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

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**FORM 10-Q**

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

For the quarterly period ended June 30, 2006

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: 000-51136

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**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)

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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, or a non-accelerated filer. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one): Large accelerated filer  Accelerated filer  Non-accelerated filer

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

On August 1, 2006, there were 37,409,717 shares of common stock, par value \$0.001 per share, of Threshold Pharmaceuticals, Inc. outstanding.

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**Threshold Pharmaceuticals, Inc.**  
**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.

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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)**

	<u>June 30,</u> <u>2006</u>	<u>December 31,</u> <u>2005</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 46,060	\$ 74,947
Marketable securities	30,101	24,707
Prepaid expenses and other current assets	<u>1,045</u>	<u>563</u>
Total current assets	77,206	100,217
Property and equipment, net	3,487	1,667
Restricted cash and other assets	<u>509</u>	<u>217</u>
Total assets	<u>\$ 81,202</u>	<u>\$ 102,101</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 778	\$ 1,237
Accrued clinical and development expenses	5,135	4,500
Accrued liabilities	2,564	2,158
Deferred revenue, current portion	1,437	1,437
Notes payable, current portion	<u>984</u>	<u>230</u>
Total current liabilities	10,898	9,562
Deferred revenue, less current portion	2,155	2,873
Notes payable, less current portion	1,743	151
Deferred rent	<u>333</u>	<u>147</u>
Total liabilities	15,129	12,733
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 2,000,000 shares; no shares issued and outstanding	—	—
Common stock, \$0.001 par value, 150,000,000 shares authorized; issued and outstanding: 37,409,717 shares at June 30, 2006 and 37,231,572 shares at December 31, 2005	37	37
Additional paid-in capital	183,042	179,634
Deferred stock-based compensation	(8,603)	(11,356)
Accumulated other comprehensive income (loss)	(79)	24
Deficit accumulated during the development stage	<u>(108,324)</u>	<u>(78,971)</u>
Total stockholders' equity	<u>66,073</u>	<u>89,368</u>
Total liabilities and stockholders' equity	<u>\$ 81,202</u>	<u>\$ 102,101</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>June 30,</u>		<u>Six Months Ended June</u> <u>30,</u>		<u>Cumulative</u> <u>Period from</u> <u>October 17, 2001</u> <u>(date of inception)</u> <u>to June 30, 2006</u>
	<u>2006</u>	<u>2005</u>	<u>2006</u>	<u>2005</u>	
Revenue	\$ 359	\$ —	\$ 718	\$ —	\$ 1,408
Operating expenses:					
Research and development	13,063	7,872	24,501	13,123	85,285
General and administrative	3,763	2,741	7,576	5,306	29,024
Total operating expenses	<u>16,826</u>	<u>10,613</u>	<u>32,077</u>	<u>18,429</u>	<u>114,309</u>
Loss from operations	(16,467)	(10,613)	(31,359)	(18,429)	(112,901)
Interest income, net	993	436	2,065	720	4,759
Interest expense	(53)	(9)	(59)	(17)	(182)
Net loss	(15,527)	(10,186)	(29,353)	(17,726)	(108,324)
Dividend related to beneficial conversion feature of redeemable convertible preferred stock	—	—	—	—	(40,862)
Net loss attributable to common stockholders	<u>\$(15,527)</u>	<u>\$(10,186)</u>	<u>\$(29,353)</u>	<u>\$(17,726)</u>	<u>\$ (149,186)</u>
Net loss per common share, basic and diluted	<u>\$ (0.43)</u>	<u>\$ (0.36)</u>	<u>\$ (0.81)</u>	<u>\$ (0.79)</u>	
Weighted average number of shares used in per common share calculations: basic and diluted	<u>36,178</u>	<u>28,679</u>	<u>36,018</u>	<u>22,559</u>	

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

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

	<u>Six Months Ended</u> <u>June 30,</u>		<u>Cumulative</u> <u>Period from</u> <u>October 17, 2001</u> <u>(date of inception)</u> <u>to June 30,</u> <u>2006</u>
	<u>2006</u>	<u>2005</u>	
<b>Cash flows from operating activities:</b>			
Net loss	\$(29,353)	\$(17,726)	\$ (108,324)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	318	274	1,135
Stock-based compensation expense	5,764	3,311	22,248
Amortization of debt issuance costs	—	—	44
Gain on sale of investments, property and equipment	(41)	—	(36)
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(482)	(1,032)	(1,071)
Accounts payable	(459)	132	778
Accrued clinical and development expenses	635	2,121	5,135
Accrued liabilities	406	782	2,564
Deferred rent	186	—	333
Deferred revenue	(718)	39	3,592
Net cash used in operating activities	<u>(23,744)</u>	<u>(12,099)</u>	<u>(73,602)</u>
<b>Cash flows from investing activities:</b>			
Acquisition of property and equipment	(2,173)	(1,074)	(4,662)
Acquisition of marketable securities	(27,234)	(14,409)	(98,603)
Proceeds from sale of marketable securities	21,813	14,056	68,499
Restricted cash	(292)	85	(484)
Net cash used in investing activities	<u>(7,886)</u>	<u>(1,342)</u>	<u>(35,250)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from redeemable convertible preferred stock, net	—	—	49,839
Proceeds from issuance of common stock, net of offering expenses	397	39,179	102,346
Proceeds from issuance of notes payable	2,616	—	3,616
Repayment of notes payable	(270)	(164)	(889)
Net cash provided by financing activities	<u>2,743</u>	<u>39,015</u>	<u>154,912</u>
Net increase (decrease) in cash and cash equivalents	(28,887)	25,574	46,060
Cash and cash equivalents, beginning of period	74,947	14,339	—
Cash and cash equivalents, end of period	<u>\$ 46,060</u>	<u>\$ 39,913</u>	<u>\$ 46,060</u>
<b>Supplemental schedule of non-cash investing and financing activities</b>			
Deferred stock-based compensation	<u>\$ —</u>	<u>\$ 2,645</u>	<u>\$ 23,201</u>
Fair value of redeemable convertible preferred stock warrant	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 44</u>
Deferred offering costs in connection with initial public offering	<u>\$ —</u>	<u>\$ (1,287)</u>	<u>\$ —</u>
Change in unrealized loss on marketable securities	<u>\$ (103)</u>	<u>\$ (61)</u>	<u>\$ (79)</u>
Conversion of redeemable preferred stock	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 49,839</u>
Dividend related to beneficial conversion feature of redeemable convertible preferred stock.	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 40,862</u>

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 development stage enterprise engaged primarily in the research and development of targeted small molecule therapies initially for the treatment of cancer. The Company was incorporated in the State of Delaware on October 17, 2001, and has devoted substantially all of its time and efforts to performing research and development, raising capital and recruiting personnel. The Company has incurred losses since its inception.

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. As discussed in Note 3, on January 1, 2006, the Company began accounting for stock options and stock purchase rights related to the Company’s 2004 Employee Stock Purchase Plan (“ESPP”) under the provisions of Statement of Financial Accounting Standards No. 123(R), “*Share-Based Payments*” (“SFAS 123(R)”), which requires the recognition of the fair value of stock-based compensation. 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. 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, 2005 included in the Company’s annual report on Form 10-K filed with the Securities and Exchange Commission on March 28, 2006.

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.

***Recent Accounting Pronouncements***

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, “Accounting for Uncertainty in Income Taxes — an Interpretation of FASB Statement No. 109” (FIN 48), which clarifies the accounting for uncertainty in tax positions. This Interpretation requires that the Company recognize in its financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective for fiscal years beginning after December 16, 2006, with the cumulative effect, if any, of the change in accounting principle recorded as an adjustment to opening retained earnings. The Company is currently evaluating the impact of adopting FIN 48 on its unaudited condensed consolidated financial statements.

**NOTE 2 — NET LOSS PER COMMON SHARE**

Basic net loss per common share is computed by dividing net loss per share by the weighted-average number of vested common shares outstanding during the period, including shares of restricted stock. Diluted net loss per common share

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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		Six Months Ended June	
	June 30,		30,	
	2006	2005	2006	2005
<b>Numerator:</b>				
Net loss	<u>\$ (15,527)</u>	<u>\$ (10,186)</u>	<u>\$ (29,353)</u>	<u>\$ (17,726)</u>
<b>Denominator:</b>				
Weighted average common shares outstanding	37,339	30,748	37,302	24,696
Less: Weighted average unvested common shares subject to repurchase	<u>(1,161)</u>	<u>(2,069)</u>	<u>(1,284)</u>	<u>(2,137)</u>
Denominator for basic and diluted calculations	<u>36,178</u>	<u>28,679</u>	<u>36,018</u>	<u>22,559</u>
Basic and diluted net loss per share	<u>\$ (0.43)</u>	<u>\$ (0.36)</u>	<u>\$ (0.81)</u>	<u>\$ (0.79)</u>

The following outstanding stock options and warrants and common shares 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 June 30,	
	2006	2005
Shares issuable upon exercise of stock options	2,556	493
Shares issuable related to the ESPP	106	43
Shares issuable upon exercise of warrants	—	23
Common shares subject to repurchase	1,064	1,979

### NOTE 3— STOCK BASED COMPENSATION

#### Equity Incentive Plans

**2004 Equity Incentive Plan** The 2004 Amended and Restated Equity Incentive Plan, adopted by the board of directors and approved by stockholders, provides for the granting of incentive stock options, nonstatutory stock options, stock appreciation rights, stock awards and cash awards to employees, officers, non-employee directors and consultants. Stock options to employees and officers are generally granted with an exercise price equal to the closing market price of the Company's stock at the date of grant; those option awards expire after 10 years or three months after termination of service and generally vest based over four years of continuous service, with options for new employees generally including a one-year cliff vesting period. At June 30, 2006, 1,295,415 shares were authorized and available for issuance under the stock option plan.

**2004 Employee Stock Purchase Plan** The 2004 Employee Stock Purchase Plan, adopted by the board of directors and approved by the stockholders, contains consecutive, overlapping 24-month offering periods. Each offering period includes four six-month purchase periods. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of the purchase period. At June 30, 2006, plan participants had \$0.4 million withheld to purchase stock on August 14, 2006, which is included in accrued liabilities on the accompanying unaudited condensed consolidated balance sheet. At June 30, 2006, 1,013,324 shares were authorized and available for issuance under the ESPP.

#### Adoption of SFAS No. 123(R)

Prior to January 1, 2006 the Company accounted for stock-based employee compensation arrangements in accordance with the recognition and measurement provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and complied with the disclosure 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." Under APB 25, unearned stock compensation is based on the

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difference, if any, on the date of grant, between the fair value of the Company's common stock and the exercise price. Stock-based compensation expense was recognized under APB 25 for options granted prior to the Company's initial public offering of its common stock in February 2005 based upon the intrinsic value (the difference between the exercise price at the date of grant and the deemed fair value of the common stock based on the anticipated initial public offering stock price.) The Company did not recognize stock-based compensation cost in its statement of operations for periods prior to January 1, 2006, for option grants that had an exercise price equal to the market value of the underlying common stock on the date of grant.

On January 1, 2006, the Company adopted the fair value provisions of 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 six months ended June 30, 2006 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 six months ended June 30, 2006 based on the recognition of the grant date fair value estimated in accordance with the original provisions of SFAS 123 over the service period, which is generally the vesting period;
- compensation cost for all stock-based awards granted subsequent to January 1, 2006, that were earned during the three and six months ended June 30, 2006 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
- compensation cost for options granted prior to the Company's initial public offering in February 2005 that were earned during the three and six months ended June 30, 2006, based on the grant date intrinsic value over the service period, which is generally the vesting period.

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. Under the modified prospective transition method, results for prior periods have not been restated.

Employee stock-based compensation expense recognized under SFAS 123(R) and APB 25 in the unaudited condensed consolidated statement of operations for the three months and six months ended June 30, 2006 related to stock options and ESPP was \$2.6 million and \$5.0 million, respectively. The stock-based compensation expense for the three and six months ended June 30, 2006, included \$1.2 million and \$2.4 million, respectively, 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. As a result of adopting SFAS 123(R) on January 1, 2006, the Company's loss from operations and net loss for the three and six months ended June 30, 2006 was \$1.3 million and \$2.6 million, respectively, higher than if it had continued to account for share-based compensation under APB 25. Basic and diluted net loss per share for the three and six months ended June 30, 2006 would have been \$0.40 and \$0.75, respectively, if the Company had not adopted SFAS 123(R). The implementation did not have an impact on cash flows from operating activities or financing activities during the six months ended June 30, 2006.

### 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 six months ended June 30, 2006 and 2005:

	Three Months ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
<b>Employee Stock Options</b>				
Risk-free interest rate	5.00%	3.77%	4.76%	3.55%
Expected life (in years)	6.02	4.0	6.02	3.6
Dividend yield	—	—	—	—
Volatility	77%	67%	77%	67%
Weighted-average fair value of stock options granted	\$ 7.10	\$ 4.69	\$ 9.66	\$ 8.24
<b>Employee Stock Purchase Plan (ESPP):</b>				
Risk-free interest rate	4.70%	3.34%	4.70%	3.34%
Expected life (in years)	1.25	0.5	1.25	0.5
Dividend yield	—	—	—	—
Volatility	67%	67%	67%	67%
Weighted-average fair value of ESPP purchase rights	\$ 6.07	\$ 3.72	\$ 6.07	\$ 3.72



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To determine the expected term of the Company's employee stock options granted during the three months and six months ended June 30, 2006, the Company utilized the simplified approach as defined by SEC Staff Accounting Bulletin No. 107, "Share-Based Payment" ("SAB 107"), which resulted in an expected term of 6.02 years. 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 six months ended June 30, 2006, 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 six months ended June 30, 2006 was based on expected stock price volatilities of the Company's industry peers, as well as the historical volatility of the Company's common stock as the Company had trading history for its common stock in excess of the expected term of the stock purchase rights under the ESPP. The fair value of all the Company's stock based award assumes no dividends as the Company does not anticipate paying cash dividends on its common stock.

### Employee Stock-based Compensation Expense

**Deferred stock-based compensation** Prior to the initial public offering, the Company issued options to certain employees with exercise prices below the fair market value of the Company's common stock at the date of grant, determined with hindsight. In accordance with the requirements of APB 25, the Company recorded deferred stock-based compensation aggregating \$22.9 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 June 30, 2006, the Company amortized approximately \$14.3 million of such compensation expense, net of forfeitures, with approximately \$1.2 million and \$2.4 million being amortized in the three and six months ended June 30, 2006, respectively and \$1.5 million and \$3.0 million being amortized in the three and six months ended June 30, 2005, respectively.

**Stock-based compensation expense** As required by SFAS 123(R) the Company recognized \$1.2 million and \$2.4 million of stock-based compensation expense related to stock options granted subsequent to the Company's initial public offering in February 2005, under the Company's stock option plans, for the three and six months ended June 30, 2006, respectively, in addition to the amortization of deferred compensation above. As of June 30, 2006, the total compensation cost related to unvested stock-based awards granted to employees under the Company's stock option plans was approximately \$17.1 million, net of estimated forfeitures of \$0.4 million. This cost will be amortized on a straight-line basis over the remaining weighted average requisite service period of approximately 3.5 years.

The stock-based compensation expense in connection with the ESPP for the three and six months ended June 30, 2006 was \$0.1 million and \$0.2 million, respectively. In February 2006, 53,682 shares of common stock of the Company were purchased at a weighted average price of \$6.26 under the ESPP.

Amortization of stock-based compensation for employees was allocated to research and development and general and administrative as follows (in thousands):

	Three Months Ended		Six Months Ended	
	June 30,	June 30,	June 30,	June 30,
	2006	2005	2006	2005
Amortization of employee stock-based compensation:				
Research and development	\$ 1,150	\$ 701	\$2,111	\$1,402
General and administrative	<u>1,427</u>	<u>777</u>	<u>2,929</u>	<u>1,554</u>
	<u>\$ 2,577</u>	<u>\$ 1,478</u>	<u>\$5,040</u>	<u>\$2,956</u>

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### *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 \$0.2 million and \$0.7 million for the three and six months ended June 30, 2006, respectively, and approximately \$0.2 million and \$0.4 million for the three and six months ended June 30, 2005, respectively.

### *Stock Option Activity*

The following table summarizes information about stock options issued under the Company's stock option plans:

<u>Options</u>	<u>Number of Shares</u>	<u>Weighted- Average Exercise Price</u>	<u>Weighted- Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at January 1, 2006	926,357	\$ 8.29	—	—
Granted	1,769,500	13.62	—	—
Exercised	(131,518)	0.91	—	—
Forfeitures	(8,392)	13.19	—	—
Outstanding at June 30, 2006	<u>2,555,947</u>	\$ 12.34	9.48	\$365,178
Vested and expected to vest at June 30, 2006	<u>2,518,448</u>	\$ 12.33	9.48	\$363,375
Exercisable at June 30, 2006	<u>339,202</u>	\$ 8.83	8.99	\$201,362

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 June 30, 2006. The total intrinsic value of stock options exercised during the six months ended June 30, 2006 was \$0.5 million determined at the date of the option exercise. Cash received from stock option exercises was \$0.1 million for the six months ended June 30, 2006. 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.

### *Pro forma Disclosure*

The modified prospective transition method of SFAS 123(R) requires the presentation of pro forma information for periods presented prior to the adoption of SFAS 123(R) regarding net loss and net loss per share as if the Company had accounted for its stock options under the fair value method of SFAS 123. If compensation expense had been determined based upon the fair value at the grant date for employee compensation arrangements, consistent with the methodology prescribed under SFAS 123, the Company's pro forma net loss and pro forma net loss per share under SFAS 123 would have been as shown in the following table. For the purpose of this pro forma disclosure, the estimated value of the stock awards is recognized on a straight-line basis over the vesting periods of the awards (in thousands, except per share data):

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	Three Months ended	Six Months ended
	June 30, 2005	
Net loss attributable to common stockholders, as reported	\$ (10,186)	\$ (17,726)
Deduct: Employee total stock-based compensation determined under fair value method	(176)	(240)
Pro-forma net loss attributable to common stockholders	<u>\$ (10,362)</u>	<u>\$ (17,966)</u>
Net loss attributable to common stockholders per common share, basic and diluted:		
As reported	\$ (0.36)	\$ (0.79)
Pro-forma	<u>\$ (0.36)</u>	<u>\$ (0.80)</u>

Disclosures for the three and six months ended June 30, 2006 are not presented because stock-based employee compensation was accounted for under SFAS 123(R)'s fair-value method during this period. Additionally, the stock-based employee compensation determined under the fair-value method for the three and six months ended June 30, 2005 has been adjusted to exclude the effect of the options granted prior to the Company's initial public offering in February 2005, as those options were valued for pro forma disclosure purposes using the minimum value method. The total intrinsic value of stock options exercised during the six months ended June 30, 2005 was \$0.1 million determined at the date of the option exercise. Cash received from stock option exercises was \$0.2 million for the six months ended June 30, 2005.

### NOTE 4— NOTES PAYABLE

In April 2006, the Company amended the existing loan and security agreement with a financial institution 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. Upon the signing of the amendment, the Company borrowed \$2.0 million under this facility, which will be repaid over a 36-month period from the date of borrowing. In May 2006, the Company borrowed an additional \$0.6 million under this facility. The interest rate on these borrowings is approximately 7.2% per annum. The amended agreement requires the Company to maintain the lower of 85% of its total cash and cash equivalents or \$10.0 million at the financial institution. At June, 2006, the Company was in compliance with this covenant.

At June 30, 2006, future principal payments under the amended loan and security agreement are as follows (in thousands):

Years Ending December 31,	
2006 (remaining six months)	\$ 483
2007	997
2008	910
2009	337
Total	<u>\$2,727</u>

### NOTE 5— 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 Sheet. On February 3, 2006, the Company entered into a lease for an additional 34,205 square feet of space and increase the lease term for the existing space located at the Company's headquarters in Redwood City, California. The lease is for a period of 66 months, beginning on April 1, 2006 with respect to the additional square footage and 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.

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The future rental payments required by the Company for all of its facilities under noncancelable operating leases are as follows (in thousands):

Years Ending December 31,	
2006 (remaining six months)	\$ 517
2007	1,232
2008	1,358
2009	1,398
2010	1,462
Thereafter	1,129
Total	<u>\$7,096</u>

The Company's purchase commitments at June 30, 2006 were \$1.8 million.

### Indemnification

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

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

### NOTE 6— 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 June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Net loss	<u>\$(15,527)</u>	<u>\$(10,186)</u>	<u>\$(29,353)</u>	<u>\$(17,726)</u>
Other comprehensive loss:				
Unrealized loss on marketable securities	<u>(29)</u>	<u>(39)</u>	<u>(103)</u>	<u>(61)</u>
Total comprehensive loss	<u>\$(15,556)</u>	<u>\$(10,225)</u>	<u>\$(29,456)</u>	<u>\$(17,787)</u>

### NOTE 7— SUBSEQUENT EVENTS

In August 2006, the Company adopted a plan to reduce its operating expenses, following its decision to discontinue development of TH-070 for benign prostatic hyperplasia. The plan includes a reduction of 30 positions in both research and development and general and administrative areas of the Company as well as a reduction in certain external expenses. As a result of the staffing reduction the Company expects to pay severance benefits of approximately \$1.2 million in the second half of 2006, and to incur other non cash expenses.

On August 8, 2006, the board of directors of the Company adopted a Stockholder Rights Plan under which preferred stock purchase rights (the "rights") will be distributed to stockholders of record as of August 23, 2006, at the rate of one right for each share of common stock held. The rights become exercisable only upon the occurrence of certain events related to changes in ownership of the Company's common stock. Once exercisable, each right entitles the holder to purchase, at a price of \$25, one one-thousandth of a share of Series A Participating Preferred Stock. The Company has initially reserved 200,000 shares of preferred stock pursuant to the exercise of these rights. These rights expire on August 8, 2016.

## 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 Management's Discussion and Analysis of Financial Condition and Results of Operations. 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 Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. 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
- uncertainties and estimates associated with restructuring plans.

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 carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission.

### Overview

We are a biotechnology company focused on the discovery and development of drugs based on Metabolic Targeting, an approach that targets fundamental differences in metabolism between normal and certain diseased cells. Two of our product candidates reflect the Metabolic Targeting approach by targeting the increased uptake of glucose in cancer cells relative to most normal cells. These product candidates, glufosfamide and 2-deoxyglucose ("2DG"), share certain structural characteristics with glucose but act instead as poisons when taken up by a cancer cell. Our other product candidate, TH-302, and the compounds our scientists are creating and testing in our laboratories, reflect the Metabolic Targeting approach by targeting the decreased blood supply and oxygenation of most tumor tissues relative to normal tissue. These compounds are relatively non-toxic when oxygen is present, as in healthy tissues, but undergo a chemical conversion in the absence of normal levels of oxygen that converts them into toxic compounds that may kill cancer cells. This pipeline of drug candidates is designed to selectively target tumor cells, and we believe that our drugs could be more efficacious and less toxic to healthy tissues than conventional drugs, and so provide significant improvement over current therapies.

Our initial clinical focus is on product candidates for the treatment of cancer. We have three product candidates for which we have exclusive worldwide marketing rights:

- Glufosfamide is our lead product candidate for the potential treatment of cancer. We initiated a pivotal Phase 3 clinical trial of glufosfamide for the second-line treatment of pancreatic cancer in September 2004. We have received a special protocol assessment from the United States Food and Drug Administration ("FDA") for this trial, as well as Fast Track designation for this indication. In January 2006, we initiated the Phase 2 stage of a study of glufosfamide plus gemcitabine for the first-line treatment of pancreatic cancer, after completing a Phase 1 dose-escalating study in patients with advanced solid tumors and pancreatic cancer. In July 2006, we completed enrollment in this Phase 2 study and in August 2006, we completed enrollment in the Phase 3 study. We plan to initiate additional Phase 2 trials of glufosfamide in all, or a subset of, ovarian cancer, sarcoma and small cell lung cancer and expect to start one or more of these trials this year.
- 2-deoxyglucose, or 2DG, our second product candidate for the potential treatment of cancer, is being evaluated in a Phase 1 clinical trial both as a single agent and combination therapy. This trial began in the first quarter of 2004 and we expect to complete this trial next year.

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- TH-302 in late-stage pre-clinical testing for the potential treatment of cancer. We have promising *in vivo* data for TH-302 and a back-up compound and expect to file an investigational new drug application (“IND”) for one of these compounds by the middle of 2007.

We also are working to discover novel drug candidates that will specifically target cancer cells and are actively seeking to in-license other promising compounds or programs.

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. As of June 30, 2006 we had cash, cash equivalents, and marketable securities of \$76.2 million. The net loss for the three months and six months ended June 30, 2006 was \$15.5 million and \$29.3 million, respectively and the cumulative net loss since our inception through June 30, 2006 was \$108.3 million.

In July 2006, we announced we were discontinuing development of TH-070 for benign prostatic hyperplasia (“BPH”) based on safety and efficacy results of recently concluded Phase 2 and Phase 3 trials. In August, 2006, we adopted a plan to reduce our operating expenses. The plan includes eliminating 30 positions, or approximately a 36% reduction in staff affecting all areas of the Company and a reduction in certain external expenses. As a result of the staffing reduction we expect to pay severance benefits of approximately \$1.2 million in the second half of 2006, and to incur other non cash expenses. Annual cash savings from the reduction in salary and benefit expenses are estimated to be approximately \$4.0 million, beginning in 2007. We also expect additional savings in certain non employee-related costs.

We expect to continue to incur losses from operations in the future. During the second half of 2006, losses are expected to increase due to expenses associated with the discontinuation of our TH-070 program, the completion of our Phase 2 and Phase 3 glufosfamide trials and initiation of additional trials, and severance expenses.

We expect expenses to decrease on an annual basis beginning in 2007 and that our cash, cash equivalents and marketable securities will be sufficient to fund our projected operating requirements through at least mid-2008, including completing our current and planned clinical trials and conducting research and discovery efforts toward additional product candidates. 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 the three and six months ended June 30, 2006, we recognized \$0.4 million and \$0.7 million, respectively in revenue 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. The payment was contingent upon the finalization of the clinical development plan, which occurred in July 2005. Revenue is being recognized on a straight-line basis over the estimated development period, currently estimated to be through 2008. We are responsible for all development activities under this agreement.

**Research and Development.** Research and development expenses were \$13.1 million for the three months ended June 30, 2006 compared to \$7.9 million for the three months ended June 30, 2005. The \$5.2 million increase in expenses is due to a \$3.0 million increase in clinical and development expenses, \$1.6 million in higher staffing expenses, and an increase in non-cash stock-based compensation expense of \$0.6 million primarily due to the adoption of Statement of Financial Accounting Standards No. 123(R), “*Share-Based Payments*” (“SFAS 123(R)”), beginning January 1, 2006. Research and development expenses were \$24.5 million for the six months ended June 30, 2006 compared to \$13.1 million for the six months ended June 30, 2005. The \$11.4 million increase in expenses is due to a \$7.3 million increase in clinical and development expenses, \$2.8 million in higher staffing expenses, and an increase in non-cash stock-based compensation expense of \$1.3 million primarily due to the adoption of SFAS 123(R) beginning January 1, 2006.

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Research and development expenses by project (in thousands)	Three months ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
TH-070	\$ 6,090	\$ 2,974	\$10,588	\$ 4,821
Glufosfamide	3,332	2,626	7,270	4,554
2DG	502	617	883	1,063
Discovery research	3,139	1,655	5,760	2,685
<b>Total research and development expenses</b>	<b>\$ 13,063</b>	<b>\$ 7,872</b>	<b>\$24,501</b>	<b>\$13,123</b>

Research and development expenses associated with TH-070 were \$6.1 million for the three months ended June 30, 2006 and \$3.0 million for the three months ended June 30 2005. This increase in expenses was primarily due to an increase of \$2.6 million in expenses associated with our Phase 2 and Phase 3 trials, including higher enrollment and expenses associated with implementing additional safety measures and collecting and analyzing safety and efficacy data following the adverse events reported in May 2006. Research and development expenses associated with glufosfamide were \$3.3 million for the three months ended June 30, 2006 and \$2.6 million for the three months ended June 30, 2005. This increase is primarily due to a \$0.5 million increase in clinical and manufacturing expenses and a \$0.2 million increase in staffing expenses. Research and development expenses associated with 2DG were \$0.5 million for the three months ended June 30, 2006 and \$0.6 million for the three months ended June 30, 2005. Discovery research and development expenses were \$3.1 million for the three months ended June 30, 2006 and \$1.7 million for the three months ended June 30, 2005. The increase was primarily due to higher staffing costs to support our discovery research programs.

Research and development expenses associated with TH-070 were \$10.6 million for the six months ended June 30, 2006 and \$4.8 million for the six months ended June 30 2005. This increase in expenses was due to an increase of \$5.3 million in expenses associated with our Phase 2 United States trial initiated in June 2005 and our EU Phase 3 trial initiated in August 2005 and \$0.5 million in higher staffing costs including \$0.3 million in non cash stock compensation expense. Research and development expenses associated with glufosfamide were \$7.3 million for the six months ended June 30, 2006 and \$4.6 million for the six months ended June 30, 2005. This increase is due to \$1.9 million increase in clinical and manufacturing expenses and \$0.8 million increase in higher staffing expenses, including \$0.3 million increase in non cash stock compensation expense. Research and development expenses associated with 2DG were \$0.9 million for the six months ended June 30, 2006 and \$1.1 million for the six months ended June 30, 2005. This decline was due to lower clinical and staffing expenses. Discovery research and development expenses were \$5.8 million for the six months ended June 30, 2006 and \$2.7 million for the six months ended June 30, 2005. The increase was primarily due to increases in staffing costs to support expansion of our discovery research programs, including an increase of \$0.9 million in non cash stock compensation expenses.

We expect to continue to devote substantial resources to research and development in future periods as we continue our current clinical trials, start additional trials and continue our discovery efforts. Research and development expenses are expected to increase in the second half of 2006 and decrease in 2007. Expenses may fluctuate significantly from period to period based largely on clinical trial activities.

**General and Administrative.** General and administrative expenses were \$3.8 million for the three months ended June 30, 2006, compared to \$2.7 million for the three months ended June 30, 2005. The increase reflects additional expenses associated with being a public company, including approximately \$0.5 million for staffing expenses, legal fees, insurance premiums and consulting services and an increase in non-cash stock-based compensation expenses of \$0.5 million primarily due to the adoption of SFAS 123(R).

General and administrative expenses were \$7.6 million for the six months ended June 30, 2006, compared to \$5.3 million for the six months ended June 30, 2005. The increase reflects additional expenses associated with being a public company, including approximately \$1.1 million for staffing expenses, legal fees, insurance premiums and consulting services, and an increase in non-cash stock-based compensation expenses of \$1.2 million primarily due to the adoption of SFAS 123(R).

We expect our general and administrative expenses to increase in 2006 due to increases in administrative and infrastructure costs as well as costs associated with implementing procedures for compliance with Section 404 of the Sarbanes-Oxley Act.

**Interest Income, Net.** Interest income for the three months ended June 30, 2006 was \$1.0 million compared to \$0.4 million for the three months ended June 30, 2005. The increase was primarily due to higher invested cash balances and higher average interest rates during the three months ended June 30, 2006 compared to the prior year due to proceeds received from our follow-on offering completed in October 2005.

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Interest income for the six months ended June 30, 2006 was \$2.1 million compared to \$0.7 million for the six months ended June 30, 2005. The increase was primarily due to higher invested cash balances and higher average interest rates during the six months ended June 30, 2006 compared to the prior year due to proceeds received from our follow-on offering completed in October 2005.

### **Liquidity and Capital Resources**

We have incurred net losses of \$108.3 million since inception through June 30, 2006. We have not generated and do not expect to generate revenue from sales of product candidates for at least the next couple of years. 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 6,112,601 shares of common stock, raising net proceeds of \$38.1 million. In October 2005, we completed a public offering of 6,399,222 shares of our common stock for net proceeds of \$62.4 million.

We had cash, cash equivalents and marketable securities of \$76.2 million and \$99.7 million at June 30, 2006 and December 31, 2005, respectively, available to fund operations.

Net cash used in operating activities for the six months ended June 30, 2006 and 2005 was \$23.7 million and \$12.1 million, respectively. The increase of \$11.7 million in cash used in operations was primarily attributable to a higher net loss in 2006, partially offset by an increase in non-cash charges related to stock-based compensation.

Net cash used in investing activities was \$7.9 million and \$1.3 million for the six months ended June 30, 2006 and 2005, respectively. The \$6.6 million increase in cash used in investing activities for the six months ended June 30, 2006 compared to the same period in 2005 was due primarily to an increase in purchases of marketable securities and to a lesser extent an increase in capital expenditures, partially offset by an increase in proceeds from sales of marketable securities.

Net cash provided by financing activities was \$2.7 million and \$39.0 million for the six months ended June 30, 2006 and 2005, respectively. The cash provided in the six months ended June 30, 2006 was primarily from \$2.5 million of proceeds under the Company's loan and security agreement. The cash provided in the six months ending June 30, 2005 was primarily from the proceeds of our initial public offering in February 2005.

### ***Obligations and Commitments***

In March 2003, we entered into a loan and security agreement with a financial institution to borrow up to \$1.0 million for working capital and equipment purchases. As of December 31, 2004, we had borrowed the full amount under this facility, which is being repaid over a 36-month period from the dates of borrowing. These borrowings bear interest at an average rate of 5.8% per year at June 30, 2006. 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. Upon the signing of the amendment, we borrowed \$2.0 million under this facility, which will be repaid over a 36-month period from the date of borrowing. In May 2006, the Company borrowed an additional \$0.6 million under this facility. The interest rate on these borrowings is approximately 7.2% per annum. At June 30, 2006 the total amount due under this facility was \$2.7 million. The amended agreement requires us to maintain the lower of 85% of our total cash and cash equivalents or \$10.0 million at the financial institution. At June 30, 2006, we were in compliance with this covenant.

In August 2004, we entered into a noncancelable facilities sublease agreement that expires on February 28, 2010. On April 1, 2005, we entered into a noncancelable facilities lease agreement that expires on February 28, 2010.

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. The lease is for a period of 66 months, beginning on April 1, 2006 with respect to the additional square footage and 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 will also be 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. In April 2006, we borrowed \$2.0 million under the amended loan and security facility, for leasehold improvements related to this additional leased space. In May 2006, we borrowed an additional \$0.6 million under this facility. We may borrow up to an additional \$1.4 million for equipment purchases.



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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 June 30, 2006, are as follows (in thousands):

	Remainder of current year (2006)	One to three years (2007 to 2009)	Four to five years (2010 to 2011)	After five Years	Total
Facilities leases	\$ 517	\$ 3,989	\$ 2,590	\$ —	\$ 7,096
Notes payable, principal and interest	575	2,440	—	—	3,015
Purchase commitments	1,825	—	—	—	1,825
Total	<u>\$ 2,917</u>	<u>\$ 6,429</u>	<u>\$ 2,590</u>	<u>\$ —</u>	<u>\$11,936</u>

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

We expect to continue to incur losses from operations in the future. During the second half of 2006, losses are expected to increase due to expenses associated with the discontinuation of our TH-070 program, the completion of our Phase2 and Phase 3 glufosfamide trials and initiation of additional trials and severance expenses. Thereafter, we expect a decline in losses.

We believe that our cash, cash equivalents and marketable securities as of June 30, 2006 will be sufficient to fund our projected operating requirements through at least mid-2008, including completing our current and planned trials, conducting research and discovery efforts towards additional product candidates, working capital and general corporate purposes. Additional funds will be required to in-license or otherwise acquire and develop additional products or programs. We 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. Additionally, we may need or choose to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our ability to raise additional funds will depend on our clinical events 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 necessary funds are not available, we may have to delay, reduce the scope or eliminate some of our research and development, which could delay the time to market for any of our product candidates.

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### ***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 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 2005 Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 28, 2006. In addition, as of January 1, 2006, we implemented the following new critical accounting policy:

**Stock-Based Compensation.** Beginning on January 1, 2006, we began accounting for stock options and stock purchase rights related to our 2004 Employee Stock Purchase Plan under the provisions of SFAS 123(R), which requires the recognition of the fair value of stock-based compensation. The fair value of stock options and ESPP shares was estimated using a Black-Scholes option valuation model. This model requires the input of subjective assumptions in implementing SFAS 123(R), including expected stock price volatility, expected life and estimated forfeitures of each award. The fair value of equity-based awards is amortized over the vesting period of the award, and we have elected to use the straight-line method of amortization. Due to the limited amount of historical data available to us, particularly with respect to stock-price volatility, employee exercise patterns and forfeitures, actual results could differ from our assumptions.

Prior to the implementation of SFAS 123(R), we accounted for stock options and ESPP shares under the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and made pro forma footnote disclosures as required by SFAS No. 148, "Accounting For Stock-Based Compensation — Transition and Disclosure," which amended SFAS No. 123, "Accounting For Stock-Based Compensation." Pro forma net loss and pro forma net loss per share disclosed in the footnotes to the unaudited condensed consolidated financial statements were estimated using a Black-Scholes option valuation model.

### ***Recent Accounting Pronouncements***

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes — an Interpretation of FASB Statement No. 109" (FIN 48), which clarifies the accounting for uncertainty in tax positions. This Interpretation requires that we recognize in our financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006, with the cumulative effect, if any, of the change in accounting principle recorded as an adjustment to opening retained earnings. We are currently evaluating the impact of adopting FIN 48 on its unaudited condensed 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 an 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. However, due to the short duration of our investment portfolio we believe an immediate 10% change in the interest rates 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 June 30, 2006, our chief executive officer and chief financial 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

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1934, as amended) were sufficiently effective to ensure that the information required to be disclosed by us in this quarterly report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC'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.***

There were no changes in our internal control over financial reporting during the three months ended June 30, 2006 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 chief financial officer, 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.

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 chief financial officer have concluded, based on their evaluation, that our disclosure controls and procedures were sufficiently effective as of June 30, 2006 to provide reasonable assurance that the objectives of our disclosure control system were met.

## **PART II. OTHER INFORMATION**

### **ITEM 1A. RISK FACTORS**

#### **RISKS RELATED TO OUR BUSINESS**

##### **Risks Related to Drug Discovery, Development and Commercialization**

***We are substantially dependent upon the success of our glufosfamide product candidate. Clinical trials for this product may not demonstrate efficacy or lead to regulatory approval.***

We will not be able to commercialize our lead product candidate, glufosfamide, until we obtain FDA approval in the United States or approval by comparable regulatory agencies in Europe and other countries. To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. 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.

Phase 1 and Phase 2 safety trials of glufosfamide were conducted on small numbers of patients and were designed to evaluate the activity of glufosfamide on a preliminary basis. However, these trials were not designed to demonstrate the efficacy of glufosfamide as a therapeutic agent. We cannot be certain that results similar to the Phase 1 and 2 trials will be observed in subsequent trials, or that such results will prove to be statistically significant or demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory agencies. In Phase 2 studies, glufosfamide has not shown clinical activity for the treatment of glioblastoma and has only demonstrated marginal activity for the treatment of non-small cell lung cancer. The clinical trial we commenced in September 2004 for the second-line treatment of pancreatic cancer is intended to serve as a pivotal Phase 3 trial. If the results from this trial are not persuasive as determined by the FDA, then this trial will not serve as the basis for FDA approval. We may decide to conduct additional clinical trials or other studies, or the FDA may require us to conduct additional clinical trials or other studies prior to accepting our NDA or granting marketing approval.

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

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

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

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing or to abandon programs;
- the results obtained in earlier stage testing may not be indicative of results in future trials;
- 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 size of the patient population required for analysis of the 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 trials. This is particularly true with respect to diseases with relatively small patient populations, such as pancreatic cancer, which is the indication we are currently testing for our glufosfamide product candidate.

***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.

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

Regulatory approval, if obtained, may be made subject to limitations on the indicated uses for which we may market a product. These limitations could adversely affect our potential product revenues. Regulatory approval may also require costly post-marketing follow-up studies. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping related to the product will be subject to extensive ongoing regulatory requirements. Furthermore, for any marketed product, its manufacturer and its manufacturing facilities will be subject to continual review and periodic inspections by the FDA or other regulatory authorities. Failure to comply with applicable regulatory requirements may, among other things, result in fines, suspensions of regulatory approvals, product recalls, product seizures, operating restrictions and criminal prosecution.

***The “Fast Track” designation for development of glufosfamide for the treatment of refractory pancreatic cancer may not lead to a faster development or regulatory review or approval process.***

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA “Fast Track” designation for a particular indication. Marketing applications filed by sponsors of products in Fast Track development may qualify for expedited FDA review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification. Although we have obtained a Fast Track designation from the FDA for glufosfamide for the treatment of second-line pancreatic cancer, we may not experience a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw our Fast Track designation at any time. If we lose our Fast Track designation, the approval process may be lengthened. In addition, our Fast Track designation does not increase the likelihood that glufosfamide will receive regulatory approval for the treatment of second-line pancreatic cancer.

***Our product candidates are based on Metabolic Targeting, which is an unproven approach to therapeutic intervention.***

All of our product candidates are based on Metabolic Targeting, a therapeutic approach that targets fundamental differences in energy metabolism between normal and certain diseased cells. We have not, nor to our knowledge has any other company, received regulatory approval for a drug based on this approach. We cannot be certain that our approach will lead to the development of approvable or marketable drugs.

In addition, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of drugs based on Metabolic Targeting, 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.***

Glufosfamide is known to cause reversible toxicity to the bone marrow and kidneys, as well as nausea and vomiting. These side effects or others 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 glufosfamide and 2DG clinical trials will begin on time, 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 trials and delays in:

- obtaining regulatory approval to commence a trial;
- obtaining clinical materials;
- reaching agreement on acceptable clinical study agreement terms with prospective sites;

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- obtaining institutional review board approval to conduct a study at a prospective site; and
- recruiting patients to participate in a study.

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

We intend to seek orphan drug designation for the cancer indications that our glufosfamide and 2DG product candidates are intended to treat. Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is defined by the FDA as a disease or condition that affects fewer than 200,000 individuals in the United States. The company that obtains the first FDA approval for a designated orphan drug indication receives marketing exclusivity for use of that drug for that indication for a period of seven years. Orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective, or if the manufacturer is unable to assure sufficient quantity of the drug. Orphan drug designation does not shorten the development or regulatory review time of a drug.

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

Moreover, due to the uncertainties associated with developing pharmaceutical products, we may not be the first to obtain marketing approval for any orphan drug indication. Even if we obtain orphan drug designation, if a competitor obtains regulatory approval for 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.

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

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

In 1997, a public registry of open clinical trials involving drugs intended to treat serious or life-threatening diseases or conditions was established under the Food and Drug Administration Modernization Act, or FDMA, in order to promote public awareness of and access to these clinical trials. Under FDMA, pharmaceutical manufacturers and other trial sponsors are required to post the general purpose of these trials, as well as the eligibility criteria, location and contact information of the trials. Since the establishment of this registry, there has been significant public debate focused on broadening the types of 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 trials that have been registered with a no-cost, publicly accessible database, such as [www.clinicaltrials.gov](http://www.clinicaltrials.gov). The Pharmaceuticals and Research Manufacturers of America has also issued voluntary principles for its members to make results from certain clinical studies 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](http://www.clinicaltrials.gov) and to require the inclusion of study 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 incur significant continued losses for the next several years, 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. We have devoted substantially all of our resources to research and development of our product candidates. Prior to our initial public offering in February 2005, we financed our operations primarily through private placements of our equity securities. For the six months ended June 30, 2006, we had a net loss of \$29.4 million, and we had an accumulated deficit of \$108.3 million. We do not expect to generate any revenue from the sale of our product candidates at least within the next couple of years. Clinical trials are costly. During the second half of 2006, losses are expected to increase due to expenses associated with the discontinuation of our TH-070 program, the completion of our Phase 2 and Phase 3 glufosfamide trials and initiation of additional trials and severance expenses.

To attain profitability, we will need to develop products successfully and market and sell them effectively. 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

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future. If our glufosfamide product candidate fails to show positive results in our ongoing clinical trials, or we do not receive regulatory approval, or if glufosfamide does not achieve market acceptance even if approved, we may not become profitable. If we fail to become profitable, or if we are unable to fund our continuing losses, we may be unable to continue our clinical development programs.

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

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

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

We believe that our cash, cash equivalents and marketable securities will be sufficient to fund our projected operating requirements through at least mid-2008, including completing our current and planned clinical trials, conducting research and discovery efforts towards additional product candidates, working capital and general corporate purposes. Additional funds will be required to in-license or otherwise acquire and develop additional products or programs. We expect to seek funds through arrangements with collaborators or others that may require us to relinquish rights to certain products candidates that we might otherwise seek to develop or commercialize independently. We cannot be certain that we will be able to enter into any such arrangements on reasonable terms, if at all.

We may need or choose to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our ability to raise additional funds will depend on financial, economic and market conditions, our clinical events and other factors, 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 necessary funds are not available, we may have to delay, reduce the scope or eliminate some of our development programs, which could delay the time to market for any or all of our product candidates.

***Raising additional funds may cause dilution to existing stockholders or require us to relinquish valuable rights.***

We may raise additional funds through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may subject us to restrictive covenants that could limit our flexibility in conducting future business activities. To the extent that we raise additional funds through collaboration and licensing arrangements, it will be necessary to relinquish some rights to our clinical product candidates.

***If we are unable to establish sales and marketing capabilities, we may be unable to successfully commercialize our product candidates.***

If our cancer product candidates are approved for commercial sale, we plan to establish our own sales force to market them in the United States and potentially Europe. We currently have no experience in selling, marketing or distributing pharmaceutical products and do not have a sales force to do so. Before we can commercialize any products, we must develop our sales, marketing and distribution capabilities, which is an expensive and time consuming process and our failure to do this successfully could delay any product launch. Our efforts to develop internal sales and marketing capabilities could face a number of risks, including:

- we may not be able to attract a sufficient number of qualified sales and marketing personnel;



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- the cost of establishing a marketing or sales force may not be justifiable in light of the potential revenues for any particular product; and
- our internal sales and marketing efforts may not be effective.

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

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management and scientific staff, particularly our Chief Executive Officer, Dr. Harold E. Selick, and our Chief Medical Officer, Dr. Alan B. Colowick. We do not have employment contracts with Drs. Selick or Colowick. The loss of the services of Drs. Selick and Colowick 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 commercialization of our product candidates.

As of June 30, 2006, we had 82 employees. In August 2006, we announced a plan to reduce the number of full-time employees to 53 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 strategy.

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

The recent reduction in our work force will impose 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 will need to increase our use of various third parties, including contract research organizations, manufacturers and others, including potential collaborators, 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.

***We are required to comply with Section 404 of the Sarbanes-Oxley Act of 2002 for our annual report on Form 10-K for our fiscal year ending December 31, 2006. Due to our limited resources, especially with the recent reduction in resources, we may be unable to meet this deadline.***

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the company's internal control over financial reporting in their annual reports on Form 10-K. In addition, the independent registered public accounting firm auditing the company's financial statements must attest to and report on management's assessment of the effectiveness of the company's internal control over financial reporting. This requirement will first apply to our annual report on Form 10-K for our fiscal year ending December 31, 2006. Substantial uncertainty exists regarding our ability to comply with these requirements by applicable deadlines especially since the reduction in force will decrease resources available to work on this effort. If we are unable to complete the required assessment as to the adequacy of our internal control reporting or if we conclude that our internal control over financial reporting are not effective or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2006 and future year ends, investors could lose confidence in the reliability of our financial reporting.

***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

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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 glufosfamide and 2DG. If these parties do not manufacture the active pharmaceutical ingredients or finished 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 initial supplies of glufosfamide were prepared by a subsidiary of Baxter International, Inc. and were used to initiate our current clinical trials. We are currently using glufosfamide API and drug product that were manufactured, tested and released by other suppliers and we believe this material will be sufficient through completion of our currently ongoing Phase 2 and Phase 3 trials. If this material does not continue to meet specifications, we may experience a significant delay in the completion of these trials until additional materials may be produced and qualified. We are in the process of qualifying an additional vendor to manufacture glufosfamide API. If we experience unexpected delays, or if the API or finished product does not meet specifications, we may experience a significant delay in the initiation of additional trials.

We believe that we have a sufficient supply of 2DG for our anticipated clinical trials over the next year, although we cannot be certain that these supplies will remain stable and usable during this period. If these materials are not stable, we may experience a significant delay in our 2DG clinical program.

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. For regulatory purposes, we will have to demonstrate comparability of the same drug substance from different manufacturers. Our inability to do so could delay our clinical programs.

To date, our product candidates have been manufactured in quantities sufficient for preclinical studies or clinical trials. If any of our product candidates is approved by the FDA or other regulatory agencies for commercial sale, we will need to have it manufactured in commercial quantities. We may not be able to increase the manufacturing capacity for any of our product candidates in a timely or economic manner successfully or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA and other regulatory agencies must review and approve. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed, or there may be a shortage of supply which could limit our sales.

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

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

The facilities used by our contract manufacturers must undergo an inspection by the FDA for compliance with current good manufacturing practice, or cGMP regulations, before the respective product candidates can be approved. In the event these facilities do not receive a satisfactory cGMP inspection for the manufacture of our product candidates, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for such product candidate. In addition, our contract manufacturers, and any alternative contract manufacturer we may utilize, will be subject to ongoing periodic inspection by the FDA and corresponding state and foreign agencies for compliance with cGMP regulations, similar foreign regulations and other regulatory standards. We do not have

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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 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 are using clinical research organizations to oversee our ongoing glufosfamide clinical trials and expect to use the same or similar organizations for our future 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 studies are conducted in compliance with FDA requirements. Completion of our ongoing and future studies of glufosfamide are and will be dependent upon the accrual of patients at clinical sites outside the United States. Any third-party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials and in our plans to file NDAs, the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented.

***We may rely on strategic collaborators to market and sell our products.***

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

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

## **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.

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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 one issued patent that covers the treatment of breast cancer with 2DG in combination with paclitaxel or docetaxel. 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.

***Metabolic Targeting 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 Metabolic Targeting 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.

***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.

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.

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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 patents and pending patent applications, which are owned by third parties, exist in the general field of cancer and BPH 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

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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, Eli Lilly and Company and Pfizer and from generic pharmaceutical manufacturers. In particular, our glufosfamide product candidate for pancreatic cancer will compete with Gemzar, marketed by Eli Lilly and Company, 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<sup>®</sup>, marketed by Pfizer, Erbitux<sup>®</sup>, marketed by Imclone Systems Incorporated and Bristol-Myers Squibb Company, Taxotere<sup>®</sup>, marketed by the sanofi-aventis Group, Xeloda<sup>®</sup>, marketed by Roche, and Alimta<sup>®</sup>, marketed by Eli Lilly and Company, are under investigation as possible combination therapies for first-line treatment of pancreatic cancer and other compounds are under investigation as first or second line treatments for pancreatic cancer. Additionally OSI Pharmaceuticals and Genentech market Tarceva<sup>®</sup> as a combination therapy with gemcitabine for the first-line treatment of pancreatic cancer.

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

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

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

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

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

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

We have product liability insurance that covers our clinical trials up to an \$8 million annual aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates or any other compound that we may develop. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or at all, and the insurance coverage that we obtain may not be adequate to cover potential claims or losses.

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

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

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

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

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

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

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

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

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

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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.

***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

*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 of glufosfamide or 2DG;
- 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;
- changes in accounting principles; and
- loss of any of our key scientific or management personnel.

In the past, following periods of volatility in the market price of a particular company's securities, litigation has often been brought against that company. If litigation of this type is brought against us, it could be extremely expensive and divert management's attention and our company's resources.

*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 August 1, 2006, our officers, directors and holders of 5% or more of our outstanding common stock beneficially own approximately 32% 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.*

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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 stockholder rights plan, the provisions of which could make it more difficult for a potential acquirer to consummate a transaction.

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

- (b) In connection with our initial public offering on February 4, 2005, we sold 6,112,601 shares of our common stock for net offering proceeds to us after deducting expenses totaling \$38.1 million. In connection with our offering completed on October 28, 2005, we sold 6,399,222 shares of our common stock for net offering proceeds to us after deducting expenses totaling \$62.4 million. As of June 30, 2006, we used approximately \$50.7 million of the net proceeds of our initial public offering and follow-on offering, including approximately \$35.2 million for the clinical development of glufosfamide, TH-070 and 2DG, \$8.7 million for research and development of additional product candidates, and approximately \$6.8 million for working capital, capital expenditures and other general corporate purposes. The balance of net offering proceeds has been invested in short-term investment grade securities and cash equivalent instruments.
- (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
04/01/2006 to 06/30/2006	3,879*	\$ 0.37	—	—

\* 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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On May 25, 2006, the Annual Meeting of Stockholders of Threshold Pharmaceuticals was held at our offices in Redwood City, California.

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An election of Class II directors was held with the following individuals being elected to our Board of Directors to serve until our 2009 Annual Meeting of Stockholders:

Mr. William A. Halter	(32,338,091 votes for, 521,495 votes withheld)
Dr. Wilfred E. Jaeger	(32,394,855 votes for, 464,731 votes withheld)

The Company's directors whose terms continued after the Annual Meeting are Bruce C. Cozadd, Patrick G. Enright, Dr. George G.C. Parker, Dr. Michael F. Powell and Dr. Harold E. Selick.

Other matters voted upon and approved at the meeting and the number of affirmations, negative votes cast and abstentions with respect to each such matter were as follows:

- Ratification of the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2006 (32,799,850 votes in favor, 32,610 votes opposed, 27,126 votes abstaining).

## **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.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

	Threshold Pharmaceuticals, Inc.
Date: August 10, 2006	<u>/s/ Harold E. Selick</u> Harold E. Selick, Ph.D. Chief Executive Officer (Principal Executive Officer)
Date: August 10, 2006	<u>/s/ Janet I. Swearson</u> Janet I. Swearson Chief Financial Officer (Principal Financial and Accounting Officer)

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
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 Janet I. Swearson.
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 Janet I. Swearson.

CERTIFICATION

I, Harold E. Selick, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2006, 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)) 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) [Paragraph omitted pursuant to SEC Release 33-8238];
  - (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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2006

/s/ Harold E. Selick

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

CERTIFICATION

I, Janet I. Swearson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2006, 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)) 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) [Paragraph omitted pursuant to SEC Release 33-8238];
  - (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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2006

/s/ Janet I. Swearson

Janet I. Swearson  
Chief Financial 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 June 30, 2006, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Harold E. Slick, 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: August 10, 2006

/s/ Harold E. Slick

Harold E. Slick, 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 June 30, 2006, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Janet I. Swearson, 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: August 10, 2006

/s/ Janet I. Swearson

Janet I. Swearson  
Chief Financial Officer