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

FORM 10-Q

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

For the quarterly period ended June 30, 2005

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

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

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

1300 Seaport Boulevard
Redwood City, CA 94063
(Address of principal executive offices, including zip code)

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

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

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

On July 31, 2005, there were 30,776,393 shares of common stock, par value $.001 per share, of Threshold Pharmaceuticals, Inc. outstanding.

Threshold Pharmaceuticals, Inc.
FORM 10-Q
QUARTER ENDED June 30, 2005

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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)

	June 30, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,913	$ 14,339
Marketable securities	14,618	14,326
Prepaid expenses and other current assets	1,324	1,604
Restricted cash	—	85
Total current assets	55,855	30,354
Property and equipment, net	1,878	1,667
Restricted cash and other assets	218	192
Total assets	$ 57,951	$ 32,213
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,112	$ 1,550
Accrued clinical and development expenses	2,564	444
Accrued liabilities	1,827	1,062
Notes payable, current portion	314	331
Advance on research and development contract	5,000	5,000
Total current liabilities	10,817	8,387
Notes payable, less current portion	234	382
Deferred rent	117	78
Total liabilities	11,168	8,847
Redeemable convertible preferred stock	—	49,839
Stockholders' equity (deficit):		
Common stock, $0.001 par value, 150,000,000 shares authorized; issued and outstanding: 30,761,214 shares at June 30, 2005 and 3,690,567 shares at December 31, 2004	31	4
Additional paid-in capital	115,325	24,619
Deferred stock-based compensation	(16,327)	(16,637)
Accumulated other comprehensive income	43	104
Deficit accumulated during the development stage	(52,289)	(34,563)
Total stockholders' equity (deficit)	46,783	(26,473)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 57,951	$ 32,213

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

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

	Three Months Ended June 30,		Six Months Ended June 30,		Cumulative Period from October 17, 2001 (date of inception) to June 30, 2005
	2005	2004	2005	2004	
Operating expenses:					
Research and development	$ 7,872	$ 4,133	$ 13,123	$ 6,130	$ 37,916
General and administrative	2,741	2,225	5,306	3,097	15,517
Total operating expenses	10,613	6,358	18,429	9,227	53,433
Loss from operations	(10,613)	(6,358)	(18,429)	(9,227)	(53,433)
Interest income, net	436	101	720	193	1,254
Interest expense	(9)	(5)	(17)	(21)	(110)
Net loss	(10,186)	(6,262)	(17,726)	(9,055)	(52,289)
Dividend related to beneficial conversion feature of redeemable convertible preferred stock	—	—	—	—	(40,862)
Net loss attributable to common stockholders	$(10,186)	$(6,262)	$(17,726)	$(9,055)	$ (93,151)
Net loss per common share, basic and diluted	$ (0.36)	$ (5.83)	$ (0.79)	$(12.90)	
Weighted average number of shares used in per common share calculations: basic and diluted	28,679	1,075	22,559	702	

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)

	Six Months Ended June 30,		Cumulative Period from October 17, 2001 (date of inception) to June 30, 2005
	2005	2004	
Cash flows from operating activities:			
Net loss	$(17,726)	$ (9,055)	$ (52,289)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	274	62	518
Stock-based compensation expense	3,311	1,689	10,374
Amortization of debt issuance costs	—	10	44
Loss on disposal of property and equipment	—	—	5
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(1,032)	(985)	(1,349)
Accounts payable	132	216	1,112
Accrued clinical and development expenses	2,121	208	2,564
Accrued liabilities	782	862	1,826
Advance on research and development contract	—	—	5,000
Deferred rent	39	—	117
Net cash used in operating activities	(12,099)	(6,993)	(32,078)
Cash flows from investing activities:			
Acquisition of property and equipment	(1,074)	(153)	(2,401)
Acquisition of marketable securities	(14,409)	(17,369)	(52,654)
Proceeds from sale of marketable securities	14,056	—	38,079
Restricted cash	85	—	(192)
Net cash used in investing activities	(1,342)	(17,522)	(17,168)
Cash flows from financing activities:			
Proceeds from redeemable convertible preferred stock, net	—	—	49,839
Proceeds from initial public offering, net	38,970	—	37,683
Proceeds from issuance of common stock	209	811	1,088
Proceeds from issuance of notes payable	—	122	1,000
Repayment of notes payable	(164)	(82)	(451)
Net cash provided by financing activities	39,015	851	89,159
Net increase (decrease) in cash and cash equivalents	25,574	(23,664)	39,913
Cash and cash equivalents, beginning of period	14,339	40,609	—
Cash and cash equivalents, end of period	$ 39,913	$ 16,945	$ 39,913
Supplemental schedule of non-cash investing and financing activities			
Deferred stock-based compensation	$ 2,645	$ 16,497	$ 25,387
Fair value of redeemable convertible preferred stock warrant	$ —	$ —	$ 44
Deferred offering costs in connection with initial public offering	$ (1,287)	$ (509)	$ —
Change in unrealized gain (loss) on marketable securities	$ (61)	$ (73)	$ 43
Dividend related to beneficial conversion feature of redeemable convertible preferred stock.	$ —	$ —	$ 40,862

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

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

NOTE 1 — ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

The Company

Threshold Pharmaceuticals, Inc. (the "Company") is a development stage enterprise engaged primarily in the research, development and commercialization of targeted small molecule therapies initially for the treatment of cancer and benign prostatic hyperplasia (BPH). 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 financial statements have been prepared on the same basis as the annual financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments necessary for the fair statement of results for the periods presented, have been included. The results of operations of any interim period are not necessarily indicative of the results of operations for the full year or any other interim period.

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

The financial statements and related disclosures have been prepared with the presumption that users of the interim financial statements have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2004 included in the Company's Form 10-K filed with the Securities and Exchange Commission.

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

Critical Accounting Policies

There are no critical accounting policies other than those disclosed in the Company's Annual Report on Form 10-K, and there have been no changes to the policies discussed therein.

Stock-Based Compensation

The Company accounts for stock-based employee compensation arrangements in accordance with provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB No. 25") and complies with the disclosure provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123"), as amended by SFAS No. 148, "Accounting for Stock-Based Compensation, Transition and Disclosure." Under APB No. 25, unearned stock compensation is based on the difference, if any, on the date of grant, between the fair value of the Company's common stock and the exercise price.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Amortization of stock-based compensation:				
Research and development	$ 701	$ 569	$1,402	$ 588
General and administrative	777	746	1,554	874
	$ 1,478	$ 1,315	$2,956	$1,462

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 No. 123, the Company's pro forma net loss attributable to common stock holders and pro forma net loss per common share attributable to common stockholders under SFAS No. 123 would have been as follows (in thousands, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Net loss attributable to common stockholders, as reported	$(10,186)	$(6,262)	$(17,726)	$(9,055)
Add: Employee stock-based compensation included in reported net loss	1,478	1,315	2,956	1,462
Deduct: Employee total stock-based compensation determined under fair value method	(1,728)	(1,043)	(3,405)	(1,191)
Pro-forma net loss attributable to common stockholders	$(10,436)	$(5,990)	$(18,175)	$(8,784)
Net loss attributable to common stockholders per common share, basic and diluted:				
As reported	$ (0.36)	$ (5.83)	$ (0.79)	$(12.90)
Pro-forma	$ (0.36)	$ (5.57)	$ (0.81)	$(12.51)

The resulting effect on net loss attributable to common stockholders and net loss per share attributable to common stockholders is not likely to be representative of the effects on net loss attributable to common stockholders and net loss per share attributable to common stockholders in future periods, as subsequent periods may include additional grants and periods of vesting.

Prior to the closing of the Company's initial public offering, the fair value of options was computed using the minimum value method. Following the offering, the value of each employee option and each employee purchase right under the Employee Stock Purchase Plan has been estimated at the date of the grant using the Black-Scholes model, assuming the following weighted-average assumptions:

	Three Months ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Employee Stock Options				
Weighted average risk-free interest rate	3.77%	3.72%	3.55%	2.72%
Expected life (in years)	4.0	4.0	3.6	4.0
Dividend yield	—	—	—	—
Volatility	67%	0%	67%	0%
Employee Stock Purchase Plan (ESPP)*:				
Weighted average risk-free interest rate	3.34%	—	3.34%	—
Expected life (in years)	0.5	—	0.5	—
Dividend yield	—	—	—	—
Volatility	67%	—	67%	—

* The ESPP started in February 2005

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 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 Model. All unvested shares are marked to market until such options vest. In connection with the grant of stock options to non-employees, the Company recorded stock-based compensation of approximately $206,000 and $105,000 for the quarters ended June 30, 2005 and 2004, respectively, and approximately $355,000 and $227,000 for the six month periods ended June 30, 2005 and 2004, respectively.

Recent Accounting Pronouncements

Share-Based Payment: In December 2004, the FASB issued SFAS No. 123R, *'Share-Based Payment — An Amendment of FASB Statements No. 123 and 95"*("SFAS 123R"*).* The new pronouncement replaces the existing requirements under SFAS 123 and APB 25. According to SFAS 123R, all forms of share-based payments to employees, including employee stock options and employee stock purchase plans, would be treated the same as any other form of compensation by recognizing the related cost in the statement of operations. This pronouncement eliminates the ability to account for stock-based compensation transactions using APB 25 and generally would require that such transactions be accounted for using a fair-value based method. The statement requires companies to assess the most appropriate model to calculate the value of the options. The Company currently uses the Black-Scholes option pricing model to value options and is currently assessing which model to use in the future under the new statement and may deem an alternative model to be the most appropriate. The use of a different model to value options may result in a different fair value than the use of the Black-Scholes option pricing model. In addition, there are a number of other requirements under the new standard that would result in differing accounting treatment than currently required. These differences include, but are not limited to, the accounting for the tax benefit on employee stock options and for stock issued under the Company's employee stock purchase plan, and the presentation of these tax benefits within the statement of cash flows. In addition to the appropriate fair value model to be used for valuing share-based payments, the Company will also be required to determine the transition method to be used at date of adoption. The allowed transition methods include prospective and retroactive adoption options. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated.

In April 2005, the Securities and Exchange Commission announced the adoption of a new rule that amends the effective date of SFAS 123R. The effective date of the new standard under these new rules for the Company's financial statements is January 1, 2006. Adoption of this statement could have a significant impact on the Company's financial statements as the Company will be required to expense the fair value of its stock option grants and stock purchases under the Company's employee stock purchase plan rather than disclose the impact on the Company's net loss within our footnotes, as is the current practice. The impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. The Company is in the process of evaluating the impact of this standard on its financial statements.

***Exchanges of Nonmonetary Assets*:** On December 16, 2004, the FASB issued Statement No. 153,*Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions.* Statement 153 addresses the measurement of exchanges of nonmonetary assets and redefines the scope of transactions that should be measured based on the fair value of the assets exchanged. Statement 153 is effective for nonmonetary asset exchanges for fiscal periods beginning after June 15, 2005. The Company does not believe adoption of Statement 153 will have a material effect on its financial position, results of operations or cash flows.

***Accounting Changes and Error Corrections*:** On June 7, 2005, the FASB issued Statement No. 154,*Accounting Changes and Error Corrections,* a replacement of APB Opinion No. 20, *Accounting Changes*, and Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements.* Statement 154 changes the requirements for the accounting for and reporting of a change in accounting principle. Previously, most voluntary changes in accounting principles were required recognition via a cumulative effect adjustment within net income of the period of the change. Statement 154 requires retrospective application to prior periods' financial statements, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. Statement 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005; however, the Statement does not change the transition provisions of any existing accounting pronouncements. The Company does not believe adoption of Statement 154 will have a material effect on its financial position, results of operations or cash flows.

NOTE 2 — NET LOSS PER COMMON SHARE:

Basic net loss per common share attributable to common stockholders is calculated based on the weighted-average number of vested common shares outstanding during the period excluding those shares that are subject to repurchase. Diluted net loss per common share is computed by giving effect to all potential dilutive common shares, including options, warrants, common stock subject to repurchase and redeemable convertible preferred stock. A reconciliation of shares used in the calculation is as follows (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Numerator:				
Net loss attributable to common stockholders	$(10,186)	$(6,262)	$(17,726)	$(9,055)
Denominator:				
Weighted average common shares outstanding	30,748	2,316	24,696	1,258
Less: Weighted average unvested common shares subject to repurchase	(2,069)	(1,241)	(2,137)	(556)
Denominator for basic and diluted calculations	28,679	1,075	22,559	702
Basic and diluted net loss per share attributable to common stockholders	$ (0.36)	$ (5.83)	$ (0.79)	$(12.90)

The following outstanding stock options and warrants, common stock subject to repurchase and redeemable convertible preferred stock (on an as-if-converted basis) were excluded from the computation of diluted net loss per share attributable to common stockholders as they had an antidilutive effect (in thousands):

	As of June 30,	
	2005	2004
Shares issuable upon exercise of stock options	493	537
Shares issuable related to the ESPP	43	—
Shares issuable upon exercise of warrants	23	23
Common stock subject to repurchase	1,979	2,070
Shares issuable upon conversion of redeemable convertible preferred stock	—	20,553

NOTE 3 —STOCKHOLDERS' EQUITY (DEFICIT):

Initial Public Offering

On February 4, 2005 the Company sold 5,333,333 shares of common stock in an initial public offering for aggregate gross proceeds of $37.3 million. After deducting the underwriters' commission and offering expenses the Company received net proceeds of approximately $32.6 million. On March 4, 2005 the Company received an aggregate of $5.5 million from the exercise of the underwriters' over-allotment option. After deducting the underwriter's commission, the Company received net proceeds of $5.1 million. Upon completion of the initial public offering all redeemable convertible preferred stock converted to common stock.

Directors Compensation Program

On May 19, 2005, the Board of Directors approved revised compensation arrangements for non-employee directors of the Company. Effective May 19, 2005, non-employee directors receive an annual retainer. On May 19, 2005, each non-employee director was granted an option to purchase 15,000 shares of the Company's common stock under the Company's 2004 Amended and Restated Equity Incentive Plan. In addition, at each annual meeting of stockholders of the Company, each non-employee director who has served as director at least six months prior to such meeting will receive an automatic grant of an option to purchase 15,000 shares of the Company's common stock.

NOTE 4 — COMMITMENTS AND CONTINGENCIES

On April 1, 2005 the Company entered into a noncancelable facility operating lease for approximately 6,489 square feet of laboratory space. The lease expires in February 2010. In connection with the execution of the lease, the Company paid a security deposit of approximately $25,000. The Company recognizes rent expense using the straight line method. The future rental payments required by the Company under the noncancelable operating lease at June 30, 2005 are as follows (in thousands):

Years Ending December 31,	
Remainder of 2005	$ 56
2006	139
2007	143
2008	146
2009	151
2010	25
Total	$660

NOTE 5 — Subsequent Event

Pursuant to a Development Agreement entered into in November 2004, the Company and MediBIC Co. Ltd., signed a Development Plan on July 8, 2005 for the development of glufosfamide in certain Asian countries. Upon entering into the Development Agreement, the Company received an upfront payment of $4.75 million to support development expenses incurred by the Company, and a $250,000 option payment, which were recorded as "Advance on research and development contract" on the accompanying condensed consolidated balance sheets. The Company is responsible for all development expenses and will receive no other funding pursuant to the Development Agreement.

The upfront payments will be classified as "Deferred revenue" on the Company's balance sheet, and will be recognized as revenue over the period in which the related development costs are incurred.

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 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; and
- uncertainties associated with obtaining and enforcing patents and other intellectual property rights.

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 "Risk Factors" and "Overview" sections of this Management's Discussion and Analysis of Financial Condition and Results of Operations. Forward-looking statements reflect our view only as of the date of this report. We undertake no obligations 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, development and commercialization of drugs based on Metabolic Targeting, an approach that targets fundamental differences in metabolism between normal and certain diseased cells. We are building a pipeline of drugs that are designed to target tumor and diseased cells selectively so that the drugs are less toxic to healthy tissues than conventional drugs, thereby providing improvements over current therapies.

Our initial clinical focus is the treatment of cancer and benign prostatic hyperplasia (BPH). We have three product candidates.

- Glufosfamide, our lead product candidate for cancer, has completed two Phase 1 and five Phase 2 clinical trials in patients with various solid tumors. In September 2004, we initiated a pivotal Phase 3 clinical trial of glufosfamide for the second-line treatment of pancreatic cancer. We have received a Special Protocol Assessment from the Food and Drug Administration (FDA) for this trial. Glufosfamide for the treatment of pancreatic cancer has also received FDA Fast Track designation. We also initiated a Phase1/2 trial for glufosfamide in December of 2004 for the first-line treatment of pancreatic cancer in combination with Gemzar.
- TH-070, our lead product candidate for the treatment of symptomatic BPH, has completed a Phase 2 clinical trial in Italy. We initiated a Phase 2 trial in the United States in June 2005 and a Phase 3 trial in Europe in August 2005, both of which are multi-centered, randomized, blinded and placebo controlled trials.
- 2-deoxyglucose, or 2DG, our product candidate for the treatment of solid tumors is being evaluated in a Phase 1 clinical trial alone and as a combination therapy, which means that it is administered in conjunction with another chemotherapy agent. This trial began in the first quarter 2004.

We are also working to discover novel drug candidates that will specifically target cancer cells, and we have identified lead compounds with promising *in vitro* data. In addition, we are investigating additional compounds for activity against BPH.

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 achieved any revenue from operations, and, through 2004, we funded our operations through the private placement of equity securities. In February 2005, we completed our initial public offering which raised net proceeds of approximately $37.7 million. As of June 30, 2005 we had cash, cash

equivalents, and marketable securities of $54.5 million which is expected to last through 2006. We believe we have sufficient funds to complete our current trials of glufosfamide, TH-070 and 2DG. Net loss for the quarter ended June 30, 2005 was $10.2 million and the cumulative net loss since our inception through June 30, 2005 was $52.3 million.

We expect our net losses to increase primarily due to our anticipated clinical trial activities. Clinical trials are costly, and as we continue to advance our product candidates through development, we expect our research and development expenses to increase significantly, especially as we continue our pivotal Phase 3 clinical trial of glufosfamide and our Phase 3 and Phase 2 trials for TH-070 for the treatment of symptomatic BPH. These clinical trials will involve a greater number of patients, will be conducted at multiple sites and in several countries, will be conducted over a longer period of time and require greater quantities of drug product. Costs associated with these clinical trials will fluctuate from period to period based largely on clinical trial activities including patient enrollment. Additionally we plan to significantly expand our infrastructure and facilities and hire additional personnel, including clinical development, research, commercial operations and administrative personnel. We are unable to predict when, if ever, we will be able to commence sales of any product.

Results of Operations

Comparison of Three and Six Month Periods Ended June 30, 2005 and June 30, 2004

Research and Development. Research and development expenses were $7.9 million for the three months ended June 30, 2005 compared to $4.1 million for the three months ended June 30, 2004. The $3.8 million increase in expenses is primarily due to a $3.0 million increase in clinical and development expenses, $0.7 million in higher staffing levels and related costs, and an increase in non-cash stock-based compensation expense of $0.1 million. Research and development expenses were $13.1 million for the six months ended June 30, 2005 compared to $6.1 million for the six months ended June 30, 2004. The $7.0 million increase in expenses is primarily due to a $4.3 million increase in clinical and development expenses, $2.0 million in higher staffing levels and related costs, and an increase in non-cash stock-based compensation expense of $0.7 million.

	Three months ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
TH-070	$ 2,974	$ 1,132	$ 4,821	$1,631
Glufosfamide	2,626	1,377	4,554	1,754
2DG	617	740	1,063	1,354
Discovery Research	1,655	884	2,685	1,391
Total Research and Development Expenses	$ 7,872	$ 4,133	$13,123	$6,130

Research and development expenses associated with TH-070 were $3.0 million for the quarter ended June 30, 2005 and $1.1 million for the quarter ended June 30, 2004. This increase in expenses was primarily due to expenses associated with the initiation of our Phase 2 trial in the United States and our Phase 3 trial in Europe. Research and development expenses associated with glufosfamide were $2.6 million for the quarter ended June 30, 2005 and were $1.4 million for the quarter ended June 30, 2004. This increase is primarily due to expenses associated with our Phase 3 clinical trial which was initiated in September 2004. Research and development expenses associated with 2DG were $0.6 million for the quarter ended June 30, 2005 and $0.7 million for the quarter ended June 30, 2004. The decrease is primarily attributable to a minor reduction in 2DG project staffing in 2005. Discovery research and development expenses were $1.7 million for the quarter ended June 30, 2005 and were $0.9 million for the quarter ended June 30, 2004. The increase was primarily due to increases in staffing and related costs.

Research and development expenses associated with TH-070 were $4.8 million for the six months ended June 30, 2005 and $1.6 million for the six months ended June 30, 2004. This increase in expenses was primarily due to the initiation of our Phase 2 United States and Phase 3 European trials and an increase in staffing and related expenses. Research and development expenses associated with glufosfamide were $4.6 million and $1.8 million for the six months ended June 30, 2005 and 2004, respectively. This increase is primarily due to expenses associated with the Phase 1/2 and Phase 3 clinical trials. Research and development expenses associated with 2DG were $1.1 million and $1.4 million for the six months ended June 30, 2005 and 2004, respectively. The decrease is primarily attributable to a reduction in 2DG project staffing and related costs. Discovery research and development expenses were $2.7 million for the six months ended June 30, 2005 and were $1.4 million for the six months ended June 30, 2004. The increase was primarily due to increases in staffing and related costs to support expansion of the company’s discovery research program.

We expect to continue to devote substantial resources to research and development in future periods as we continue our current clinical trials and start additional trials. Research and development expenses will likely increase in future periods but will fluctuate from period to period based largely on clinical trial activities, including patient enrollment.

General and Administrative. General and administrative expenses were $2.7 million for the three months ended June 30, 2005, compared to $2.2 million for the three months ended June 30, 2004. The $0.5 million increase in general and administrative expenses reflect increased costs of $0.2 million for higher staffing and related costs, an increase in non-cash stock-based compensation expenses of $0.2 million and $0.1 million for higher legal and accounting services costs.

For the six months ended June 30, 2005 and 2004, general and administrative expenses were $5.3 million and $3.1 million, respectively. The $2.2 million increase in general and administrative expenses reflect increased costs of $1.1 million for higher staffing and related costs, an increase in non-cash stock-based compensation expenses of $0.9 million and $0.2 million for higher legal and accounting costs.

We expect our general and administrative expenses to continue to increase due to the additional administrative and infrastructure costs associated with being a public company, including costs associated with implementing procedures for compliance with Section 404 of the Sarbanes-Oxley Act.

Interest and Other Income, Net. Interest income for the three months ended June 30, 2005 was $436,000 compared to $101,000 for the three months ended June 30, 2004. The increase was primarily due to higher average interest rates and greater invested cash balances during the quarter ended June 30, 2005 compared to the prior year due to proceeds received from our initial public offering completed February 4, 2005.

Interest income for the six months ended June 30, 2005 was $720,000 compared to $193,000 for the six months ended June 30, 2004. The increase was primarily due to higher average interest rates and greater invested cash balances due to proceeds received from our initial public offering completed February 2005.

Liquidity and Capital Resources

We have incurred net losses of $52.3 million since inception through June 30, 2005. We have not generated any revenues and do not expect to generate revenue from sales of product candidates for several 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 5,333,333 shares of common stock at $7.00 per share which raised gross proceeds of $37.3 million. Additionally, the underwriters exercised 779,268 shares of their over-allotment for gross proceeds of $5.5 million. Net proceeds from our initial public offering after deducting underwriter's discounts and offering expenses were $37.7 million.

At June 30, 2005, we had cash and cash equivalents of $39.9 million compared to $14.3 million at December 31, 2004. In addition, we had marketable securities balances of $14.6 million and $14.3 million as of June 30, 2005 and December 31, 2004, respectively, available to fund operations.

Net cash used in operating activities for the six months ended June 30, 2005 and 2004 was $12.1 million and $7.0 million, respectively. The $5.1 million increase in cash used in operating activities in 2005 compared to 2004 was primarily attributable to a higher net loss in 2005, partially offset by an increase in clinical and development expense accruals and non-cash charges related to deferred stock-based compensation.

Net cash used in investing activities was $1.3 million and $17.5 million for the six months ended June 30, 2005 and 2004 respectively. The $16.2 million decline in cash used in investing activities in 2005 compared to 2004 was due to an increase in proceeds from sales and fewer purchases of marketable securities, partially offset by higher capital expenditures for leasehold improvements for the Company's new facility.

Net cash provided by financing activities was $39.0 million and $0.9 million for the six months ended June 30, 2005 and 2004, respectively. The $38.1 million increase in cash provided by financing activities in 2005 compared to 2004 was due to the proceeds from our initial public offering in February 2005.

On August 31, 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.

As of June 30, 2005, the Company had lease and financing obligations of (in thousands):

	Remaining of current year (2005)	One to three Years (2006 to 2008)	Four to five Years (2009 to 2010)	After five Years	Total
Facilities sublease and lease	$ 260	$ 1,763	$ 799	$ —	$2,822
Financing line	181	403	—	—	584
Total	$ 441	$ 2,166	$ 799	$ —	$3,406

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 securing manufacturing capabilities for our clinical product candidates and commercial products, if any; and
- the costs of establishing sales, marketing and distribution capabilities.

We expect to incur losses from operations in the future. We expect to incur increasing research and development expenses, including expenses related to clinical trials and additional personnel. We expect that our general and administrative expenses will increase in the future as we expand our staff, add infrastructure and incur additional expenses related to being a public company.

We believe that our cash on hand and marketable securities as of June 30, 2005, will be sufficient to fund our projected operating requirements through 2006, including our current clinical trials of glufosfamide, TH-070 and 2DG, the research and discovery efforts towards additional product candidates, the initial development of a commercialization effort, working capital and general corporate purposes. We intend to seek funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently. Additionally, we will need 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, market conditions and other factors, many of which are beyond our control. There can be no assurance 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.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our 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 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. We have not identified any critical accounting policies other than those discussed in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 31, 2005.

Recent Accounting Pronouncements

Share-Based Payment: In December 2004, the FASB issued SFAS No. 123R, *"Share-Based Payment — An Amendment of FASB Statements No. 123 and 95"* ("SFAS 123R"*).* The new pronouncement replaces the existing requirements under SFAS 123 and APB 25. According to SFAS 123R, all forms of share-based payments to employees, including employee stock options and employee stock purchase plans, would be treated the same as any other form of compensation by recognizing the related cost in the statement of operations. This pronouncement eliminates the ability to account for stock-based compensation transactions using APB 25 and generally would require that such transactions be accounted for using a fair-value based method. The statement requires companies to assess the most appropriate model to calculate the value of the options. We currently use the Black-Scholes option pricing model to value options and is currently assessing which model to use in the future under the new statement and may deem an alternative model to be the most appropriate. The use of a different model to value options may result in a different fair value than the use of the Black-Scholes option pricing model. In addition, there are a number of other requirements under the new standard that would result in differing accounting treatment than currently required. These differences include, but are not limited to, the accounting for the tax benefit on employee stock options and for stock issued under our employee stock purchase plan, and the presentation of these tax benefits within the statement of cash flows. In addition to the appropriate fair value model to be used for valuing share-based payments, we will also be required to determine the transition method to be used at date of adoption. The allowed transition methods include prospective and retroactive adoption options. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated.

In April 2005, the Securities and Exchange Commission announced the adoption of a new rule that amends the effective date of SFAS 123R. The effective date of the new standard under these new rules for our financial statements is January 1, 2006. Adoption of this statement could have a significant impact on our financial statements as we will be required to expense the fair value of stock option grants and stock purchases under our employee stock purchase plan rather than disclose the impact on our net loss within our footnotes, as is the current practice. The impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. We are in the process of evaluating the impact of this standard on its financial statements.

Exchanges of Nonmonetary Assets: On December 16, 2004, the FASB issued Statement No. 153,*Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions.* Statement 153 addresses the measurement of exchanges of nonmonetary assets and redefines the scope of transactions that should be measured based on the fair value of the assets exchanged. Statement 153 is effective for nonmonetary asset exchanges for fiscal periods beginning after June 15, 2005. We do not believe adoption of Statement 153 will have a material effect on our financial position, results of operations or cash flows.

Accounting Changes and Error Corrections: On June 7, 2005, the FASB issued Statement No. 154,*Accounting Changes and Error Corrections, a replacement* of APB Opinion No. 20, *Accounting Changes,* and Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements.* Statement 154 changes the requirements for the accounting for and reporting of a change in accounting principle. Previously, most voluntary changes in accounting principles were required recognition via a cumulative effect adjustment within net income of the period of the change. Statement 154 requires retrospective application to prior periods' financial statements, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. Statement 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005; however, the Statement does not change the transition provisions of any existing accounting pronouncements. We do not believe adoption of Statement 154 will have a material effect on our financial position, results of operations or cash flows.

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 and TH-070 product candidates. Pivotal clinical trials for our products may not demonstrate efficacy or lead to regulatory approval.

We will not be able to commercialize our lead product candidates, glufosfamide and TH-070, 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 biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials. For example, estimates of survival time or percentages obtained from small scale Phase 2 clinical trials are not necessarily indicative of the results in larger 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. Although we believe the Phase 1 and Phase 2 trials of glufosfamide have generated promising early data, there can be no assurance that similar results 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. We believe that the clinical trial we commenced in September 2004 for the second-line treatment of pancreatic cancer will 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. Even though we have a Special Protocol Assessment for this trial, 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.

While we believe that results of our Phase 2 Italian trial for TH-070 suggest it may effectively treat symptomatic BPH, there can be no assurance that our registrational program will confirm those results, will show that beneficial results of TH-070 will be sustained beyond 28 days, or will lead to regulatory approval. We initiated a Phase 2 trial in the United States in June 2005 and a Phase 3 trial in several European countries in August 2005 for this indication; however, we expect regulatory agencies will require additional clinical trials and may require additional preclinical studies to support approval of TH-070 for the treatment of symptomatic BPH.

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 assured 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 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 an indication for our glufosfamide product candidate. In addition, we are aware that our planned trials for TH-070 for the treatment of symptomatic BPH may be subject to competition for patients by competing trials, which could delay enrollment for our trials.

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

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

Changes in the regulatory approval policy 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 refractory 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 guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that glufosfamide will receive regulatory approval for the treatment of refractory 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. There can be no assurance 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 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. TH-070, which we are developing to treat patients with BPH, has been investigated as a male contraceptive and is known to affect fertility in animals. In human clinical trials at doses significantly higher than the doses of TH-070 we contemplate investigating for BPH, muscle and testicular pain have been observed. These side effects or others that could be 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 and prevent regulatory approval or limit their market acceptance if they are approved.

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

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

- obtaining regulatory approval to commence a trial;
- obtaining clinical materials;
- reaching agreement on acceptable clinical study agreement terms with prospective sites;
- 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, but does provide limited advantages in the regulatory review and approval process. Because the prevalence of BPH is greater than 200,000 individuals in the United States, TH-070 for the treatment of symptomatic BPH is not eligible for orphan drug designation and we cannot rely on this protection to provide marketing exclusivity.

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 are 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 us, 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 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.

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 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, 2005, we had a net loss of $17.7 million, and we had an accumulated deficit of $52.3 million at June 30, 2005. We do not expect to generate any revenue from the sale of our product candidates over the next several years. Clinical trials are costly, and as we continue to advance our product candidates through development, we expect our research and development expenses to increase significantly, especially as we continue our pivotal Phase 3 clinical trial for glufosfamide and our Phase 2 and Phase 3 clinical trials for TH-070 for the treatment of BPH. In addition, we plan to expand our operations, and will need to expand our infrastructure and facilities and hire additional personnel. As a result, we expect that our annual operating losses will increase significantly over the next several years.

To attain profitability, we will need to develop products successfully and market and sell them effectively. We have never generated revenue from our product candidates, and there is no guarantee that we will be able to do so in the future. If our glufosfamide or TH-070 product candidates fail to show positive results in our ongoing clinical trials, or we do not receive regulatory approval for one or more of them, or if these product candidates do not achieve market acceptance even if approved, we will not become profitable for at least the next several years. 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 and other arrangements that we may establish;
- the progress and cost of our clinical trials and other research and development activities;
- the costs and timing of obtaining regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights;
- the cost and timing of securing manufacturing capabilities for our clinical product candidates and commercial products, if any; and
- the costs of establishing sales, marketing and distribution capabilities.

We believe that the net proceeds from our initial public offering in February 2005 together with our cash on hand and marketable securities, will be sufficient to fund our projected operating requirements through 2006 including our ongoing clinical trials of glufosfamide, TH-070 and 2DG, the initial development of a commercialization effort, general corporate purposes and for the research and discovery of additional product candidates. 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. There can be no assurance that we will be able to enter into any such arrangements on reasonable terms, if at all.

We will need 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 and other factors, many of which are beyond our control. There can be no assurance 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 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 further 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 cancer and BPH 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 may also establish a sales force to market TH-070 for the treatment of symptomatic BPH. 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;
- 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 recruiting and retaining key personnel and, if we fail to do so, it may be more difficult for us to execute our business strategy. We are currently a small organization and will 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, our founder and President, Dr. George F. Tidmarsh and our Chief Medical Officer, Dr. Alan Colowick. We do not have employment contracts with Drs. Selick, Tidmarsh or Colowick. The loss of the services of Drs. Selick, Tidmarsh, 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, 2005, we had 58 employees. Our success will depend on our ability to hire additional qualified personnel. 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 recruitment efforts, we may be unable to execute our strategy.

As we expand our operations, we may experience difficulties in managing our growth.

Future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure. As our operations expand, we expect that we will need to manage additional relationships with collaborators and various third parties, including contract research organizations, manufacturers and others. Our ability to manage our operations and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy.

Because we have operated as a private company, we have no experience complying with public company obligations, including recently enacted changes in securities laws and regulations. Compliance with these requirements will increase our costs and require additional management resources, and we still may fail to comply.

We are a small company with limited resources. Prior to our initial public offering February 2005, we operated as a private company, not subject to many of the requirements applicable to public companies. While we plan to expand our staff, we may encounter substantial difficulty attracting qualified staff with requisite experience due to the high level of competition for experienced financial professionals.

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 controls 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 controls 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. 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 controls 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 controls 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 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, TH-070 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 current supplies of glufosfamide have been prepared by a subsidiary of Baxter International, Inc. and we are using those materials to conduct our current clinical trials. We will be required to use materials from alternative suppliers to complete our current glufosfamide trials. We have obtained glufosfamide API and drug product that was manufactured, tested and released by other suppliers and, pending regulatory filings and, as necessary, regulatory approvals, we plan to use these materials when needed. If we are not able to obtain required regulatory approvals to use these materials, we may experience a significant delay in our glufosfamide clinical trials. We believe that our suppliers will be able to manufacture additional quantities sufficient to complete our planned clinical trials, although there can be no assurance that they will be able to do so. If we cannot obtain additional glufosfamide drug product as needed, we may experience delays in our clinical trials.

We believe we have sufficient drug product that has been tested and released by Pharmaceutics International, Incorporated (PII) for our United States Phase 2 and our European Phase 3 trial of TH-070 for the treatment of BPH. Additionally, for future trials, we have identified alternative suppliers for TH-070 active pharmaceutical ingredient, or API. Failure of any of these suppliers to provide acceptable API or drug product could delay clinical trials or commercialization of TH-070, if approved.

We believe that we have a sufficient supply of 2DG for our anticipated clinical trials over the next two years, although there can be no assurance 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. There can be no assurance 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 and similar foreign standards. We do not have control over our contract manufacturers' compliance with these regulations and standards. Any failure by our third-party manufacturers or suppliers to comply with applicable regulations could result in sanctions being imposed on them (including fines, injunctions and civil penalties), failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecution.

We rely on third parties to conduct 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 and TH-070 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. We will rely significantly 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 TH-070 for the treatment of BPH either outside the United States or worldwide and our potential cancer products outside the United States.

We have no sales and marketing experience. We may contract with strategic collaborators to sell and market TH-070 for the treatment of symptomatic BPH either outside the United States or worldwide and our cancer products outside the United States. 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

TH-070 and 2DG are known compounds that are not protected by patents as compounds per se.

TH-070 and 2DG are known compounds that are no longer eligible for patent protection as compounds per se. 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, these compounds and certain of their uses are in the public domain. Acraf, S.p.a. has rights to market TH-070 in certain European countries for the treatment of cancer, and we cannot prevent its sale for that indication or for indications where we have not received patent protection. Even if we obtain patents for TH-070 to treat BPH, there may be off-label use of competitive products for our patented indication.

We have in-licensed one issued patent that covers the treatment of breast cancer with 2DG in combination with paclitaxel or docetaxel and related applications that cover other 2DG combination therapies, but there can be no assurance that any other patent application under this license or that our own patent applications relating to treating cancer with 2DG will be issued. As a result, others may develop and market 2DG for the treatment of other cancers or for the treatment of breast cancer in combination with chemotherapy agents where we do not obtain patents claiming such use.

Metabolic Targeting is not protected by patents, and others may be able to develop competitive drugs using this approach.

We do not have issued patents or patent applications that would prevent others from taking advantage of Metabolic Targeting generally to discover and develop new therapies for cancer, BPH 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 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 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. Accordingly, 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 patents or in the patents 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 which fall outside the scope of our or our licensors' patents;
- we may not develop or in-license additional patentable proprietary technologies related to our product candidates; or
- the patents of others may prevent us from marketing one or more of our product candidates for one or more indications that may be valuable to our business strategy.

Moreover, an issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing related product candidates or could limit the length of the term of patent protection of our product candidates. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our product candidates. 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.

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, there can be no assurance they do not, and competitors or other parties may assert that we infringe their proprietary rights in any event.

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

RISKS RELATED TO OUR INDUSTRY

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

Competition in the biotechnology and pharmaceutical industries is intense and continues to increase, particularly in the area of cancer treatment. Most major pharmaceutical companies and many biotechnology companies are aggressively pursuing oncology development programs, including traditional therapies and therapies with novel mechanisms of action. Our cancer product candidates face competition from established biotechnology and pharmaceutical companies, including sanofi-aventis Group, Lilly, Pfizer and SuperGen and from generic pharmaceutical manufacturers. In particular, our glufosfamide product candidate for pancreatic cancer will compete with Gemzar, marketed by Lilly, and 5-flurouracil, or 5-FU, a generic product which is sold by many manufacturers. In addition, Camptosar®, marketed by Pfizer, and Taxotere, marketed by the sanofi-aventis Group, are under investigation as possible combination therapies for first-line treatment of pancreatic cancer. Additionally, the FDA has accepted for filing and review a Supplemental New Drug Application from OSI Pharmaceuticals and Genentech for the use of Tarceva plus gemcitabine for the first-line treatment of pancreatic cancer. PANVAC™ -VF, a vaccine under development by Therion Biologics, is being tested in a Phase 3 trial as a second-line treatment for pancreatic cancer.

Currently available BPH drugs are marketed by large pharmaceutical companies with significantly more experience and resources than we have. Our TH-070 product candidate for the treatment of symptomatic BPH will compete with alpha adrenergic receptor blockers, including Flomax® , co-marketed by Boehringer Ingelheim and Abbott Laboratories, and Cardura® , marketed by Pfizer, and with 5-alpha reductase inhibitors, including Proscar® , marketed by Merck, Avodart® , marketed by GlaxoSmithKline, and Xatral® , marketed by the sanofi-aventis Group. In addition, we are aware that several other companies are developing drugs to treat BPH. We also will compete with other treatment alternatives such as surgery and other non-drug interventions.

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

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

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

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

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

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

We have product liability insurance that covers our clinical trials up to a $5 million annual aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates or any other compound that we may develop. However, insurance coverage is 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 the governmental and 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 government payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to obtain reimbursement.

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

The health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products. The Medicare Prescription Drug, Improvement and Modernization Act of 2003, or MMA, became law in November 2003 and created a broader prescription drug benefit for Medicare beneficiaries. The MMA also contains provisions intended to reduce or eliminate delays in the introduction of generic drug competition at the end of patent or nonpatent market exclusivity. The impact of the MMA on drug prices and new drug utilization over the next several years is unknown. The MMA also made adjustments to the physician fee schedule and the measure by which prescription drugs are presently paid, changing from Average Wholesale Price to Average Sales Price. The effects of these changes are unknown but may include decreased utilization of new medicines in physician prescribing patterns, and further pressure on drug company sponsors to provide discount programs and reimbursement support programs. There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect reimbursement levels for our future products. In addition, the Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions.

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

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

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 may be volatile.

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. In addition, since our initial public offering, the average daily trading volume of our common stock was 70,525 shares through July 29, 2005. The limited trading volume of our stock may contribute to its 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, TH-070 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 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 our strategic alliances or acquisitions;
- 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.

A significant portion of our total outstanding shares were restricted from immediate resale subsequent to our initial public offering in February 2005. As of August 3, 2005, these shares are tradable subject to Rule 144. If there are substantial sales of our common stock, the price of our common stock could decline.

Sales of substantial amounts of our common stock in the public market could adversely affect the price of our common stock. Certain of our existing stockholders and their affiliated entities purchased an aggregate of approximately 1.5 million shares of our common stock in our initial public offering in February 2005. Shares purchased by our affiliates in this offering

may only be sold in compliance with the volume limitations of Rule 144. These volume limitations restrict the number of shares that may be sold by an affiliate in any three-month period to the greater of 1% of the number of shares then outstanding, which equals approximately 307,612, or the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Holders of approximately 23,921,574 shares of our common stock entered into lock-up agreements that prevent the sale of such shares for up to 180 days after our initial public offering. This lock-up period ended on August 2, 2005. These shares are now tradable subject to Rule 144. Holders of an aggregate of 20,552,815 shares of common stock plus the 1,500,003 additional shares that existing stockholders purchased in our initial public offering have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Due to these factors, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

Provisions of Delaware law, 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.

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 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. Accordingly, we believe that while the cash, cash equivalents and marketable securities we hold are subject to changes in the financial standing of the financial institution, we are not subject to any material risks arising from changes in interest rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments. 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.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Based on their evaluation as of June 30, 2005, 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 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.

Changes in internal controls.

There were no changes in our internal controls over financial reporting during the quarter ended June 30, 2005, 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 Threshold 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 there can be no assurance 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, 2005 to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II. OTHER INFORMATION

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 at the initial public offering price per share of $7.00. The net offering proceeds to us after deducting total expenses were $37.7 million. During the period covered by this quarterly report on Form 10-Q, we used approximately $12.1 million of the net proceeds of our initial public offering, including approximately $7.3 million for the clinical development of glufosfamide, TH-070 and 2DG, $2.2 million for research and development of additional product candidates, and $2.6 million for working capital and general corporate expenses. The balance of net offering proceeds has been invested in short-term investment grade securities and cash equivalent instruments.

(c) There were no shares repurchased during the three months ended June 30, 2005.

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

On May 19, 2005, the Annual Meeting of Stockholders of Threshold Pharmaceuticals was held at our offices in Redwood City, California.

An election of Class I directors was held with the following individuals being elected to our Board of Directors to serve until our 2008 Annual Meeting of Stockholders:

Dr. Michael F. Powell	(29,112,256 votes for, 52,272 votes withheld)
Dr. Harold E. Selick	(29,122,090 votes for, 42,438 votes withheld)

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, 2005 (29,151,238 votes in favor, 4,792 votes opposed, 8,498 votes abstaining).

ITEM 6. EXHIBITS

(a) 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.

(b) Reports on Form 8-K

On April 20, 2005, we filed a Report on Form 8-K under Item 5.02—Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers, reporting the reclassification of the Company's Board of Directors.

On May 24, 2005, we filed a Report on Form 8-K under Item 1.01- Entry into a Material Definitive Agreement, reporting the approval of a revised compensation program for non-employee members of the Company's Board of Directors.

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 12, 2005

/s/ Harold E. Selick

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

Date: August 12, 2005

/s/ Janet I. Swearson

Janet I. Swearson
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a) of Harold E. Selick.
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a) of 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.

Exhibit 31.1

CERTIFICATION

I, Harold E. Selick, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2005, 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 officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2005

/s/ Harold E. Selick

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

Exhibit 31.2

CERTIFICATION

I, Janet I. Swearson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2005, 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 officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2005

/s/ Janet I. Swearson

Janet I. Swearson
Chief Financial Officer

Exhibit 32.1

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

In connection with the Quarterly Report of Threshold Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Harold E. Selick, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 12, 2005

/s/ Harold E. Selick

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

Exhibit 32.2

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

In connection with the Quarterly Report of Threshold Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Janet I. Swearson, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 12, 2005

/s/ Janet I. Swearson

Janet I. Swearson
Chief Financial Officer