended September 30, 2007. The decrease of \$1.1 million is due to \$0.6 million of decrease in stock-based compensation expenses, \$0.4 million in lower staffing and facilities expenses related to staff reductions in 2007 and \$0.1 million of decreased consulting expenses.

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General and administrative expenses were \$5.1 million for the nine months ended September 30, 2008, compared to \$7.5 million for the nine months ended September 30, 2007. The decrease of \$2.4 million is due to a \$1.3 million decrease in stock-based compensation expenses and \$1.2 million in lower staffing and facilities expenses related to staff reductions in October 2007. These reductions in expenses were partially offset by \$0.1 million increase in consulting expenses.

General and administrative expenses are expected to decrease in 2008 due to lower employee-related costs as a result of 2007 staff reductions.

Interest Income, Net. Interest income for the three and nine months ended September 30, 2008 was \$0.1 million and \$0.4 million, respectively, compared to \$0.4 million and \$1.5 million for the three and nine months ended September 30, 2007, respectively. The decrease was primarily due to lower invested cash balances and, lower interest rates during the three and nine months ended September 30, 2008 compared to the prior year.

Liquidity and Capital Resources

We have incurred net losses of \$178.8 million since inception through September 30, 2008. 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 the private placement 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 its common stock for a purchase price equal to \$2.04 per share and warrants exercisable for a total of 3,588,221 shares of its common stock with an exercise price equal to \$2.34 per share (subject to adjustment). We received aggregate gross proceeds equal to \$18.3 million in connection with the offering. 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 \$26.5 million and \$22.7 million at September 30, 2008 and December 31, 2007, respectively, available to fund operations.

Net cash used in operating activities for the nine months ended September 30, 2008 and 2007 was \$12.3 million and \$22.7 million, respectively. The decrease of \$10.4 million in cash used in operations was primarily attributable to a lower net loss in 2008, partially offset by lower accounts payable and accrual balances.

Net cash provided by investing activities for the nine months ended September 30, 2008 and 2007 was \$7.6 million and \$10.8 million, respectively. The \$3.2 million decrease in cash provided by investing activities was due primarily to a decrease in proceeds from the sale and maturities of marketable securities, partially offset by a decrease in the purchases of marketable securities.

Net cash provided by financing activities for the nine months ended September 30, 2008 was \$16.2 million, compared to net cash used in financing activities for the nine months ended September 30, 2007 of \$0.7 million. The increase of \$16.9 million reflects primarily the \$16.8 million net proceeds from the sale of our common stock 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 will be 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 is being repaid over a 36-month period from the date of borrowing. The interest rate on these borrowings was approximately 7.2% per annum. At September 30, 2008, the total amount due under this facility was \$0.6 million. Under the amended loan and security agreement, we are required to maintain the lower of 85% of our total cash and cash equivalents or \$10.0 million with the financial institution. Borrowings under the equipment line of credit are collateralized by the related equipment. At September 30, 2008, we were in compliance with all financial covenants in the agreement.

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.

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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 financing and lease agreements, and purchase commitments. Contractual obligations and related scheduled payments as of September 30, 2008, are as follows (in thousands):

	Remainder of current year (2008)	One to three years (2009 to 2011)	Four to five years (2012 to 2013)	After five Years	Total
Facilities leases	\$ 341	\$ 3,989	\$ —	\$ —	\$4,330
Notes payable, principal and interest	242	343	—	—	585
Purchase commitments	2,150	—	—	—	2,150
Total	<u>\$ 2,733</u>	<u>\$ 4,332</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$7,065</u>

We expect 2008 cash requirements to be in the range of \$17.0 million to \$20.0 million. We believe that our cash, cash equivalents and marketable securities as of September 30, 2008 will be sufficient to fund our projected operating requirements through the fourth quarter of 2009, 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 requirements and no further action was required on our part. 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 \$5 million or a market value of at least \$15 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.

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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 of our critical accounting policies, see the discussion of critical accounting policies in our 2007 Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 12, 2008.

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, 2007, filed with the SEC on March 12, 2008.

The Company adopted SFAS No. 157 in the first quarter of 2008. SFAS 157 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. SFAS 157 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.

SFAS No. 157 requires us to maximize the use of observable inputs and minimize the use of unobservable inputs. If a financial instrument uses inputs that fall in different levels of the hierarchy, the instrument will be categorized based upon the lowest level of input that is significant to the fair value calculation. Our financial assets measured at fair value on a recurring basis include securities available for sale. Securities available for sale include money market funds, government securities, commercial paper, corporate bonds and asset-backed securities.

Recent Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* ("SFAS No. 141(R)"), which replaces SFAS No. 141. SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree and the goodwill acquired. SFAS No. 141(R) also establishes disclosure requirements which will enable users to evaluate the nature and financial effects of the business combination. SFAS No. 141(R) is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We are currently evaluating the impact of the adoption of SFAS No. 141(R) on our consolidated financial statements.

In February 2008, the FASB issued FASB Staff Position No. FAS 157-2, "Effective Date of FASB Statement No. 157" ("FSP 157-2"), to partially defer FASB Statement No. 157, "Fair Value Measurements" ("SFAS 157"). FSP 157-2 defers the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), to fiscal years, and interim periods within those fiscal years, beginning after November 15, 2008. We adopted SFAS No. 157 in the first quarter of 2008 and are currently evaluating the impact of adopting the provisions of FSP 157-2 on our consolidated financial statements.

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In June 2008, the FASB ratified the consensus reached on EITF Issue No. 07-5, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock" ("EITF 07-5"). EITF 07-5 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. EITF 07-5 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. The adoption of EITF 07-5 may result in the reclassification of our outstanding warrants from stockholders' equity to liability, which would require the warrants to be marked to market at each reporting period, with the changes in market value recorded in our consolidated statement of operations. At September 30, 2008, we had warrants outstanding to purchase 3,588,221 shares of common stock at an exercise price of \$2.34 per share. We are currently evaluating the impact of the pending adoption of EITF 07-5 on our consolidated 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, 2008, our chief executive officer and principal financial and accounting officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) 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, 2008 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 controls 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 the Company 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.

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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, 2008 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 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 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 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 II and Phase III clinical trials of Lonidamine (TH-070). We believe that Plaintiffs' claims are without merit and intend to defend against the actions vigorously. We cannot reasonably predict the outcome of this matter at this time.

ITEM 1A. RISK FACTORS

Risks Related to Drug Discovery, Development and Commercialization

We are substantially dependent upon the success of our product candidates. Clinical trials may not demonstrate efficacy or lead to regulatory approval.

We will not be able to commercialize our drug candidates until we obtain U.S. Food and Drug Administration, or 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. For example, preliminary results from clinical trials of TH-302 may not be confirmed by later analysis or subsequent 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;

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- 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.

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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 or enhanced activation of glufosfamide in cancer cells relative to most normal cells. Our product candidates glufosfamide and 2DG share certain structural characteristics with glucose but act instead as poisons 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, glufosfamide 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

In September 2006, the FDA granted orphan drug designation to glufosfamide for the treatment of pancreatic cancer. 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

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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, glufosfamide 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

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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 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 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, 2008, we had a net loss of \$13.5 million and an accumulated deficit of \$178.8 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.

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;

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- 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, 2008, will be sufficient to fund our projected operating requirements through the fourth quarter of 2009, including prosecuting our current clinical trials, conducting research and discovery efforts towards additional HAP 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.

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, 2008, we had 31 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.

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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. We expect that we may need to 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, glufosfamide 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 for the initial stage of our Phase 1 clinical trial, which commenced in July 2007. Additional clinical trial material continues to be manufactured as required. This amount will be partially dependent on the maximum tolerated dose of TH-302 as a single agent and as a combination agent with chemotherapy. In addition, we will need to obtain additional supplies of TH-302 API and drug product to complete our currently initiated Phase 1/2 clinical trials and any other additional trials. 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.

Our initial supplies of glufosfamide were prepared by a subsidiary of Baxter International, Inc. and were used to initiate some of our clinical trials. We subsequently relied on new contract manufacturers for the manufacturing of glufosfamide API and drug product. If we seek a partner to continue development of glufosfamide, we will be dependent on contract manufacturers to produce additional API and drug product. If we are not successful, we may experience a significant delay in our glufosfamide clinical development 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.

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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 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 our 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;

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- 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.

Risks Related to Our Intellectual Property

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 two issued U.S. patents that cover the treatment of certain cancers with 2DG in combination with other specific anti-cancer agents. We also have applications related to the issued licensed patent that cover other 2DG combination therapies, but we cannot be certain that any other patent application under this license will be issued. 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.

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.

We have not issued patents or 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 product candidates.

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 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 successfully 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 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.

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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 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. For glufosfamide, the major European counterparts to the U.S. patent expire in 2009 and the U.S. patent expires in 2014. Patent term extension 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 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 secrets 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

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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. However, 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, 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 Group, AstraZeneca PLC, Genentech, Inc., 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-fluorouracil, 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 the Sanofi-Aventis Group, Xeloda[®], marketed by Roche, 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, 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 in clinical trials 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.

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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.

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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 and 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.

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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 4450(a)(5). To regain compliance, effective August 20, 2008, we implemented a 1-for-6 reverse stock split of our common stock. Since that date, our common stock has traded above the minimum \$1.00 bid price for at least ten consecutive business days. On September 5, 2008, the NASDAQ Stock Market notified us that we had regained compliance with the minimum bid price requirements and no further action was required on our part. On October 16, 2008, the NASDAQ Stock Market suspended the enforcement of the minimum bid price and market value requirements through January 16, 2009. Even though we regained compliance with the minimum bid price requirement, we cannot assure you 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.

The reverse stock split may have an effect on the trading market for our shares.

The reduction in the number of issued and outstanding shares occasioned by the reverse stock split resulted in an increase in the market price of our common stock, although such price increase is not necessarily in proportion to the ratio of the reverse stock split. The trading price of our common stock depends on many factors, many which are beyond our control. A higher stock price may increase investor interest and reduce resistance of brokerage firms to recommend the purchase of our common stock. On the other hand, to the extent that negative investor sentiment regarding our common stock is not based on our underlying business fundamentals, the reverse stock split may not overcome such sentiment enough to increase our stock price. In addition, the liquidity of our common stock may be adversely affected by the reduced number of shares outstanding after the reverse stock split, and the reverse stock split will increase the number of stockholders who own "odd lots," which consist of blocks of fewer than 100 shares. Stockholders who hold "odd lots" may be required to pay higher brokerage commissions when they sell their shares and may have greater difficulty in making sales.

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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 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. 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 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 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 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

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Phase II and Phase III clinical trials of Lonidamine (TH-070). We believe that Plaintiffs' claims are without merit and intend to defend against the actions vigorously. Due to the early stage of these actions, we cannot reasonably predict the outcome of this matter at this time. 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 September 30, 2008, our officers, directors and holders of 5% or more of our outstanding common stock beneficially own approximately 93.2% of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

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

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

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

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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
07/01/2008 to 07/31/2008	—	\$ —	—	—
08/01/2008 to 08/30/2008	—	\$ —	—	—
09/01/2008 to 09/30/2008	—	\$ —	—	—

* Shares repurchased from former employees upon termination of their employment pursuant to our contractual repurchase rights under the terms of the 2004 Amended and Restated Equity Incentive Plan.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

On August 22, 2008, a Special Meeting of Stockholders of Threshold Pharmaceuticals Inc. was held at our offices in Redwood City, California.

The following matter was voted upon and approved at the meeting and the number of affirmations, negative votes cast and abstentions with respect to such matter was as follows:

- * 1. Proposal to approve the sale and issuance of 8,970,574 shares of the Company's Common Stock (subject to adjustment) for a purchase price equal to \$2.04 per share (subject to adjustment) and warrants exercisable for a total of 3,588,221 shares of the Company's Common Stock (subject to adjustment) at an exercise price equal to \$2.34 per share (subject to adjustment) to those prospective investors who are party to the Securities Purchase Agreement (including certain officers and affiliates of the Company), in exchange for aggregate gross proceeds of \$18.3 million and the issuance to the investors, on a pro rata basis, of a number of Alternate Warrants equal to, in the aggregate, 19.9% of the outstanding shares of common stock as of the date of the Securities Purchase Agreement if our Board of Directors elects not to proceed with the private placement, subject to certain exceptions. (20,956,982 votes in favor, 380,194 votes opposed, 5,260 votes abstaining).

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.

Date: November 6, 2008

Threshold Pharmaceuticals, Inc.

/s/ Harold E. Selick

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

Date: November 6, 2008

/s/ Joel A. Fernandes

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

EXHIBIT INDEX

Exhibit Number	Description
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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.

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 6, 2008

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

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 6, 2008

/s/ Joel A. Fernandes

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

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, 2008, 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 6, 2008

/s/ Harold E. Selick

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

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, 2008, 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 6, 2008

/s/ Joel A. Fernandes

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