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, 2016

or

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

For the transition period from_____ to _____

Commission File Number: 001-32979

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

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

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

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

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

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

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

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

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

On July 25, 2016, there were 71,511,425 shares of common stock, par value $0.001 per share, of Threshold Pharmaceuticals, Inc. outstanding.

Threshold Pharmaceuticals, Inc.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2016	December 31, 2015 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,402	$ 9,589
Marketable securities, current	21,189	39,091
Collaboration receivable	921	1,891
Prepaid expenses and other current assets	1,294	2,599
Total current assets	35,806	53,170
Property and equipment, net	208	333
Other assets	166	166
Total assets	$ 36,180	$ 53,669
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,076	$ 725
Accrued clinical and development expenses	2,097	6,834
Accrued liabilities	616	3,269
Total current liabilities	5,789	10,828
Warrant liability	2,490	1,864
Deferred rent	87	131
Total liabilities	8,366	12,823
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 2,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value, shares authorized: 150,000,000 shares; issued and outstanding: 71,511,425 shares at June 30, 2016 and 71,462,059 shares at December 31, 2015	72	71
Additional paid-in capital	371,893	370,236
Accumulated other comprehensive loss	5	(21)
Accumulated deficit	(344,156)	(329,440)
Total stockholders' equity	27,814	40,846
Total liabilities and stockholders' equity	$ 36,180	$ 53,669

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue	$ —	$ 3,680	$ —	$ 7,361
Operating expenses:				
Research and development	4,016	10,141	10,021	20,821
General and administrative	1,892	2,480	4,141	5,096
Total operating expenses	5,908	12,621	14,162	25,917
Loss from operations	(5,908)	(8,941)	(14,162)	(18,556)
Interest income (expense), net	40	39	72	72
Other income (expense), net	(996)	596	(626)	(976)
Net loss	(6,864)	(8,306)	(14,716)	(19,460)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	4	(3)	26	(5)
Comprehensive loss	$ (6,860)	$ (8,309)	$ (14,690)	$ (19,465)
Net loss per share:				
Basic	$ (0.10)	$ (0.12)	$ (0.21)	$ (0.28)
Diluted	$ (0.10)	$ (0.12)	$ (0.21)	$ (0.28)
Weighted average number of shares used in net loss per share calculations:				
Basic	71,511	71,334	71,500	69,046
Diluted	71,511	72,815	71,500	69,046

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

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

	Six Months Ended June 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (14,716)	$ (19,460)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	305	503
(Gain) loss on sale of investments, property and equipment	(51)	14
Stock-based compensation expense	1,645	3,316
Change in common stock warrant fair value	626	974
Changes in operating assets and liabilities:		
Collaboration receivable	970	3,601
Prepaid expenses and other assets	1,305	(773)
Accounts payable	2,351	(1,439)
Accrued clinical and development expenses	(4,737)	1,722
Accrued liabilities	(2,653)	(729)
Deferred rent	(44)	(74)
Deferred revenue	—	(7,361)
Net cash used in operating activities	(14,999)	(19,706)
Cash flows from investing activities:		
Acquisition of property and equipment	—	(55)
Purchases of marketable securities	(13,454)	(39,479)
Proceeds from sale of property and equipment	61	—
Proceeds from sale of marketable securities	—	1,997
Proceeds from maturities of marketable securities	31,192	30,907
Net cash (used in) provided by investing activities	17,799	(6,630)
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net of offering expenses	13	28,514
Net cash provided by financing activities	13	28,514
Net increase (decrease) in cash and cash equivalents	2,813	2,178
Cash and cash equivalents, beginning of period	9,589	8,391
Cash and cash equivalents, end of period	$ 12,402	$ 10,569

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

NOTE 1 — ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company

Threshold Pharmaceuticals, Inc. (the "Company") is a biotechnology company using its expertise in the tumor microenvironment to discover and develop therapeutic agents that selectively target tumor cells for the treatment of patients living with cancer.

Basis of Presentation

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

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

The unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the interim unaudited condensed consolidated financial statements have read or have access to the audited consolidated financial statements for the preceding fiscal year. The condensed consolidated balance sheet at December 31, 2015 has been derived from the audited financial statements at that date but does not include all the information and footnotes required by accounting principles generally accepted in the United States of America. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2015 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 10, 2016.

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

Revenue Recognition

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

The Company's revenues in prior periods were related to its former collaboration arrangement with Merck KGaA, which was entered in February 2012. The collaboration with Merck KGaA provided for various types of payments to the Company, including nonrefundable upfront license, milestone and royalty payments. The Company recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. The Company also received reimbursement for Merck KGaA's 70% share for eligible worldwide development expenses for evofosfamide (formerly TH-302). Such reimbursement was reflected as a reduction of operating expenses. In March 2016, the Company and Merck KGaA agreed to terminate the collaboration and all rights evofosfamide were returned to the Company. As a result of the termination of the collaboration the Company is no longer eligible to receive any further milestone payments from Merck KGaA. In addition, the Company is no longer eligible to receive 70% reimbursement of expenses from Merck KGaA related to the further development of evofosfamide other than for costs to wind down the discontinued trials and return the evofosfamide rights back to the Company.

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

Deferred revenue associated with a non-refundable payment received under a collaborative agreement for which the developmental performance obligations are terminated will result in an immediate recognition of any remaining deferred revenue in the period that termination occurred provided that all performance obligations have been satisfied. As a result of Merck KGaA's and the Company's decision to cease further joint development of evofosfamide in December 2015, the Company immediately recognized all of the remaining deferred revenue into revenue during the quarter ended December 31, 2015.

NOTE 2 — NET LOSS PER SHARE

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Numerator:				
Net loss	$ (6,864)	$ (8,306)	$ (14,716)	$ (19,460)
Less: noncash income from change in fair value of common stock warrants	—	(308)	—	—
Net loss - diluted	(6,864)	(8,614)	(14,716)	(19,460)
Denominator:				
Weighted average common shares outstanding - basic	71,511	71,334	71,500	69,046
Dilutive effect of warrants	—	1,481	—	—
Weighted-average common shares outstanding and dilutive potential common shares — diluted	71,511	72,815	71,500	69,046
Net loss per share:				
Basic	$ (0.10)	$ (0.12)	$ (0.21)	$ (0.28)
Diluted	$ (0.10)	$ (0.12)	$ (0.21)	$ (0.28)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Shares issuable upon exercise of warrants	8,300	8,300	8,300	12,146
Shares issuable upon exercise of stock options	11,635	10,151	11,635	10,151
Shares issuable related to the 2004 Purchase Plan	42	73	42	73

NOTE 3 — COLLABORATION ARRANGEMENTS

On February 3, 2012, the Company entered into a global license and co-development agreement, or License Agreement, with Merck KGaA, of Darmstadt, Germany, to co-develop and commercialize evofosfamide, the Company's small molecule hypoxia-targeted drug. Under the terms of the License Agreement, Merck KGaA received co-development rights, exclusive global commercialization rights and provided the Company with an option to co-commercialize evofosfamide in the United States. To date the Company has received $110 million in upfront and milestone payments. The milestones earned to date were not deemed to be substantive milestones because the work related to the achievement of these items was predominately completed prior to the inception of the arrangement or was not commensurate with Company's performance subsequent to the inception of the arrangement to achieve the milestone.

The Company's deliverables under the License Agreement with Merck KGaA, which included delivery of the rights and license for evofosfamide and performance of research and development activities, were determined to be a single unit of accounting. The delivered license did not have standalone value at the inception of the arrangement due to the Company's proprietary expertise with respect to the licensed compound and related ongoing developmental participation under the License Agreement, which was required for Merck KGaA to fully realize the value from the delivered license. Therefore, the revenue relating to this unit of accounting was recorded as deferred revenue and recognized over the estimated performance period under the License Agreement, which is the product development period. The Company recorded $110 million of the upfront payment and milestones payments as deferred revenue and was amortizing them ratably over the estimated period of performance, which the Company originally estimated to end on March 31, 2020 for the nine months ended September 30, 2015. Merck KGaA's decision to cease further joint development of evofosfamide in December 2015 resulted in the immediate recognition of all the remaining deferred revenue into revenue during the quarter ended December 31, 2015. As a result, the Company recognized $0 revenue during the three and six months ended June 30, 2016, and $3.7 million and $7.4 million of revenue during the three and six months ended June 30, 2015, respectively. Further, in March 2016, the Company and Merck KGaA agreed to terminate the License Agreement pursuant to a termination agreement, or the Termination Agreement. Under the terms of the Termination Agreement, all rights under the License Agreement were returned to the Company, as well as all rights to Merck KGaA technology developed under the License Agreement. Under the Termination Agreement Merck KGaA is entitled to tiered royalties on net sales if any, and milestone payments contingent upon the future successful partnering, development and commercialization of evofosfamide. Also as a result of the termination of the License Agreement the Company is no longer eligible to receive any further milestone payments from Merck KGaA

Merck KGaA also paid 70% of worldwide development expenses for evofosfamide under the terms of the License Agreement. With the decision to cease further joint development of evofosfamide and the termination of the License Agreement, the Company is no longer eligible to receive payments from Merck KGaA for expenses related to further development of evofosfamide other than for costs to wind down the discontinued trials and return the evofosfamide rights back to the Company. The Company earned $0.9 million and $1.7 million reimbursement for eligible worldwide expenses for evofosfamide from Merck KGaA during the six and six months ended June 30, 2016, which expenses were solely for trial wind-down efforts, compared to $3.6 million and $5.6 million for eligible worldwide development expenses incurred during the six and six months ended June 30, 2015. Such earned reimbursement has been reflected as a reduction of research and development expenses.

NOTE 4 — STOCKHOLDERS' EQUITY

Common Stock Warrant Valuation

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

At both June 30, 2016 and December 31, 2015 the Company had warrants outstanding to purchase 8.3 million shares of common stock, having an initial exercise price of $10.86 per share, which warrants were issued by the Company in the Company's February 2015 public offering of common stock and warrants. The exercise price was adjusted to $3.62 on January 21, 2016 pursuant to the terms of warrant. The fair value of these warrants on June 30, 2016 and December 31, 2015 was determined using a Black-Scholes model with the following key level 3 inputs:

	June 30, 2016	December 31, 2015
Risk-free interest rate	1.01 %	1.76 %
Expected life (in years)	3.64	4.14
Dividend yield	—	—
Volatility	116 %	112 %
Stock price	$ 0.64	$ 0.48

During the three and six months ended June 30, 2016 the change in fair value of $1.0 million and $0.7 million, respectively, of noncash expense related to the February 2015 warrants was recorded as other income (expense) in the Company's consolidated statement of operations.

On March 16, 2016, warrants outstanding, which were initially issued by the Company in an underwritten public offering in March 2011, to purchase 3.8 million shares of common stock expired and noncash income of $38,000 related to the expired warrants was recognized as other income (expense) in the Company's consolidated statement of operations. At December 31, 2015, the Company had March 2011 warrants outstanding to purchase 3.8 million shares of common stock, having an exercise price of $2.46 per share. The fair value of these warrants on December 31, 2015 was determined using a Black Scholes valuation model with the following key level 3 inputs:

	December 31, 2015
Risk-free interest rate	0.16 %
Expected life (in years)	0.21
Dividend yield	—
Volatility	179 %
Stock price	$ 0.48

The following table sets forth the Company's financial liabilities, related to warrants issued in the February 2015 and March 2011 offerings, subject to fair value measurements as of June 30, 2016 and December 31, 2015:

(in thousands)	Fair Value as of June 30, 2016	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
February 2015 warrants	$ 2,490	$ —	$ —	$ 2,490

(in thousands)	Fair Value as of December 31, 2015	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
March 2011 warrants	38	—	—	38
February 2015 warrants	1,826	—	—	1,826
Total common stock warrants	$ 1,864	$ —	$ —	$ 1,864

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

	Warrant Liability
Balance at December 31, 2015	$ 1,864
Change in fair value related to expired March 2016 common stock warrants	(38)
Change in fair value of common stock warrants during six months ended June 30, 2016	664
Exercise of warrants during six months ended June 30, 2016	—
Balance at June 30, 2016	$ 2,490

NOTE 5 — STOCK BASED COMPENSATION

The Company recognizes stock-based compensation in accordance with ASC 718, "Compensation—Stock Compensation." Stock-based compensation expense, which consists of the compensation cost for employee stock options and the 2004 Purchase Plan, and the value of options issued to non-employees for services rendered, was allocated to research and development and general and administrative expenses in the unaudited consolidated statements of operations for the three and six months ended June 30, 2016 and 2015 as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Amortization of stock-based compensation:				
Research and development	$ 306	$ 1,174	$ 624	$ 1,991
General and administrative	496	721	1,021	1,325
	$ 802	$ 1,895	$ 1,645	$ 3,316

Valuation Assumptions

The Company estimated the fair value of stock options granted using the Black-Scholes option-pricing formula and a single option award approach. This fair value is being amortized ratably over the requisite service periods of the awards, which is generally the vesting period. The fair value of employee stock options and employee purchase rights under the 2004 Purchase Plan was estimated using the following weighted-average assumptions for the three and six months ended June 30, 2016 and 2015:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Employee Stock Options:				
Risk-free interest rate	1.08%	1.69%	1.60%	1.70%
Expected term (in years)	5.27	5.58	5.97	5.98
Dividend yield	—	—	—	—
Volatility	109%	79%	108%	83%
Weighted-average fair value of stock options granted	$ 0.30	$ 2.65	$ 0.44	$ 3.08

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Employee Stock Purchase Plan (ESPP):				
Risk-free interest rate	0.56%	0.38%	0.56%	0.38%
Expected term (in years)	1.24	1.24	1.24	1.24
Dividend yield	—	—	—	—
Volatility	161%	51%	161%	51%
Weighted-average fair value of ESPP purchase rights	$ 0.22	$ 1.59	$ 0.22	$ 1.59

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

Employee Stock-based Compensation Expense

As required by ASC 718, the Company recognized $0.8 million and $1.6 million of stock-based compensation expense related to stock options and purchase rights under the Company's equity incentive plans and 2004 Purchase Plan for the three and six months ended June 30, 2016 and $1.9 million and $3.3 million of stock-based compensation for the three and six months ended June 30, 2015. As of June 30, 2016, the total unrecognized compensation cost related to unvested stock-based awards granted to employees under the Company's equity incentive plans was approximately $2.4 million before forfeitures. This cost will be recorded as compensation expense on a ratable basis over the remaining weighted average requisite service period of approximately 2.7 years.

Equity Incentive Plans

Equity Incentive Plans At June 30, 2016, 857,479 shares were authorized and available for issuance under the 2014 Equity Incentive Plan.

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

Options	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2015	9,032,136	$ 3.77	—	—
Granted	2,945,000	$ 0.53	—	—
Exercised	—	$ —	—	—
Forfeitures	(341,939)	$ 3.07	—	—
Outstanding at June 30, 2016	11,635,197	$ 2.97	6.32	$ 300,142
Vested and expected to vest June 30, 2016	11,527,107	$ 2.99	6.29	$ 292,477
Exercisable at June 30, 2016	7,444,072	$ 3.61	4.70	$ 16,920

No stock options were exercised during the six months ended June 30, 2016. The total intrinsic value of stock options exercised during six months ended June 30, 2015 was $0.2 million, as determined at the date of the option exercise. Cash received from stock option exercises was $0.1 million for the six months ended June 30, 2015. The Company issues new shares of common stock upon exercise of options. In connection with these exercises, there was no tax benefit realized by the Company due to the Company's current loss position.

2004 Employee Stock Purchase Plan On January 1, 2016, an additional 100,000 shares was authorized for issuance under the 2004 Purchase Plan pursuant to the annual automatic increase to the authorized shares under the 2004 Purchase Plan. For the six months ended June 30, 2016, plan participants had purchased 49,366 shares at an average purchase price of $0.24 for total cash proceeds of $12,000. At June 30, 2016, 177,471 shares were authorized and available for issuance under the 2004 Purchase Plan.

NOTE 6 —MARKETABLE SECURITIES AND FAIR VALUE

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

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

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

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

The Company utilizes the market approach to measure fair value for its financial assets and liabilities. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities. For Level 2 securities that have market prices from multiples sources, a "consensus price" or a weighted average price for each of these securities can be derived from a distribution-curve-based algorithm which includes market prices obtained from a variety of industrial standard data providers (e.g. Bloomberg), security master files from large financial institutions, and other third-party sources. Level 2 securities with short maturities and infrequent secondary market trades are typically priced using mathematical calculations adjusted for observable inputs when available.

The following table sets forth the Company's financial assets (cash equivalents and marketable securities) at fair value on a recurring basis as of June 30, 2016 and December 31, 2015:

(in thousands)	Fair Value as of June 30, 2016	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	$ 1,857	$ 1,857	$ —	$ —
Certificates of deposit	100	—	100	—
Corporate debt securities	4,067	—	4,067	—
Government securities	13,580	—	13,580	—
Commercial paper	13,987	—	13,987	—
Total cash equivalents and marketable securities	$ 33,591	$ 1,857	$ 31,734	$ —

(in thousands)	Fair Value as of December 31, 2015	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	$ 5,421	$ 5,421	$ —	$ —
Certificates of deposit	696	—	696	—
Corporate debt securities	12,571	—	12,571	—
Government securities	21,769	—	21,769	—
Municipal securities	1,908	—	1,908	—
Commercial paper	6,145	—	6,145	—
Total cash equivalents and marketable securities	$ 48,510	$ 5,421	$ 43,089	$ —

The Company invests in highly-liquid, investment-grade securities. The following is a summary of the Company's available-for-sale securities at June 30, 2016 and December 31, 2015:

As of June 30, 2016 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 1,857	$ —	$ —	$ 1,857
Certificates of deposit	100	—	—	100
Corporate debt securities	4,068	—	(1)	4,067
U.S. Government securities	13,574	7	(1)	13,580
Commercial paper	13,987	—	—	13,987
	33,586	7	(2)	33,591
Less cash equivalents	12,402	—	—	12,402
Total marketable securities	$ 21,184	$ 7	$ (2)	$ 21,189

As of December 31, 2015 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 5,421	$ —	$ —	$ 5,421
Certificates of deposit	696	—	—	696
Corporate debt securities	12,578	1	(8)	12,571
Municipal securities	1,908	—	—	1,908
U.S. Government securities	21,783	—	(14)	21,769
Commercial paper	6,145	—	—	6,145
	48,531	1	(22)	48,510
Less cash equivalents	9,419	—	—	9,419
Total marketable securities	$ 39,112	$ 1	$ (22)	$ 39,091

There were no realized gains or losses in six months ended June 30, 2016 and 2015, respectively. As of June 30, 2016, the weighted average maturity for the Company's available for sale securities was 3.2 months, with the longest maturity being June 2017.

The Company does not intend to sell the investments that are in an unrealized loss position, and it is unlikely that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. The following table provides the breakdown of the marketable securities with unrealized losses at June 30, 2016 (in thousands):

	In loss position for less than twelve months	
As of June 30, 2016 (in thousands):	Fair Value	Unrealized Loss
Corporate debt securities	$ 2,504	$ (1)
U.S. government securities	3,020	(1)
Total marketable securities	$ 5,524	$ (2)

The Company determined the fair value of the liability associated with its February 2015 warrants to purchase in aggregate 8.3 million shares of outstanding common stock using a Black-Scholes Model. See detailed discussion in Note 4 — Stockholders' Equity.

NOTE 7 — COMMITMENTS AND CONTINGENCIES

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

Years Ending December 31,	
2016	388
2017	260
Thereafter	—
Total	$ 648

Indemnification

The Company enters into indemnification provisions under its agreements with other companies in the ordinary course of business, including business partners, contractors and parties performing its clinical trials. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party as a result of the Company's activities. The duration of these indemnification agreements is generally perpetual. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of these agreements is minimal. The Company maintains commercial general liability insurance and products liability insurance to offset certain of its potential liabilities under these indemnification provisions. Accordingly, the Company has not recognized any liabilities relating to these agreements as of June 30, 2016.

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

NOTE 8 — ACCRUED SEVERANCE BENEFITS

In December 2015, the Company adopted a plan to reduce its operating expenses, following its decision to discontinue joint development of evofosfamide under its former collaboration with Merck KGaA. The plan included a reduction of approximately 40 full-time employees in both research and development and to a lesser extent general and administrative areas of the Company. As a result of the staffing reduction, the Company incurred expenses related to severance benefits of approximately $2.5 million during the quarter ended December 31, 2015, which included approximately $0.2 million of noncash stock compensation expense related to the extension of post-termination exercise period for the outstanding vested stock options for the affected employees. The payout of the accrued expenses related to severance benefits at December 31, 2015 was completed during the first quarter of 2016.

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the "Risk Factors" section of this Quarterly Report on Form 10-Q. Other than statements of historical fact, statements made in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of Section 21E of the Exchange Act, and Section 27A of the Act . When used in this report or elsewhere by management from time to time, the words "believe," "will," "may," "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 implementation of our business strategies, including our ability to pursue any development pathways and regulatory strategies for evofosfamide (formerly TH-302);
- our ability to advance the development of our product candidates, if at all;
- our plans to pursue discussions with regulatory authorities, and the anticipated timing, scope and outcome of related regulatory actions or guidance;
- our ability to establish and maintain potential new partnering or collaboration arrangements for the development and commercialization of evofosfamide and tarloxotinib bromide or tarloxotinib (formerly referred to as TH-4000, PR610 or Hypoxin™);
- our financial condition, including our ability to obtain the funding necessary to advance the development of our product candidates;
- the anticipated progress of our product candidate development programs, including whether our ongoing and potential future clinical trials will achieve clinically relevant results;
- our ability to generate data and conduct analyses to support the regulatory approval of our product candidates;
- our ability to establish and maintain intellectual property rights for our product candidates;
- whether any product candidates that we are able to commercialize are safer or more effective than other marketed products, treatments or therapies;
- our ability to discover and develop additional product candidates suitable for clinical testing;
- our ability to identify, in-license or otherwise acquire additional product candidates and development programs, and to obtain the additional funding that would be necessary in order to complete any such transaction;
- our anticipated research and development activities and projected expenditures;
- our ability to complete preclinical and clinical testing successfully for new product candidates, such as tarloxotinib, that we may develop or license;
- our ability to have manufactured active pharmaceutical ingredient, or API, and drug product that meet required release and stability specifications;
- our ability to have manufactured sufficient supplies of drug product for clinical testing and commercialization;
- our ability to obtain licenses to any necessary third-party intellectual property;
- our ability to retain and hire necessary employees and appropriately staff our development programs;
- the sufficiency of our cash resources; and
- our projected financial performance.

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" section in Part II, Item 1A of this quarterly report on Form 10-Q. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements reflect our view only as of the date of this report. You should read this report completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by our cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons that actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Overview

We are a clinical-stage biopharmaceutical company using our expertise in the tumor microenvironment to discover and develop therapeutic and diagnostic agents that selectively target tumor cells for the treatment of patients living with cancer. We are evaluating two therapeutic product candidates based on hypoxia-activated prodrug technology: evofosfamide and tarloxotinib. To date, evofosfamide has been studied in more than 1600 patients with cancer and has demonstrated anti-tumor activity as a monotherapy and in combination with other chemotherapeutics or targeted therapies across multiple types of solid tumors and in some hematological malignancies. The safety profile of evofosfamide has been consistent with manageable side-effects. In December 2015, we announced topline results from two pivotal Phase 3 clinical trials of evofosfamide: TH-CR-406 conducted by Threshold in patients with soft tissue sarcoma and MAESTRO conducted by Merck KGaA, Darmstadt, Germany, or Merck KGaA, in patients with advanced pancreatic cancer. Based on our analysis of the TH-CR-406 study and Merck KGaA's analysis of the MAESTRO study, we reported that neither trial met its primary endpoint of demonstrating a statistically significant improvement in overall survival. As a result, and following Merck KGaA's and our decision to discontinue joint development of evofosfamide under our former collaboration with Merck KGaA, in December 2015 we adopted a plan to reduce our operating expenses. The plan included a reduction of approximately 40 full-time employees in both research and development and general and administrative areas. In addition, we have discontinued enrollment in all company-sponsored clinical trials of evofosfamide as we conducted our own analyses of the data from the MAESTRO trial and evaluate potential next steps for the development of evofosfamide and tarloxotinib. While we continue to conduct limited activities with respect to evofosfamide and are continuing to conduct our two tarloxotinib Phase 2 proof-of-concept trials, our current strategy does not include the expenditure of material resources on the continued development of evofosfamide or tarloxotinib in future periods absent significant additional funding, whether through new collaborative or partnering arrangements or otherwise.

As a result of the staffing reduction, we incurred expenses related to severance benefits of approximately $2.5 million during the quarter ended December 31, 2015, which included approximately $0.2 million of noncash stock compensation expense related to the extension of post-termination exercise period for the outstanding vested stock options for the affected employees. The payout of the accrued expenses related to severance benefits was completed in the first quarter of 2016.

In January 2016, we announced that a sponsor-initiated interim futility analysis of the randomized, controlled Phase 2 trial (TH-CR-415) of evofosfamide ("the 415 trial") was conducted by an independent Data Safety Monitoring Board ("IDSMB"). IDSMB concluded that the trial was unlikely to reach its primary endpoint of improving overall survival with statistical significance. While evofosfamide plus pemetrexed demonstrated statistically significant improvement in progression-free survival (PFS) associated with a reduction in the risk of progression or death by approximately 30%, enrollment in the 415 trial was stopped. Three investigator-sponsored trials of evofosfamide continue to enroll patients. In January 2016 at the American Society of Clinical Oncology 2016 Gastrointestinal Cancers Symposium (ASCO GI), Merck KGaA's initial analyses of the results from the Phase 3 MAESTRO trial were presented. While the primary efficacy endpoint of overall survival did not meet statistical significance, efficacy endpoints of progression-free survival and confirmed overall response rates demonstrated significant improvements for patients treated with the combination of evofosfamide and gemcitabine (the "treatment arm") compared to gemcitabine plus placebo (the "control arm"). Since December 2015, we have conducted additional analyses of data from the MAESTRO trial in pancreatic cancer. In June 2016 at the Annual Meeting of the American Society of Clinical Oncology (ASCO), the updated analyses of the results from the Phase 3 MAESTRO trial were presented. Of particular note based on the data from the September 1, 2015 cut-off date for the MAESTRO trial, a meaningful improvement in overall survival was reported for a subgroup of 123 Asian patients (enrolled at Japanese and South Korean sites) in which the risk of death was reduced by 48 percent for patients on the treatment arm compared to patients on the control arm. The hazard ratio ("HR") for this subgroup was 0.52 (95% confidence interval (or "CI": 0.32 – 0.85). In particular and based upon Merck KGaA's MAESTRO data, the 116 patients from Japan from the treatment arm had a median overall survival of 13.6 months versus 9.1 months for those patients on the control arm with significant improvements in progression free survival, objective response rates, and reductions in the pancreatic cancer biomarker, CA19-9. No new safety findings were identified in the MAESTRO study and the safety profile was consistent with that previously reported in other studies of evofosfamide plus gemcitabine. In March 2016, we and Merck KGaA agreed to terminate our former collaboration with Merck KGaA, and all rights to evofosfamide were returned to us. On June 2, 2016, we received preliminary comments from the FDA relating to our request for a meeting indicating that our analysis of the data from the MAESTRO study, conducted under a Special Protocol Agreement with the FDA, and the data from the supporting randomized Phase 2 study, TH-CR-404 (N=214), would not provide adequate efficacy data to support the submission of a new drug application, or NDA, for evofosfamide for the treatment of patients with locally advanced unresectable or metastatic pancreatic adenocarcinoma previously untreated with chemotherapy. Accordingly, we would be required to successfully conduct one or more additional Phase 3 clinical trials before the FDA would accept any NDA for evofosfamide. We intend to discuss potential registration pathways with the Pharmaceuticals and Medical Devices Agency, or PMDA, in Japan based on the results seen in the Japanese sub-population. If these discussions do not lead to a registration pathway, our strategy would not include any further development of evofosfamide unless such development is part of a new collaborative or partnering arrangement or other strategic transaction and we are otherwise able to raise significant additional funding.

Our second product candidate, tarloxotinib, is a prodrug designed to selectively release a covalent (irreversible) EGFR tyrosine kinase inhibitor under hypoxic conditions. Aberrant EGFR signaling is implicated in the growth and spread of certain tumor types. Accordingly, tarloxotinib has the potential to effectively shut down aberrant EGFR signaling in a tumor-selective manner, thus potentially avoiding or reducing the systemic side effects associated with currently available EGFR tyrosine kinase inhibitors. Tarloxotinib is currently being evaluated in two Phase 2 proof-of-concept trials: one for the treatment of patients with mutant EGFR-positive, T790M-negative advanced non-small cell lung cancer progressing on an EGFR tyrosine kinase inhibitor, and the other for patients with recurrent or metastatic squamous cell carcinomas of the head and neck or skin. Threshold licensed exclusive worldwide rights to tarloxotinib from Auckland Uniservices Ltd in September 2014.

We were incorporated in October 2001. We have devoted substantially all of our resources to research and development of our product candidates. We have not generated any revenue from the commercial sales of our product candidates, and since inception we have funded our operations through the private placement and public offering of equity securities and through payments received under our former collaboration with Merck KGaA. As of June 30, 2016 and December 31, 2015, we had cash, cash equivalents and marketable securities of $33.6 million and $48.7 million, respectively. The Company continues to seek out new collaborative partners for evofosfamide as well as new in-licensing opportunities in parallel with continued funding for those opportunities.

Subject to our ability to obtain additional funding and to otherwise advance the development of our product candidates, we expect to devote substantial resources to research and development in future periods as we potentially start additional clinical trials on our own or with a potential future partner or collaborator. Research and development expenses are expected to decrease in 2016 compared to 2015 primarily as a result of Merck KGaA's and our decision to cease further joint development of evofosfamide and our decision to cease further enrollment in all Threshold-sponsored clinical trials of evofosfamide and, to a lesser extent, the impact of workforce reduction implemented in December 2015. However, we cannot currently predict whether and to what extent we may continue or increase product candidate development activities in future periods, if at all, and what our future cash needs may be for any such activities.

We believe that our cash, cash equivalents and marketable securities will be sufficient to fund our projected operating requirements for at least the next twelve months based upon current operating plans and spending assumptions. However, we will need to raise additional capital to advance the clinical development of evofosfamide and tarloxotinib, whether through new collaborative or partnering arrangements or otherwise, and to in-license or otherwise acquire and develop additional product candidates or programs. In particular, our ability to advance the clinical development of evofosfamide is dependent upon our ability to enter into new collaborative or partnering arrangements for evofosfamide, or to otherwise obtain sufficient additional funding for such development, particularly since we are no longer eligible to receive any further milestone payments or other funding from Merck KGaA, including the 70% of worldwide development costs for evofosfamide that were previously borne by Merck KGaA. If we are unable to secure additional funding on a timely basis or on terms favorable to us, we may be required to cease or reduce certain development projects, to conduct additional workforce reductions, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. Insufficient funds may require us to delay, scale back, or eliminate some or all of our activities, and if we are unable to obtain additional funding, there is uncertainty regarding our continued existence.

Results of Operations

Revenue. For each of the three and six months ended June 30, 2016, we recognized no revenue, compared to $3.7 million and $7.4 million in revenue for the three and six months ended June 30, 2015, respectively, from the amortization of the aggregate of $110 million in upfront and milestone payments earned in 2013 and 2012 from our former collaboration with Merck KGaA. We were amortizing them ratably over the estimated period of performance, which we originally estimated to end on March 31, 2020. Merck KGaA's and our decision to cease further joint development of evofosfamide in December 2015, resulted in the immediate recognition of all the remaining deferred revenue into revenue during the quarter ended December 31, 2015. Further, in March 2016, we and Merck KGaA agreed to terminate the collaboration pursuant to a termination agreement and under the terms of that termination agreement, all rights under the original collaboration agreement were returned to Threshold, as well as all rights to Merck KGaA technology developed under the original collaboration agreement. Also as a result of the termination of our former collaboration, we were no longer eligible to receive any further milestone payments from Merck KGaA.

Research and Development. Research and development expenses were $4.0 million for the three months ended June 30, 2016 compared to $10.1 million for the three months ended June 30, 2015, in each case net of the reimbursement for Merck KGaA's 70% share of total development expenses for evofosfamide. The $6.1 million decrease in expenses was due primarily to a $3.6 million decrease in employee related expenses (including a $0.9 million decrease in noncash stock-based compensation), a $2.0 million decrease in clinical development expenses net of the reimbursement for Merck KGaA's 70% share of total development expenses for evofosfamide, and a decrease of $0.5 million in consulting expenses. Research and development expenses were $10.0 million for the six months ended June 30, 2016 compared to $20.8 million for the six months ended June 30, 2015, in each case net of the reimbursement for Merck KGaA's 70% share of total development expenses for evofosfamide. The $10.8 million decrease in expenses was due primarily to a $6.7 million decrease in employee related expenses (including a $1.4 million decrease in noncash stock-based stock compensation expense), a $3.5 million decrease in clinical development expenses net of the reimbursement for Merck KGaA's 70% share of total development expenses for evofosfamide, and a decrease of $0.6 million in consulting expenses. The decrease in employee related expenses was primarily due to the reduction in workforce of 34 employees in clinical development and discovery research in December 2015. As a result of the termination of our former collaboration with Merck KGaA, we are no longer entitled to any reimbursement for evofosfamide development expenses apart from Merck KGaA's 70% reimbursement obligation for costs to wind down the discontinued trials andreturn the evofosfamide rights back to us.

During the three and six months ended June 30, 2016 and 2015, we were engaged in three primary research and development programs: the development of evofosfamide, which was the subject of two pivotal Phase 3 clinical trials and multiple Phase 2 and Phase 1 clinical trials; the clinical development of tarloxotinib, which is subject of two Phase 2 proof of concept trials; and our discovery research program aimed at identifying new drug candidates. Research and development expenses consist primarily of costs of conducting clinical trials, salaries and related costs for personnel including noncash stock-based compensation, costs of clinical materials, costs for research projects and preclinical studies, costs related to regulatory filings, and facility costs. Contracting and consulting expenses are a significant component of our research and development expenses as we rely on consultants and contractors in many of these areas. The following table summarizes our research and development expenses (net of reimbursement for Merck KGaA's 70% share of total development expenses in the case of evofosfamide) attributable to each of our programs for each period presented:

Research and Development Expenses by Project (in thousands):	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Evofosfamide	$ 2,914	$ 7,700	$ 7,192	$ 16,294
Tarloxotinib	1,018	1,078	2,351	1,908
Discovery Research	84	1,363	478	2,619
Total Research and Development Expenses	$ 4,016	$ 10,141	$ 10,021	$ 20,821

Research and development expenses associated with our internally discovered compound evofosfamide were $2.9 million and $7.2 million for the three and six months ended June 30, 2016, respectively, and $7.7 million and $16.3 million for the three and six months ended June 30, 2015, respectively, in each case net of the reimbursement for Merck KGaA's 70% share of total eligible collaboration expenses for evofosfamide. The decrease of $4.8 million and $9.1 million during the three and six months ended June 30, 2016, respectively, compared to the same period in 2015, was due to Merck KGaA's and our joint decision to cease further development in evofosfamide in December 2015 and the related discontinuation of enrollment in and closure of all company-sponsored evofosfamide trials.

Research and developments expenses associated with tarloxotinib, which we licensed rights to in September 2014, were $1.0 million and $2.4 million for the three and six months ended June 30, 2016, respectively, compared to $1.1 million and $1.9 million for the three and six months ended June 30, 2015, respectively. The increase of $0.4 million for the six months ended June 30, 2016, compared to the same period in 2015, was due to the continued enrollment of two Phase 2 proof-of-concept clinical trials of tarloxotinib beginning in the middle of 2015. Discovery research and development expenses were $0.1 million and $0.5 million for the three and six months ended June 30, 2016, respectively, compared to $1.4 million and $2.6 million for the three and six months ended June 30, 2015, respectively. With the reduction in workforce enacted in December of 2015 pursuant to which we eliminated our in-house discovery research activities, we expect a substantial decrease in our discovery research expense for 2016.

The largest component of our total operating expenses has historically been our ongoing investment in our research and development activities, primarily with respect to the development of evofosfamide. Subject to our ability to obtain additional funding and to otherwise advance the development of our product candidates, we expect to devote substantial resources to research and development in future periods as we potentially start new clinical trials on our own or with a potential future partner or collaborator. However, research and development expenses are expected to decrease in 2016 compared to 2015 due primarily to our and Merck KGaA's decision to cease further joint development of evofosfamide in December 2015 and our subsequent decision to cease enrollment in all Threshold-sponsored clinical trials of evofosfamide. In addition, the reduction in workforce implemented in December 2015 will also result in a decrease in employee-related expenses.

The process of conducting the clinical research necessary to obtain FDA and foreign regulatory approvals is costly, uncertain and time consuming. We consider the active management of our research and development programs to be critical to our long-term success. The actual probability of success for evofosfamide, tarloxotinib and potential future clinical product candidates may be impacted by a variety of factors, including, among others, the quality of the product candidate, early clinical data, investment in the program and the availability of adequate funding, competition, manufacturing capability and commercial viability. Furthermore, our strategy depends upon our ability to enter into potential new partnering or collaborative arrangements with third parties to assist in the development of our product candidates, including evofosfamide, or to otherwise obtain sufficient additional funding to permit such development. In the event we enter into partnering or collaborative arrangements for our product candidates, the preclinical development or clinical trial process for a product candidate and the estimated completion date may largely be under the control of that third party and not under our control. We cannot forecast with any degree of certainty which of our product candidates will be subject to future collaborations or how such arrangements would affect our development plans or capital requirements. In addition, the length of time required for clinical development of a particular product candidate and our development costs for that product candidate may be impacted by the scope and timing of enrollment in clinical trials for the product candidate, unanticipated additional clinical trials that may be required, future decisions to develop a product candidate for subsequent indications, and whether in the future we decide to pursue development of the product candidate with a collaborator or independently. For example, evofosfamide may have the potential to be approved for multiple indications, and we do not yet know how many of those indications we and a potential future collaborator will pursue. In this regard, the decision to pursue regulatory approval for subsequent indications will depend on several variables outside of our control, including the strength of the data generated in our prior and ongoing clinical studies and the willingness of potential collaborators to jointly fund such additional work. Furthermore, the scope and number of clinical studies required to obtain regulatory approval for each pursued indication is subject to the input of the applicable regulatory authorities, and we have not yet sought such input for all potential indications that we may elect to pursue, and even after having given such input applicable regulatory authorities may subsequently require additional clinical studies prior to granting regulatory approval based on new data generated by us or other companies, or for other reasons outside of our control. In addition, our development of tarloxotinib is at an early stage and it is possible that tarloxotinib may not be found to be safe or effective in our two ongoing Phase 2 proof-of- concept clinical trials or in any other studies that we may conduct, and we may otherwise fail to realize the anticipated benefits of our licensing of this product candidate.

We did not track research and development expenses by project prior to 2003, and therefore we cannot provide cumulative project expenses to date. The risks and uncertainties associated with our research and development projects are discussed more fully in the "Risk Factors" section in Part II, Item 1A of this quarterly report on Form 10-Q. As a result of the risks and uncertainties discussed in the "Risk Factors" section and above, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, anticipated completion dates or when and to what extent we will receive cash inflows from the commercialization and sale of a product candidate, including evofosfamide, if ever. In addition, we cannot predict whether and to what extent we may continue or increase product candidate development activities in future periods, if at all, and what our future cash needs may be for any such activities. To date, we have not commercialized any of our product candidates and in fact may never do so.

General and Administrative. General and administrative expenses were $1.9 million for the three months ended June 30, 2016 compared to $2.5 million for three months ended June 30, 2015. The $0.6 million decrease was due to a $0.5 million decrease in employee related expenses and a $0.1 million decrease in consulting expenses. General and administrative expenses were $4.1 million for the six months ended June 30, 2016 compared to $5.1 million for six months ended June 30, 2015. The $1.0 million decrease was due to a $0.8 million decrease in employee related expenses and a $0.2 million decrease in consulting expenses. We currently expect our general and administrative expenses to decrease in 2016 compared to 2015 due to the termination of the collaboration with Merck KGaA and to a lesser extent due to the reduction in workforce in December 2015.

Interest Income (Expense), Net. Interest income (expense), net for the three and six months ended June 30, 2016 was $40,000 and $72,000, respectively, compared to $39,000 and $72,000 of interest income for same period in 2015, respectively.

Other Income (Expense). Other income (expense) for the three and six months ended June 30, 2016 was noncash expense of $1.0 million and $0.6 million, respectively, compared to noncash income of $0.6 million and noncash expense of $1.0 million for the three and six months ended June 30, 2015, respectively. The noncash expense during the three and six months ended June 30, 2016 was due to a net increase in the fair value of the outstanding warrants as a result of an increase in the underlying price of the common stock during those periods. The noncash income during the three months ended June 30, 2015, was due to a net decrease in the fair value of the outstanding warrants as a result of a decrease in the underlying price of the common stock during that period. The noncash expense during the six months ended June 30, 2015, was due to a net increase in the fair value of the outstanding warrants as a result of an increase in the underlying price of the common stock during that period.

Liquidity and Capital Resources

We have not generated and do not expect to generate revenue from sales of product candidates in the near term. Since our inception we have funded our operations primarily through private placements and public offerings of equity securities and through payments received under our former collaboration with Merck KGaA. We have received $110 million in upfront and milestone payments from our former collaboration with Merck KGaA. We had cash, cash equivalents and marketable securities of $33.6 million and $48.7 million at June 30, 2016 and December 31, 2015, respectively, available to fund operations.

Net cash used in operating activities for the six months ended June 30, 2016 was $15.0 million compared to net cash used in operating activities of $19.7 million for the six months ended June 30, 2015. The decrease of $4.7 million in cash used in operations was due to a net decrease in payments of operating cash expenses, partially offset by a decrease in the 70% cash reimbursement of expenses related to our former collaboration with Merck KGaA.

Net cash provided by investing activities for the six months ended June 30, 2016 was $17.8 million compared with net cash used in investing activities of $6.6 million for the six months ended June 30, 2015. The $24.4 million increase in net cash provided by investing activities was due primarily to a decrease in purchases of marketable securities.

Net cash provided by financing activities for the six months ended June 30, 2016 and 2015 was $13,000 and $28.5 million, respectively. The $28.5 million decrease in cash provided by financing activities was primarily due to the $28.1 million net proceeds received from the completion of our underwritten public offering in February 2015 and to lesser extent a $0.4 million decrease in proceeds for the exercise of stock options and purchase rights under our equity plans.

We believe that our cash, cash equivalents and marketable securities will be sufficient to fund our projected operating requirements for at least the next 12 months based upon current operating plans and spending assumptions. However, we will need to raise additional capital to advance the clinical development of evofosfamide and tarloxotinib, whether through new collaborative or partnering arrangements or otherwise, and to in-license or otherwise acquire and develop additional product candidates or programs. In particular, our ability to advance the clinical development of evofosfamide is dependent upon our ability to enter into new collaborative or partnering arrangements for evofosfamide, or to otherwise obtain sufficient additional funding for such development, particularly since we are no longer eligible to receive any further milestone payments or other funding from Merck KGaA, including the 70% of worldwide development costs for evofosfamide that were previously borne by Merck KGaA.

While we have been able to fund our operations to date, we currently have no ongoing collaborations for the development and commercialization of our product candidates and no source of revenue, nor do we expect to generate revenue for the foreseeable future. We also do not have any commitments for future external funding. Until we can generate a sufficient amount of product revenue, which we may never do, we expect to finance future cash needs through a variety of sources, including:

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

Our ability to raise additional funds and the terms upon which we are able to raise such funds have been severely harmed by the negative results reported from our two pivotal Phase 3 clinical trials of evofosfamide, and may in the future be adversely impacted by the uncertainty regarding the prospects for future development ofevofosfamide and our ability to advance the development of evofosfamide and tarloxotinib or otherwise realize any return on our investments in evofosfamide and tarloxotinib, if at all. Our ability to raise additional funds and the terms upon which we are able to raise such funds may also be adversely affected by the uncertainties regarding our financial condition, the sufficiency of our capital resources, our ability to maintain the listing of our common stock on The NASDAQ Capital Market and recent and potential future management turnover. As a result of these and other factors, we cannot be certain that sufficient funds will be available to us or on satisfactory terms, if at allTo the extent we raise additional funds by issuing equity securities, our stockholders may experience significant dilution, particularly given our currently depressed stock price, and debt financing, if available, may involve restrictive covenants. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to our product candidates, technologies or potential markets, any of which could result in our stockholders having little or no continuing interest in our evofosfamide or tarloxotinib programs as stockholders or otherwise, or which could delay or require that we curtail or eliminate some or all of our development activities or otherwise have a material adverse effect on our business, financial condition and results of operations.

On January 21, 2016, we received a letter from the staff, or Staff, of theNASDAQ Stock Market, or NASDAQ, providing notification that, for the previous 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share requirement for continued listing on The NASDAQ Capital Market, or the Bid Price Requirement. The notification had no immediate effect on the listing of our common stock. In accordance with NASDAQ listing rules, we were afforded 180 calendar days, or until July 19, 2016, to regain compliance with the Bid Price Requireme nt. On July 20, 2016, we received a letter from the Staff notifying us that we were eligible for an additional 180 calendar day period, or until January 17, 2017, to regain compliance with the minimum $1.00 Bid Price Requirement. In the letter, the Staff noted that our common stock had not regained compliance with the Bid Price Requirement during the initial 180-day compliance period that ended onJuly 19, 2016 and that we had submitted written notice of our intention to cure the Bid Price Requirement deficiency by effecting a reverse stock split during the second 180-day compliance period, if necessary. If we cannot demonstrate compliance with the Bid Price Requirement by January 17, 2017, the Staff will notify us that our common stock will be delisted. In the event of such a notification, we may appeal the Staff's determination to delist our common stock, but there can be no assurance the Staff would grant our request for continued listing. In addition, we may be unable to meet other applicable NASDAQlisting requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock in which case, our common stock could be delisted notwithstanding our ability to demonstrate compliance with the Bid Price Requirement, whether through the implementation of a reverse stock split or otherwise. In this regard, on February 10, 2016, we received a letter from the Staff of NASDAQ providing notification that, for the previous 30 consecutive business days, the minimum market value of listed securities, or MLVS, for our common stock was below the $35 million minimum MVLS requirement for continued listing on The NASDAQ Capital Market, or the MVLS Requirement. Although as a result of our reporting stockholders' equity of $40.8 million for the year ended December 31, 2015, the Staff notified us that the deficiency related to our failure to meet MVLS Requirement is now closed, there can be no assurance that we will continue to meet other applicable NASDAQ listing requirements. If our common stock is delisted, this would, among other things, substantially impair our ability to raise additional funds to fund our operations, to advance the development of evofosfamide and tarloxotinib and/or to acquire or in-license additional product candidates or development programs , and could result in the loss of institutional investor interest and fewer development opportunities for us.

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

"At-the-Market" Sales Agreements

On November 2, 2015, we entered into a sales agreement, with Cowen and Company, LLC, or Cowen, or the Cowen Sales Agreement, which provides that, upon the terms and subject to the conditions and limitations set forth in the Cowen Sales Agreement, we may elect to issue and sell shares of our common stock having an aggregate offering price of up to $50.0 million from time to time through Cowen as our sales agent. Sales of our common stock through Cowen, if any, will be made on The NASDAQ Capital Market by means of ordinary brokers' transactions at market prices, in block transactions or as otherwise agreed by us and Cowen. Subject to the terms and conditions of the sales agreement, Cowen would use commercially reasonable efforts to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We are not obligated to make any sales of common stock under the Cowen Sales Agreement. We would pay Cowen an aggregate commission rate of up to 3.0% of the gross proceeds of the sales price per share of any common stock sold under the Cowen Sales Agreement. Although the Cowen Sales Agreement remains in effect, the Cowen Sales Agreement is not currently a practical source of liquidity for us. In this regard, given our currently-depressed stock price, we are significantly limited in our ability to sell shares of common stock through Cowen under the Cowen Sales Agreement since the issuance and sale of common stock under the Cowen Sales Agreement, if it occurs, would be effected under a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, and in accordance with the rules governing those registration statements, we generally can only sell shares of our common stock under that registration statement in an amount not to exceed one-third of our public float, which limitation for all practical purposes precludes our ability to obtain any meaningful funding through the Cowen Sales Agreement at this time. Even if our stock price and public float substantially increases, the number of shares we would be able to sell under the Cowen Sales Agreement would be limited in practice based on the trading volume of our common stock. In addition, we must maintain the effectiveness of our registration statement on Form S-3 to be filed with the Securities and Exchange Commission in order to sell any common stock under the Cowen Sales Agreement. We have not yet sold any common stock pursuant to the Cowen Sales Agreement.

Obligations and Commitments

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

During the six months ended June 30, 2016, there have been no significant changes in our payments due under contractual obligations and commitments, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, which we filed with Securities and Exchange Commission on March 10, 2016.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses based on historical experience and on various assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. For further information on our critical accounting policies, see the discussion of critical accounting policies in our Annual Report on Form 10-K for the year ended December 31, 2015, which we filed with the SEC on March 10, 2016.

Recent Accounting Pronouncements Not Yet Adopted

In May 2014, the Financial Accounting Standards Board ("FASB") issued an accounting standard update regarding revenue from customer contracts to transfer goods and services or non-financial assets unless the contracts are covered by other standards (for example, insurance or lease contracts). Under the new guidance, an entity should recognize revenue in connection with the transfer of promised goods or services to customers in an amount that reflects the consideration that the entity expects to be entitled to receive in exchange for those goods or services. In addition, the new standard requires that reporting companies disclose the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. In August 2015, the FASB deferred the effective date of the update by one year, with early adoption on the original effective date permitted. The updates are effective for us beginning in the first quarter of the fiscal year 2018. The new revenue standard may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized as of the date of adoption. We are currently evaluating the impact of this accounting standard update on our consolidated financial statements.

In August 2014, the FASB issued an accounting standard update that is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. It requires management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments: (1) provide a definition of the term substantial doubt; (2) require an evaluation every reporting period including interim periods; (3) provide principles for considering the mitigating effect of management's plans; (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans; (5) require an express statement and other disclosures when substantial doubt is not alleviated; and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). This guidance will be effective for us beginning with our annual report for fiscal 2016 and interim periods thereafter. We are currently evaluating the impact the standard will have on our financial statements.

In November 2015, the FASB issued an accounting standard update for the presentation of deferred income taxes. Under this new guidance, deferred tax liabilities and assets should be classified as noncurrent in a classified balance sheet. The update is effective for us beginning in the first quarter of fiscal year 2018 with early adoption permitted as of the beginning of an interim or annual reporting period. Additionally, this guidance may be applied either prospectively or retrospectively to all periods presented. We are currently evaluating the impact the standard will have on our financial statements.

In February 2016, the FASB issued an accounting standard update, which requires the recognition of lease assets and lease liabilities arising from operating leases in the statement of financial position. We will adopt the standard effective the first quarter of 2019 and do not anticipate that this new accounting guidance will have a material impact on our consolidated statement of operations.

In March 2016, the FASB issued an accounting standard update, which simplifies several aspects of the accounting for share-based payments, including immediate recognition of all excess tax benefits and deficiencies in the income statement, changing the threshold to qualify for equity classification up to the employees' maximum statutory tax rates, allowing an entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures as they occur, and clarifying the classification on the statement of cash flows for the excess tax benefit and employee taxes paid when an employer withholds shares for tax-withholding purposes. We are evaluating the full effect this accounting update may have on our consolidated financial statements and will adopt the standard effective the first quarter of 2017.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by applicable Securities and Exchange Commission regulations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the six months ended June 30, 2016, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A "Quantitative and Qualitative Disclosures About Market Risk" in our annual report on Form 10-K for the year ended December 31, 2015.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

We have carried out an evaluation under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on their evaluation as of June 30, 2016, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal controls over financial reporting.

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2016 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 principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Threshold Pharmaceuticals, Inc. have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control.

The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and we cannot be certain that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation, that our disclosure controls and procedures were effective as of June 30, 2016 to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should refer to the other information contained in this quarterly report on Form 10-Q, including our condensed consolidated financial statements and related notes.

Risks Related to Drug Discovery, Development and Commercialization

We currently lack the ability to discover additional prodrug product candidates and we also may not be able to successfully acquire or in-license and develop additional prodrug product candidates or programs suitable for clinical testing, either of which could limit our growth and revenue potential.

While we remain focused on the design and development of novel cyotoxic prodrug compounds for the treatment of cancer, evofosfamide and tarloxotinib are currently our only product candidates in the clinical development stage and we may be unable to develop additional product candidates suitable for clinical testing. In this regard, as part of our workforce reduction in December 2015 that followed the reported negative results from the two Phase 3 clinical trials of evofosfamide, we eliminated our discovery research activities conducted in-house, which prevents our ability to discover additional prodrug product candidates at this time. In addition, given the uncertain prospects for evofosfamide and tarloxotinib, our strategy includes evaluating opportunities to acquire or in-license additional product candidates or development programs that build on our expertise and complement our pipeline. Any growth through acquisition or in-licensing will depend upon the availability of suitable product candidates at favorable prices and upon advantageous terms and conditions. Even if appropriate acquisition or in-licensing opportunities are available, we currently do not have, and may not in the future have, the financial resources necessary to pursue them. In addition, other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for acquisition or in-licensing opportunities. In addition, we may not be able to realize the anticipated benefits of any acquisition or in-licensing opportunity for a variety of reasons, including the possibility that a product candidate proves not to be safe or effective in later clinical trials or the integration of an acquired or licensed product candidate gives rise to unforeseen difficulties and expenditures. For example, in September 2014, we licensed rights to tarloxotinib, a clinical-stage investigational compound that we are evaluating in two Phase 2 proof-of-concept clinical trials, one in a population of patients with non-small cell lung cancer and one in a population in patients with squamous cell carcinoma of the head and neck or skin. However, our evaluation of tarloxotinib is at an early stage and it is possible that tarloxotinib may not be found to be safe or effective in our ongoing Phase 2 proof-of-concept clinical trials or in any other studies that we may conduct, and we may otherwise fail to realize the anticipated benefits of our licensing of this product candidate. In this regard, tarloxotinib was previously being developed in a different patient population than the populations we are targeting and a prior clinical trial evaluating tarloxotinib in that different patient population was terminated prematurely due to unacceptable toxicity. While we are evaluating tarloxotinib in patient populations that we believe may be responsive to tarloxotinib at doses lower than was targeted in the terminated clinical trial, we cannot assure you that we will be able to determine an appropriate dose that is both safe and effective for the patient populations we are targeting. In any event, any growth through development of additional product candidates will depend principally on our ability to identify, and then to obtain the necessary funding to pursue the acquisition of in-licensing of, additional product candidates on commercially reasonable terms, as well as our ability to develop those product candidates and our ability to obtain additional funding, whether through partnering arrangements or otherwise, to complete the development of, obtain regulatory approval for and commercialize these product candidates. If we are unable to discover or obtain suitable product candidates for development, our growth and revenue potential could be significantly harmed, and we could be required to cease operations.

We remain substantially dependent upon the success of evofosfamide. If we are unable to successfully develop and obtain regulatory approval for evofosfamide, our business and future prospects will be severely harmed.

We have focused our development activities on evofosfamide, and substantially all of our efforts and expenditures continue to be devoted to evofosfamide. Accordingly, our future prospects are substantially dependent on the successful development, regulatory approval and commercialization of evofosfamide. On June 2, 2016, we received preliminary comments from the FDA relating to our request for a meeting indicating that our analysis of the data from the MAESTRO study, conducted under a Special Protocol Agreement with the FDA, and the data from the supporting randomized Phase 2 study, TH-CR-404 (N=214),would not provide adequate efficacy data to support the submission of a new drug application, or NDA, for evofosfamide for the treatment of patients with locally advanced unresectable or metastatic pancreatic adenocarcinoma previously untreated with chemotherapy. Accordingly, we would be required to successfully conduct one or more additional Phase 3 clinical trials before the FDA would accept any NDA for evofosfamide. This has significantly harmed our future prospects. Different regulatory agencies may reach different decisions in assessing the approval evofosfamide. We have conducted additional analyses of the data from MAESTRO trial and intend to review and discuss the results of our analyseswith the Pharmaceuticals and Medical Devices Agency, or PMDA, in Japan, to determine potential registration pathways. Evofosfamide and the activities associated with its development and commercialization, including testing, manufacture, safety, efficacy, recordkeeping, labeling, and storage, are subject to approval and continuing regulation by the PMDA. Securing regulatory approval requires the submission of extensive preclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the regulatory agencies for each therapeutic indication to establish evofosfamide's safety and efficacy. Historically, Japan has required that pivotal clinical data submitted in support of a new drug application be performed on a significant population of Japanese patients. The PMDA may accept U.S. or E.U. patient data when submitted along with a bridging study, but only if it demonstrates that Japanese and non-Japanese subjects react comparably to the product. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Changes in the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of evofosfamide. The PMDA and other foreign regulatory agencies have substantial discretion in the approval process and may refuse to accept any application or may decide that the data from the MAESTRO trial are insufficient to support the approval of any marketing authorization and that one or more additional clinical trials of evofosfamide would be required to be successfully conducted by us in order to support any such approval, including with respect to any patient subgroups that we may identify that we believe may potentially benefit from treatment with evofosfamide and gemcitabine. If we are required to successfully conduct and complete any additional clinical trials of evofosfamide in order to support potential approval ofevofosfamide, we would be required to obtain additional capital and there can be no assurances that we would be successful in obtaining the additional funding, whether through new partnering or collaboration arrangements or otherwise, necessary to support any additional clinical development of evofosfamide. Any regulatory approval we ultimately obtain may be limited in scope or subject to restrictions or post-approval commitments that render the product not commercially viable. If any regulatory approval that we obtain is delayed or is limited, we may decide not to commercialize the product candidate after receiving the approval. In addition, in March 2016, we and Merck KGaA agreed to terminate our collaboration and, as a result, we will not any receive any clinical development milestones or any other funding from Merck KGaA for the purpose of conducting any further clinical development of evofosfamide. Under our former collaboration with Merck KGaA, Merck KGaA was responsible for 70% of the worldwide development expenses for evofosfamide. If we are unable to obtain sufficient additional finding for the further development of evofosfamide, whether through new partnering or collaborative arrangements or otherwise, we may be required to cease further development of our evofosfamide program. Also, issues with the successful and timely transfer of evofosfamide development activities from Merck KGaA could significantly impact our ability to pursue registration with regulatory authorities and potential partners, and there can be no assurance that such development activities will be successfully transferred to us in a timely manner or at all. For these and other reasons, we cannot assure you that we will be able to advance the development of evofosfamide. In such event, we may be required to abandon the development of evofosfamide and forego any return on our investment from ourevofosfamide program, which would severely harm our future prospects and may cause us to cease operations.

Even if we are able to advance the development of evofosfamide, the failure of evofosfamide in the future to achieve successful clinical trial endpoints, delays in clinical trial enrollment or events or in the clinical development of evofosfamide, unanticipated adverse side effects related to evofosfamide or any other unfavorable developments or information related to evofosfamide would further significantly harm our business and our future prospects. For example, in January 2016, we announced that an IDSMB concluded that our registrational Phase 2 clinical trial of evofosfamide plus pemetrexed versus pemetrexed alone in patients with non-squamous non-small cell lung cancer was unlikely to reach its primary endpoint of improving overall survival with statistical significance and, as a result, enrollment in this trial was closed and in connection therewith, we determined to cease enrollment in all Threshold-sponsored trials of evofosfamide. Moreover, evofosfamide is not expected to be commercially available in the near term, if at all. Further, the commercial success of evofosfamide, if any, will depend upon its acceptance by physicians, patients, third party payors and other key decision-makers as a therapeutic and cost effective alternative to currently available products. In any event, if we are unable to successfully develop, obtain regulatory approval for and commercialize evofosfamide, our ability to generate revenue from product sales will be significantly delayed or precluded altogether and our business would be materially and adversely affected, and we may not be able to continue as a going concern.

If we do not establish collaborations for our product candidates or otherwise raise substantial additional capital, we will likely need to alter, delay or abandon our development and any commercialization plans.

Our strategy includes selectively partnering or collaborating with other pharmaceutical and biotechnology companies to assist us in furthering the development and potential commercialization of our product candidates. In this regard, as a result of the termination of our collaboration with Merck KGaA, we are no longer eligible to receive any further milestone payments or other funding from Merck KGaA, including the 70% of worldwide development costs for evofosfamide that were previously borne by Merck KGaA. Since we are now solely responsible for the further development and commercialization ofevofosfamide at our own cost, we areevaluating potential partnering opportunities for evofosfamide, and in this regard, we are currently seeking a pharmaceutical partner for evofosfamide with a commercial presence in oncology in Japan. In this regard, our ability to advance the clinical development of evofosfamide is dependent upon our ability to enter into new collaborative or partnering arrangements for evofosfamide, or to otherwise obtain sufficient additional funding for such development. We face significant competition in seeking appropriate collaborators, and collaborations are complex and time consuming to negotiate and document. We may not be successful in entering into new collaborations with third parties on acceptable terms, or at all. In addition, we are unable to predict when, if ever, we will enter into any additional collaborative arrangements because of the numerous risks and uncertainties associated with establishing such arrangements. If we are unable to negotiate new collaborations, we may have to curtail the development of a particular product candidate, reduce, delay, or terminate its development or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. For example, we may have to cease further development of our evofosfamide program if we are unable to raise sufficient funding for any additional clinical development of evofosfamide through new partnering or collaborative arrangements with third parties or other financing alternatives. In this regard, if we decide to undertake any further development of our product candidates beyond our ongoing clinical trials and preclinical development, we would need to obtain additional funding for such development, either through financing or by entering into collaborative arrangements or partnerships with third parties for any such further development and we may be unable to do. In addition, we may not be able to dedicate further resources to tarloxotinib after the conclusion of our ongoing Phase 2 proof-of-concept clinical trials of tarloxotinib and while we are currently determining third party interest in partnering or acquiring this asset and other preclinical oncology compounds, we may be unable to partner or divest these assets in a timely manner, or at all, and therefore may not receive any return on our investment in these assets. Likewise, any meaningful preclinical development, beyond identifying other potential lead clinical compounds from our preclinical oncology program, will require us to obtain additional funding, and our ability to meaningfully advance development of other oncology compounds is subject to our ability to obtain additional funding. If we do not have sufficient funds, we will not be able to advance the development of our product candidates or otherwise bring our product candidates to market and generate product revenues.

Any collaborative arrangements that we establish in the future may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. In addition, any future collaborative arrangements may place the development and commercialization of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us

We have in the past established and intend to continue to establish collaborations with third parties to develop and commercialize our product candidates, and these collaborations may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. For example, in March 2016, we and Merck KGaA, mutually agreed to terminate our collaboration for the development and commercialization of our evofosfamide product candidate, and, as a result, we will not receive any additional milestone payments or other funding from Merck KGaA on account of our collaboration with Merck KGaA. As of the date of this report, we have no ongoing collaborations for the development and commercialization of our product candidates. We may not be able to locate third-party collaborators to develop and market our product candidates, and we lack the capital and resources necessary to develop our product candidates alone.

Dependence on collaborative arrangements subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our potential collaborators may devote to our product candidates;
- potential collaborations may experience financial difficulties or changes in business focus;
- we may be required to relinquish important rights such as marketing and distribution rights;
- should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for the compound or product candidate;
- 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;

- under certain circumstances, a collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which could delay the development and may increase the cost of developing our product candidates.

Preclinical studies and Phase 1 or 2 clinical trials of our product candidates may not predict the results of subsequent human clinical trials.

Preclinical studies, including studies of our product candidates in animal models of disease, may not accurately predict the results of human clinical trials of those product candidates. In particular, promising animal studies suggesting the efficacy of evofosfamide for the treatment of different types of cancer may not accurately predict the ability of evofosfamide to treat cancer effectively in humans. Likewise, preclinical and Phase 1 clinical data that suggest that plasma concentrations of tarloxotinib that are active in tumor xenograft models in mice could be attained in patients may not accurately predict whether a safe and effective dose can be attained in humans. Similarly, while tarloxotinib has demonstrated, in preclinical studies, an ability to overcome non-T790M mediated resistance to conventional EGFR tyrosine kinase inhibitors and in preclinical studies hypoxia has been shown to increase EGFR signaling, these preclinical studies may not accurately predict the results of our ongoing Phase 2 proof-of-concept clinical trials of tarloxotinib in patients with EGFR-positive, T790M-negative non-small cell lung cancer and in patients with recurrent or metastatic squamous cell carcinoma of the head and neck or skin. Evofosfamide, tarloxotinib or any other compounds we may develop may be found not to be efficacious in treating cancer, alone or in combination with other agents, when studied in human clinical trials. In addition, we will not be able to commercialize our product candidates until we obtain FDA approval in the United States or approval by comparable regulatory agencies in Japan, Europe and other countries. A number of companies in the pharmaceutical industry, including us and those with greater resources and experience than us, have suffered significant setbacks in Phase 3 clinical trials, even after encouraging results in earlier clinical trials.

To satisfy FDA, PMDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in early clinical trials, including in Phase 2 clinical trials, does not ensure that later clinical trials will be successful. Initial results from Phase 1 and Phase 2 clinical trials of evofosfamide have in the past not been, and may again in the future not be, confirmed by later analysis or in subsequent larger clinical trials. For example, the results that achieved the primary endpoint for progression-free survival in the Phase 2b trial of evofosfamide in pancreatic cancer did not predict the results of overall survival for patients in the MAESTRO trial. Likewise, the results in the Phase 1/2 trial of evofosfamide in patients with soft tissue sarcoma did not predict the results of overall survival for patients in the 406 trial. In both cases, the 406 trial and the MAESTRO trial failed to meet their primary endpoints of demonstrating a statistically significant improvement in overall survival, based on our analyses for the 406 trial and Merck KGaA's analyses for the MAESTRO trial, notwithstanding positive results in earlier clinical trials. In addition, in January 2016, we announced that an IDSMB concluded that our registrational Phase 2 clinical trial of evofosfamide plus pemetrexed versus pemetrexed alone in patients with non-squamous non-small cell lung cancer was unlikely to reach its primary endpoint of improving overall survival with statistical significance and, as a result, enrollment in this trial was closed and in connection therewith, we determined to cease enrollment in all Threshold-sponsored trials of evofosfamide. As these examples illustrate, despite the results reported in earlier clinical trials for evofosfamide, we do not know whether potential future clinical trials that we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market evofosfamide. Our failure to successfully complete any potential future clinical trials and obtain regulatory approval for evofosfamide would materially and adversely affect our business and severely harm our future prospects.

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

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

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

- delays in obtaining regulatory approval to commence new trials;
- changes to clinical trial protocols.

Delays in clinical trials can also result from difficulties in enrolling patients in our clinical trials, which could increase the costs or affect the timing or outcome of these clinical trials. This is particularly true with respect to diseases with relatively small patient populations. Timely completion of clinical trials depends, in addition to the factors outlined above, on our ability to enroll a sufficient number of patients, which itself is a function of many factors, including:

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

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

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

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

We cannot be certain of our successfully completing clinical testing within the time frames we have planned or anticipated, 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, such as the results in the 406 trial and the MAESTRO trial, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing or to abandon programs;
- the results obtained in earlier stage clinical testing may not be indicative of results in future clinical trials;
- clinical trial results may not meet the level of statistical significance required by the FDA, the PMDA or other regulatory agencies;
- enrollment in clinical trials for our product candidates may be slower than we anticipate, resulting in significant delays and additional expense;
- we or regulators may suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks; and
- the effects of our product candidates on patients may not be the desired effects or may include undesirable side effects or other characteristics that may delay or preclude regulatory approval or limit their commercial use, if approved.

In addition, clinical results are susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse safety events, including patient fatalities that may be attributable to our product candidates, during a clinical trial could cause the trial to be terminated or require additional studies. Furthermore, any of our future clinical trials may be overseen by IDMCs or Data and Safety Monitoring Boards, or DSMBs. These independent oversight bodies are comprised of external experts who review the progress of the ongoing clinical trials as well as safety from other trials, and make recommendations concerning a trial's continuation, modification, or termination based on periodic review of, unblinded data. Any of our potential future clinical trials overseen by an IDMC or DSMB may be discontinued or amended in response to recommendations made by responsible IDMCs or DSMBs based on their review of trial results and an IDMC or DSMB may determine to delay or suspend the trial due to safety or futility findings based on events occurring during a clinical trial. For example, in January 2016, we announced that an IDSMB concluded that our registrational Phase 2 clinical trial of evofosfamide plus pemetrexed versus pemetrexed alone in patients with non-squamous non-small cell lung cancer was unlikely to reach its primary endpoint of improving overall survival with statistical significance and, as a result, enrollment in this trial was closed and in connection therewith, we determined to cease enrollment in all Threshold-sponsored trials of evofosfamide. The recommended termination or modification of any of our potential future clinical trials by an IDMC or DSMB, could materially and adversely impact the future development of our product candidates, and our business, prospects, operating results, and financial condition may be materially harmed.

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, the PMDA and other regulatory agencies in the United States and Japan and by comparable authorities in Europe and elsewhere. We require the approval of the relevant regulatory authorities before we may commence commercial sales of our product candidates in a given market. The regulatory approval process is expensive and time consuming, and the timing of receipt of regulatory approval is difficult to predict. Our product candidates could require a significantly longer time to gain regulatory approval than expected, or may never gain approval. We cannot be certain that, even after expending substantial time and financial resources, we will obtain regulatory approval for any of our product candidates. This was the case with the FDA, which would not accept an NDA based on the data from the MAESTRO study. A delay or denial of regulatory approval could delay or prevent our ability to generate product revenues and to achieve profitability.

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

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

Our product candidates are designed to target the microenvironment of solid tumors and some hematological malignancies by, in the case of evofosfamide, harnessing hypoxia for selective toxin activation. We have not, nor to our knowledge has any other company, received regulatory approval for a drug based on this approach. We cannot be certain that our approach will lead to the development of approvable or marketable drugs. Our approach may lead to unintended, or off-target, adverse effects or may lack efficacy or contribution to efficacy in combination with other anti-cancer drugs.

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

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

Anti-tumor drugs being developed by us are expected to have undesirable side effects. For example, in clinical trials of evofosfamide, some patients have exhibited skin and/or mucosal toxicities that have in some cases caused patients to stop or delay therapy. Likewise in our ongoing clinical trials of tarloxotinib, some patients have exhibited drug induced QT interval prolongation or the lengthening of time in the heart's electrical cycle that can potentially lead to life-threatening cardiac arrhythmias, that in some cases caused patients to stop or delay therapy. The extent, severity and clinical significance of these or other undesirable side effects may not be apparent initially and may be discovered or become more significant during drug development or even post-approval. These expected side effects or other side effects identified in the course of clinical trials or that may otherwise be associated with our product candidates may outweigh the benefits of our product candidates. Side effects may prevent or delay regulatory approval or limit market acceptance if our products are approved. In this regard, our product candidates may prove to have undesirable or unintended side effects or other characteristics adversely affecting their safety, efficacy or cost effectiveness that could prevent or limit their approval for marketing and successful commercial use, or that could delay or prevent the commencement and/or completion of clinical trials for our product candidates.

We have not yet gained sufficient experience with a commercial formulation of evofosfamide.

The formulation of evofosfamide that was the subject of our clinical trials was changed to address issues with a prior formulation that was subject to storage and handling requirements that were not suitable for a commercial product. The current formulation of evofosfamide may be suitable for a commercial product, but additional data will be required to verify this and there can be no assurance that we will be able to do so in a timely manner, if at all. If we are not able to develop a viable commercial formulation of evofosfamide, then we may be required to conduct additional Phase 3 clinical trials of evofosfamide, or we may need to develop an alternative commercial formulation, either of which could delay, perhaps substantially, our ability to obtain any regulatory approvals of evofosfamide.

The initial clinical formulations developed for tarloxotinib and our potential future product candidates may not remain stable throughout the clinical testing phase.

We have limited experience and data on the drug substance synthesis and the initial formulation for tarloxotinib. This initial formulation and those of our potential future product candidates may not remain stable during the clinical testing phase. If these formulations were found to be unstable during clinical testing, we may be required to repeat the initial clinical trials which could increase our costs and delay the development of the applicable product candidate. We may be required to reformulate these product candidates, including tarloxotinib, to improve stability. However, it is possible that we might not be able to develop a formulation of tarloxotinib or other future product candidates with adequate quality that meets the need for testing in our clinical trials. We may also be required to perform additional clinical bridging studies which may further delay development. We may also be unable to scale up the manufacturing process to synthesize the current drug substance and current formulations, or the newly developed formulations, any of which could adversely affect our ability to advance the development of, and potentially obtain regulatory approval of, the applicable product candidate.

Even though we have received orphan drug designation for evofosfamide, we may not receive orphan drug marketing exclusivity for evofosfamide. Even if we obtain orphan drug exclusivity, orphan drug exclusivity would afford 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 have received orphan drug designation for evofosfamide for the treatment of pancreatic cancer in the United States and the European Union or EU. Under the Orphan Drug Act in the United States, 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. In the EU, orphan drug designation is provided for a drug that is intended to diagnose, prevent or treat a life-threatening or chronically debilitating condition which affects no more than 5 in 10,000 individuals in the EU (approximately 245,000 individuals) and for which no satisfactory method of diagnosis, prevention or treatment of the condition already exists, or if such method does exist, that the orphan product must be of significant benefit to the patient population over existing products. 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 in the U.S. and 10 years for the EU. The orphan drug designation also allows a waiver or reduction in select regulatory fees. 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.

Even if we obtain orphan drug exclusivity for evofosfamide, orphan drug exclusivity may not prevent other market entrants. A different drug, or, under limited circumstances, the same drug may be approved by the FDA for the same orphan indication. The limited circumstances include an inability to supply the drug in sufficient quantities or where a new formulation of the drug has shown superior safety or efficacy. As a result, if evofosfamide were approved for pancreatic cancer, other drugs could still be approved for use in treating the same indications covered by evofosfamide, 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. Although we have obtained orphan drug designation, if a competitor obtains regulatory approval for evofosfamide for the same indication we are targeting before we do, we would be blocked from obtaining approval for that indication for seven years, unless our product is a new formulation of the drug that has shown superior safety or efficacy, or the competitor is unable to supply sufficient quantities.

The "fast track" designation for development of any of our product candidates may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood the product candidate will receive regulatory approval.

If a product candidate is intended for the treatment of a serious or life-threatening condition and the product candidate 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 product candidates in the fast track process may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such review. Merck KGaA, has obtained fast track designation for the development of evofosfamide, administered in combination with gemcitabine, for the treatment of previously untreated patients with metastatic or locally advanced unresectable pancreatic cancer, receipt of fast track designation does not ensure a faster development process, review or FDA approval. In addition, the FDA may withdraw our fast track designation at any time. If we lose fast track designation for evofosfamide, the approval process may be delayed. In addition, fast track designation does not guarantee that we will be able to take advantage of the expedited review procedures and does not increase the likelihood that evofosfamide will receive any regulatory approvals.

Failure to successfully develop and obtain regulatory approval for companion diagnostics could harm our drug development and commercialization strategy.

In March 2013, we announced the acquisition of [18F]-HX4 [flortanidazole (18F)] from Siemens Healthcare. [18F]-HX4 is an investigational radiolabeled hypoxia Positron Emission Tomography tracer developed by Siemens Healthcare Molecular Imaging to potentially identify and quantify the degree of hypoxia in tumors *in vivo*. [18F]-HX4 could potentially be used as a companion diagnostic to hypoxia-targeted therapeutics based on our drug discovery platform. A companion diagnostic is a test or measurement intended to assist physicians in making treatment decisions for their patients. Subject to the receipt of additional funding, we initially intend to develop [18F]-HX4 to determine a patient's tumor hypoxia profile, which may identify patients who will best respond to our hypoxia targeted therapeutics. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval prior to commercialization. We may encounter difficulties in developing and obtaining approval for [18F]-HX4, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation, and we may have difficulties gaining market acceptance of the use of [18F]-HX4 in the clinical or medical community. Because [18F]-HX4 is at an early stage of development, we have yet to seek a meeting with the FDA, the PMDA or any other regulatory authorities to discuss our potential [18F]-HX4 companion diagnostic development plans, and therefore cannot yet know what these regulatory authorities will require in order to obtain regulatory approval of [18F]-HX4. In any event, we may not be able to develop or obtain any regulatory approval or clearance for [18F]-HX4, and we may therefore not realize any return on our investment in [18F]-HX4.

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

Following initial regulatory approval of any drugs we may develop, we will be subject to continuing regulatory review, including review of adverse drug experiences and clinical results that are reported after our drug products become commercially available. This would include results from any post-marketing tests or vigilance required as a condition of approval. The manufacturer and manufacturing facilities used to make any of our drug candidates will also be subject to periodic review and inspection by regulatory agencies, including the PMDA. If a previously unknown problem or problems with a product or a manufacturing and laboratory facility used by us is discovered, regulatory agencies, including the PMDA 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 regulatory agencies, including PMDA approval before the product, as modified, can be marketed. Manufacturers of our products, if approved, will be subject to ongoing regulatory agency requirements, including the PMDA's, for submission of safety and other post- market information. If such manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:

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

Regulatory authorities, including the PMDA, may impose significant restrictions on the indicated uses and marketing of pharmaceutical products.

Even if we obtain regulatory approval for evofosfamide, we would be subject to ongoing requirements by the regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of any product will continue to be closely monitored by regulatory authorities after approval. If the regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the label ultimately approved for evofosfamide, if it achieves marketing approval, may include restrictions on use. Advertising and promotion of any product candidate that obtains approval will be heavily scrutinized by government agencies and the public. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by regulatory authorities. Engaging in impermissible promotion of any approved products for off-label uses could also subject us to false claims litigation under federal and state statutes, which could lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which we promote or distribute any approved products.

If we do not lawfully promote any approved products, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could compromise our ability to become profitable.

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

We have no sales experience, as a company. There are risks involved with establishing our own sales and marketing capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force and function will require substantial expenditures and will be time-consuming, and we may not be able to effectively recruit, train or retain sales personnel. On the other hand, if we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues will be lower than if we market and sell any products that we develop ourselves. We may not be able to effectively sell our product candidates, if approved, which could materially harm our business and our financial condition.

Risks Related to Our Financial Performance and Operations

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

Due to the recognition of the remaining $65.9 million of deferred revenue from our former collaboration with Merck KGaA during the quarter ended December 31, 2015, we reported net income of $43.8 million for the year ended December 31, 2015. However, during the six months ended June 30, 2016 we had a net loss of $0.0 million and we have incurred losses in each of our other years since our inception in 2001, and we expect to incur losses for the foreseeable future. We have devoted and, subject to our ability to obtain additional funding and to otherwise advance the development of our product candidates, we expect to continue to devote, substantially all of our resources to development of our product candidates, principally evofosfamide. Accordingly, our future prospects remain substantially dependent on the successful development, regulatory approval and commercialization of evofosfamide. In this regard, a substantial portion of our efforts have been devoted to the two pivotal Phase 3 clinical trials of evofosfamide. The failure of the 406 trial and the MAESTRO trial to meet their primary endpoints of demonstrating a statistically significant improvement in overall survival as agreed upon with the FDA, based on our analyses for the 406 trial and Merck KGaA's analyses for the MAESTRO trial, has significantly depressed our stock price and harmed our future prospects. Although we have conducted our own analyses of the data from MAESTRO trial andintend to review and discuss the results of our analyseswith the PMDA in Japan, to determine whether there is an appropriate path forward for submitting marketing authorization applications based on the data from the MAESTRO trial, the PMDA and other health regulatory authorities may determine that the data from the MAESTRO trial are insufficient to support the approval of any marketing authorizations and that one or more additional clinical trials of evofosfamide would be required to be successfully conducted by us in order to support any such approval, including with respect to any patient subgroups that we may identify that we believe may potentially benefit from treatment with evofosfamide and gemcitabine, as the FDA did. If we are required to successfully conduct and complete any additional clinical trials of evofosfamide in order to support potential approval ofevofosfamide in Japan, we would be required to obtain additional capital and there can be no assurances that we would be successful in obtaining the additional funding, whether through new partnering or collaboration arrangements or otherwise, necessary to support any additional clinical development of evofosfamide. Moreover, we cannot currently predict whether and to what extent we may continue or increase evofosfamide development activities in future periods, if at all, and what our future cash needs may be for any such activities. For these and other reasons, we cannot assure you that we will be able to advance the development of evofosfamide. In such event, we may be required to abandon the development ofevofosfamide and forego any return on our investment from our evofosfamide program, which would severely harm our future prospects and may cause us to cease operations. In any event,we do not expect to generate any revenue from the commercial sales of our product candidates in the near term, and we expect to continue to have significant losses for the foreseeable future.

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

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

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

- the terms and timing of any future collaborative, licensing, acquisition or other arrangements that we may establish for our product candidates;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential future partners or collaborators, if any;
- the amount and timing of contingent licensing fees, milestone payments and royalty payments that we are obligated to pay to third parties;
- the scope, rate of progress and cost of our clinical trials and other development activities;
- the costs and timing of obtaining regulatory approvals;
- the cost of manufacturing clinical, and establishing commercial, supplies of our product candidates and any products that we may develop;
- the cost and timing of establishing sales, marketing and distribution capabilities;

- the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights;
- the cost and timing of securing manufacturing capabilities for our clinical product candidates and commercial products, if any; and
- the costs of lawsuits involving us or our product candidates.

We believe that our cash, cash equivalents and marketable securities will be sufficient to fund our projected operating requirements for at least the next 12 months based upon current operating plans and spending assumptions. However, we will need to raise additional capital to advance the clinical development of evofosfamide and tarloxotinib, whether through new collaborative or partnering arrangements or otherwise, and to in-license or otherwise acquire and develop additional product candidates or programs. In particular, our ability to advance the clinical development of evofosfamide is dependent upon our ability to enter into new collaborative or partnering arrangements for evofosfamide, or to otherwise obtain sufficient additional funding for such development, particularly since we are no longer eligible to receive any further milestone payments or other funding from Merck KGaA, including the 70% of worldwide development costs for evofosfamide that were previously borne by Merck KGaA.

While we have been able to fund our operations to date, we currently have no ongoing collaborations for the development and commercialization of our product candidates and no source of revenue, nor do we expect to generate revenue for the foreseeable future. We also do not have any commitments for future external funding. Until we can generate a sufficient amount of product revenue, which we may never do, we expect to finance future cash needs through a variety of sources, including:

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

Our ability to raise additional funds and the terms upon which we are able to raise such funds have been severely harmed by the negative results reported from our two pivotal Phase 3 clinical trials of evofosfamide, and may in the future be adversely impacted by the uncertainty regarding the prospects for future development ofevofosfamide and our ability to advance the development of evofosfamide and tarloxotinib or otherwise realize any return on our investments in evofosfamide and tarloxotinib, if at all. Our ability to raise additional funds and the terms upon which we are able to raise such funds may also be adversely affected by the uncertainties regarding our financial condition, the sufficiency of our capital resources, our ability to maintain the listing of our common stock on The NASDAQ Capital Market and recent and potential future management turnover. As a result of these and other factors, we cannot be certain that sufficient funds will be available to us or on satisfactory terms, if at all.To the extent we raise additional funds by issuing equity securities, our stockholders may experience significant dilution, particularly given our currently depressed stock price, and debt financing, if available, may involve restrictive covenants. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to our product candidates, technologies or potential markets, any of which could result in our stockholders having little or no continuing interest in our evofosfamide or tarloxotinib programs as stockholders or otherwise, or which could delay or require that we curtail or eliminate some or all of our development activities or otherwise have a material adverse effect on our business, financial condition and results of operations.

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

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

We believe that period-to-period comparisons of our operating results should not be relied upon as predictive of future performance. Our prospects must be considered in light of the risks, expenses and difficulties encountered by companies with no approved pharmaceutical products, and with product candidates that are undergoing clinical development.

Our success depends in part on attracting, retaining and motivating key personnel and, if we fail to do so, it may be more difficult for us to execute our business strategy. As a small organization we are dependent on key employees and we 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. We do not have an employment agreement with Dr. Selick. The loss of the services of Dr. Selick or one or more of our other key employees could delay or adversely impact the development of our product candidates.

In December 2015, we announced a workforce reduction constituting approximately two-thirds of our workforce and as of June 30, 2016, we had only 20 employees. Our success will depend on our ability to retain and motivate remaining personnel and hire additional qualified personnel when required, and our history of implementing workforce reductions, along with the potential for future workforce reductions, may negatively affect our ability to retain and/or attract talented employees. In addition, competition for qualified personnel in the biotechnology field is intense. We face competition for personnel from other biotechnology and pharmaceutical companies, universities, public and private research institutions and other organizations. We may not be able to attract and retain qualified personnel on acceptable terms given the competition for such personnel. If we are unsuccessful in our retention, motivation and recruitment efforts, we may be unable to execute our business strategy.

In addition, certain members of our management terms were part of our December 2015 workforce reduction, including our former senior vice presidents of regulatory affairs and pharmaceutical development and manufacturing as well as our former Chief Scientific Officer. Management transition inherently causes some loss of institutional knowledge, which can negatively affect strategy and execution and disrupt our ability to successfully manage and grow our business, and our results of operations and financial condition could suffer as a result.

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and computer viruses that may result in the impairment of production and key business processes.

In addition, our systems are potentially vulnerable to data security breaches — whether by employees or others — that may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers and others. Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post- change taxable income or taxes may be limited. Our prior and potential future equity offerings and other changes in our stock ownership, some of which are outside of our control, may have resulted or could in the future result in an ownership change. If a limitation were to apply, utilization of a portion of our domestic net operating loss and tax credit carryforwards could be limited in future periods and a portion of the carryforwards could expire before being available to reduce future income tax liabilities.

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

Risks Related to Our Dependence on Third Parties

We rely on third parties to manufacture evofosfamide and tarloxotinib and expect to rely on third parties to manufacture any other product candidates that we may develop. If these parties do not manufacture the active pharmaceutical ingredients or finished drug products of satisfactory quality, in a timely manner, in sufficient quantities or at an acceptable cost, clinical development and commercialization of evofosfamide, tarloxotinib and any other product candidates we may develop could be delayed.

We do not have our own manufacturing capability for the evofosfamide active pharmaceutical ingredient, or API, or evofosfamide drug product. To date, we have relied on, and we expect to continue to rely on, a limited number of third party contract manufacturers and excipient suppliers for the evofosfamide API and evofosfamide drug product to meet our clinical supply needs of evofosfamide. We have no long-term commitments or commercial supply agreements with any of our evofosfamide suppliers. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our ability to develop and commercialize any product candidates on a timely and competitive basis.

We need to have sufficient evofosfamide API and drug product manufactured to meet the clinical supply demands for our clinical trials. If we are not successful in having sufficient quantities of evofosfamide API and drug product manufactured, or if manufacturing is interrupted at our contract manufacturers and excipient suppliers for evofosfamide API and our evofosfamide drug product manufacturers due to regulatory or other reasons, or consume more drug product than anticipated because of a higher than expected trial utilization or have quality issues that limit the utilization of the drug product, we may experience a significant delay in our evofosfamide clinical program. In any event, we will need to order additional evofosfamide API and drug product and we have in the past experienced delays in the receipt of satisfactory drug product, and any additional delays we may experience in the receipt of satisfactory evofosfamide API or drug product could cause significant delays in our potential future evofosfamide clinical trials, which would harm our business. Moreover the need for additional supplies and preparation for registration may require manufacturing process improvements in evofosfamide API and drug product. The manufacturing processes improvements for the evofosfamide API may require facilities upgrades at our suppliers, which may lead to delays or disruption in supply, or delays in regulatory approval of evofosfamide. Changes to the formulation of evofosfamide for our potential future clinical trials may also require bridging studies to demonstrate the comparability of the new formulation with the old. These studies may delay our clinical trials and may not be successful. Even if we are successful in raising the additional capital necessary to advance the development of evofosfamide, if we are not successful in procuring sufficient evofosfamide clinical trial material, we may experience a significant delay in our evofosfamide clinical program. Finally, we have not engaged any backup or alternative suppliers for parts of our evofosfamide supply chain for our potential future evofosfamide clinical trials. If we are required to engage a backup or alternative supplier, the transfer of technical expertise and manufacturing process to the backup or alternative supplier would be difficult, costly and time-consuming and would increase the likelihood of a significant delay or interruption in manufacturing or a shortage of supply of evofosfamide.

In any event, additional agreements for more supplies of each of our product candidates, including evofosfamide, will be needed to complete clinical development and/or commercialize them. In this regard, we may need to enter into agreements for additional supplies of evofosfamide to commercialize it or develop such capability itself. We cannot be certain that we can do so on favorable terms, if at all. We will need to satisfy all current good manufacturing practice, or cGMP, regulations, including passing specifications. Our inability to satisfy these requirements could delay our clinical programs and the potential commercialization of evofosfamide if approved for commercial sale.

If evofosfamide or any of our other product candidates is approved by the FDA or other regulatory agencies for commercial sale, we will need to have it manufactured in commercial quantities. It may not be possible to successfully manufacture commercial quantities of evofosfamide or increase the manufacturing capacity for evofosfamide or any of our other product candidates in a timely or economically feasible manner. Prior to commercial launch of evofosfamide, we may be required to manufacture additional validation batches, which the FDA and other regulatory agencies must review and approve. If we are unable to successfully manufacture the additional validation batches or increase the manufacturing capacity for evofosfamide or any other product candidates, the regulatory approval or commercial launch of that product candidate may be delayed, or there may be a shortage of supply which could limit sales.

In addition, if the facility or the equipment in the facility that produces our product candidates is significantly damaged or destroyed, adversely impacted by an action of a regulatory agency or if the facility is located in another country and trade or commerce with or exportation from such country is interrupted or delayed, 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.

In addition, the evofosfamide formulation includes excipients that might be available from a limited number of suppliers. We have not signed long term supply agreements with these excipient suppliers. We will need to enter into long term supply agreements to ensure uninterrupted supply of these excipients to continuously manufacture clinical batches or commercial supplies, which we may be unable to do in a timely or economically feasible manner or at all.

We also expect to rely on contract manufacturers or other third parties to produce sufficient quantities of clinical trial product for any other product candidates that we may develop. In this regard, while we have obtained certain quantities of tarloxotinib API and drug product from our licensor, we may determine that such API and drug product is not usable or is otherwise insufficient in order for us to complete our Phase 2 proof-of-concept clinical trials of tarloxotinib and we may need to obtain sufficient supplies of tarloxotinib API and drug product from contract manufacturers in order for us to complete either or both of our Phase 2 proof-of-concept clinical trials, which could delay the completion of these clinical trials, could increase our costs and could negatively impact our tarloxotinib development program. Depending upon the duration of the clinical studies, we might need to develop a new formulation of tarloxotinib. It is possible that we might not be able to develop a formulation with adequate quality that meets the need for testing in our clinical trials. In any event, in order for us to commence any potential future clinical trials of our product candidates, we need to obtain or have manufactured sufficient quantities of clinical trial product and there can be no assurance that we will be able to obtain sufficient quantities of clinical trial product in a timely manner or at all. Any delay in receiving sufficient supplies of clinical trial product for our potential future studies could negatively impact our development programs.

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 single source contract manufacturers must undergo an inspection by the FDA, the PMDA and other foreign agencies for compliance with cGMP regulations, before the respective product candidates can be approved in their region. 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 agencies, the PMDA and other foreign agencies for compliance with cGMP regulations, similar foreign regulations and other regulatory standards. We do not have control over our contract manufacturers' compliance with these regulations and standards. Any failure by our third-party manufacturers or suppliers to comply with applicable regulations could result in sanctions being imposed on them (including fines, injunctions and civil penalties), failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, warning letters, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecution.

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

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

We are dependent on Eleison Pharmaceuticals, Inc. to develop and commercialize glufosfamide

We are dependent upon Eleison Pharmaceuticals, Inc., or Eleison to whom we exclusively licensed glufosfamide in October 2009, to develop and commercialize glufosfamide. Any profit sharing or other payments to us under the Eleison license depend almost entirely upon the efforts of Eleison, which may not be able to raise sufficient funds to continue clinical development activities with glufosfamide. Even if Eleison is successful at raising sufficient funding, it may not be successful in developing and commercializing glufosfamide. We may also be asked to provide technical assistance related to the development of glufosfamide, which may divert our resources from other activities. If the Eleison license terminates in such a way that glufosfamide reverts to us and we seek alternative arrangements with one or more other parties to develop and commercialize glufosfamide, we may not be able to enter into such an agreement with another suitable third party or third parties on acceptable terms or at all. In such event, since we have no further development plans for glufosfamide, we may not receive any further return on our investment in glufosfamide.

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

Moreover, an issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing the same or related product candidates or could limit the length of the term of patent protection of our product candidates. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. Patent term extensions may not be available for these patents. If we are not able to obtain adequate protection for, or defend, the intellectual property position of evofosfamide or any other potential future product candidates, then we may not be able to retain or attract collaborators to partner our development programs, including evofosfamide. Further, even if we can obtain protection for and defend the intellectual property position of evofosfamide or any potential future product candidates, we or any of our potential future collaborators still may not be able to exclude competitors from developing or marketing competing drugs. Should this occur, we, and potential future collaborators may not generate any revenues or profits from evofosfamide, tarloxotinib or any potential future product candidates or our revenue or profit potential would be significantly diminished.

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

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

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

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

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

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

Risks Related To Our Industry

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

Competition in the biotechnology and pharmaceutical industries is intense and continues to increase, particularly in the area of cancer treatment. Most major pharmaceutical companies and many biotechnology companies are aggressively pursuing oncology development programs, including traditional therapies and therapies with novel mechanisms of action. Our cancer product candidates face competition from established biotechnology and pharmaceutical companies and from generic pharmaceutical manufacturers. In particular, if approved for commercial sale for pancreatic cancer, evofosfamide would compete with Gemzar®, marketed by Eli Lilly and Company; Tarceva®, marketed by Roche/Genentech and Astellas Oncology; Abraxane® marketed by Celgene; and FOLFIRINOX, which is a combination of generic products that are sold individually by many manufacturers. If approved for commercial sale for treatment-resistant non-small cell lung cancer, tarloxotinib could potentially compete with other EGFR-TKIs that are approved or currently in late-stage clinical development including AstraZeneca's Tagrosso®, Clovis Oncology's CO-1686, and Pfizer's dacomitinib. If approved for commercial sale for recurrent/metastatic head and neck cancer, tarloxotinib could potentially compete with Bristol Myers Squibb's Erbitux®, an approved agent, or other agents currently in late-stage clinical development including an EGFR TKI, Boehringer Ingelheim's afatinib and Bristol Myers Squibb's nivolumab and Merck's pembrolizumab, both PD-1 inhibitors. There may also be product candidates of which we are not aware at an earlier stage of development that may compete with evofosfamide, tarloxotinib or other product candidates we may develop. In short, each cancer indication for which we are or may be developing product candidates has a number of established medical therapies with which our candidates will compete. Our evofosfamide product candidate for targeting the tumor hypoxia is likely to be in highly competitive markets and may eventually compete with other therapies offered by companies who are developing or were developing drugs that target tumor hypoxia.

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.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. As a biotechnology company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. The laws that may affect our ability to operate include:

- Federal healthcare Anti-Kickback Statute will constrain our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- Federal civil and criminal false claims laws and civil monetary penalty laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- The Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- The federal physician sunshine requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and state and foreign laws that govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

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

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

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

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

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

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

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

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

If third-party payors do not cover or 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 approved products successfully will depend in part on the extent to which coverage and 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. Coverage and reimbursement by a governmental and other third-party payor may depend upon a number of factors, including a governmental or other third-party payor's determination that use of a product is:

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

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

In March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, which, among other things, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs and included the following changes to the coverage and payment for drug products under government health care programs:

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extended Medicaid drug rebates, previously due only on fee-for-service utilization, to Medicaid managed care utilization, and created an alternate rebate formula for new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs;
- expanded the types of entities eligible for the 340B drug discount program that mandates discounts to certain hospitals, community centers and other qualifying providers; and
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale- discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

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 or otherwise result in pricing pressures with respect to our future products. In this regard, we expect further federal and state proposals and healthcare reforms to continue to be proposed to limit the price of, or to curb pricing increases for, prescription drugs, including as a result of negative publicity regarding drug pricing strategies by pharmaceutical companies and pricing increases on pharmaceutical products generally, which could limit the prices that can be charged for our future products, which in turn may limit our commercial opportunity and/or negatively impact revenues from sales of our future products. In addition, the Centers for Medicare & Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions.

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

In some foreign countries, particularly in the European Union and Japan, 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 potential future 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 agencies, may adopt regulations that may affect our research and development programs. We are unable to predict whether any agency will adopt any regulations that could have a material adverse effect on our operations. We have incurred, and will continue to incur, capital and operating expenditures and other costs in the ordinary course of our business in complying with these laws and regulations. Although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could significantly exceed our insurance coverage.

Risks Related To Our Common Stock

If we fail to meet continued listing standards of The NASDAQ Stock Market LLC, our common stock may be delisted. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease, and our ability to obtain sufficient additional capital to fund our operations and to continue as a going concern would be substantially impaired.

Our common stock is currently listed on The NASDAQ Capital Market. The NASDAQ Stock Market LLC, or NASDAQ, has minimum requirements that a company must meet in order to remain listed on The NASDAQ Capital Market. These requirements include maintaining a minimum closing bid price of $1.00 per share. On January 21, 2016, we received a letter from the staff, or Staff, of the NASDAQ Stock Market, or NASDAQ, providing notification that, for the previous 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share requirement for continued listing on The NASDAQ Capital Market, or the Bid Price Requirement. The notification had no immediate effect on the listing of our common stock. In accordance with NASDAQ listing rules, we were afforded 180 calendar days, or until July 19, 2016, to regain compliance with the Bid Price Requirement. On July 20, 2016, we received a letter from the Staff notifying us that we were eligible for an additional 180 calendar day period, or until January 17, 2017, to regain compliance with the minimum $1.00 Bid Price Requirement. In the letter, the Staff noted that our common stock had not regained compliance with the Bid Price Requirement during the initial 180-day compliance period that ended on July 19, 2016 and that we had submitted written notice of our intention to cure the Bid Price Requirement deficiency by effecting a reverse stock split during the second 180-day compliance period, if necessary. If we cannot demonstrate compliance with the Bid Price Requirement by January 17, 2017, the Staff will notify us that our common stock will be delisted. In the event of such a notification, we may appeal the Staff's determination to delist our common stock, but there can be no assurance the Staff would grant our request for continued listing. In addition, we may be unable to meet other applicable NASDAQ listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock in which case, our common stock could be delisted notwithstanding our ability to demonstrate compliance with the Bid Price Requirement, whether through the implementation of a reverse stock split or otherwise. In this regard, on February 10, 2016, we received a letter from the Staff of NASDAQ providing notification that, for the previous 30 consecutive business days, the minimum market value of listed securities, or MLVS, for our common stock was below the $35 million minimum MVLS requirement for continued listing on The NASDAQ Capital Market, or the MVLS Requirement. Although as a result of our reporting stockholders' equity of $40.8 million for the year ended December 31, 2015, the Staff notified us that the deficiency related to our failure to meet MVLS Requirement is now closed, there can be no assurance that we will continue to meet other applicable NASDAQ listing requirements.

If our common stock is delisted as a result of our failure to comply with the Bid Price Requirement, MVLS requirement or other NASDAQ requirement, we would expect our common stock to be traded in the over-the-counter market, which could adversely affect the liquidity of our common stock. Additionally, delisting would substantially impair our ability to raise additional funds to fund our operations, to advance the development of evofosfamide and tarloxotinib and/or to acquire or in-license additional product candidates or development programs, and we could face other significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- a reduced amount of news and analyst coverage for us;
- reduced liquidity for our stockholders;
- potential loss of confidence by employees and potential future partners or collaborators; and
- loss of institutional investor interest and fewer business development opportunities.

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

The stock markets in general, the markets for biotechnology stocks and, in particular, the stock price of our common stock, have experienced extreme volatility. Further price declines in our common stock could result from general market and economic conditions and a variety of other factors, including:

- announcements regarding the development of our product candidates, including any delays in any potential future clinical trials, and investor perceptions of our ability to advance the development of evofosfamide and tarloxotinib;
- adverse results or delays in current and potential future clinical trials of evofosfamideand tarloxotinib;
- our ability to raise additional capital to advance the development ofevofosfamide and tarloxotinib and the terms of any related financing arrangements;
- announcements of regulatory approval or non-approval of our product candidates, or delays in the applicable 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;
- our ability to enter into new collaborative, licensing or other strategic arrangements with respect to our product candidates;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- announcements of technological innovations, patents or new products by us or our competitors;
- regulatory developments in the United States, Japan and other foreign countries;
- any lawsuit involving us or our product candidates;
- our ability to comply with the minimum listing requirements of The NASDAQ Stock Market LLC;
- announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;
- developments concerning any strategic alliances or acquisitions we may enter into;
- actual or anticipated variations in our operating results;
- changes in recommendations by securities analysts or lack of analyst coverage;
- deviations in our operating results from the estimates of analysts;
- sales of our common stock by us, including under our sales agreement with Cowen and Company, LLC, or Cowen;
- sales of our common stock by our executive officers, directors and significant stockholders or sales of substantial amounts of common stock; and
- additional losses of any of our key scientific or management personnel.

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

If there are large sales of our common stock, the market price of our common stock could drop substantially. In addition, a significant number of shares of our common stock are subject to issuance upon exercise of outstanding options and warrants, which upon such exercise would result in dilution to our security holders.

If we or our existing stockholders sell a large number of shares of our common stock or the public market perceives that we or our existing stockholders might sell shares of our common stock, the market price of our common stock could decline significantly. As of June 30, 2016, we had 71,511,425 outstanding shares of common stock, substantially all of which may be sold in the public market without restriction, subject to any affiliate restrictions. On November 2, 2015, we entered into a sales agreement with Cowen, under which we may sell shares of our common stock from time to time through Cowen, as our agent for the offer and sale of the shares, in an aggregate amount not to exceed $50 million. Though our ability to sell shares of common stock through Cowen under our sales agreement with Cowen is practically limited or precluded altogether due to our currently-depressed stock price, to the extent that we sell shares of our common stock pursuant to the sales agreement with Cowen in the future, our stockholders will experience dilution. In addition, a significant number of shares of our common stock are subject to issuance upon the exercise of outstanding options and warrants. On February 18, 2015, we issued warrants to purchase an aggregate of 8,300,000 shares of our common stock, at an initial exercise price per share of $10.86, which exercise price was adjusted to $3.62 on January 21, 2016. In addition, as of June 30, 2016, there were 11,635,197 shares of our common stock issuable upon the exercise of outstanding options having a weighted-average exercise price of $3.61 per share. Although we cannot determine at this time how many of the currently outstanding options and warrants will ultimately be exercised, the options and warrants will likely be exercised only if the exercise price is below the market price of our common stock. To the extent that the options and warrants are exercised, additional shares of our common stock will be issued that will be eligible for resale in the public market, which will result in dilution to our security holders.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our stock price.

Section 404 of the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission, or SEC, require annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accounting firm attesting to, and reporting on, the effectiveness of our internal control over financial reporting. If we fail to maintain the adequacy of our internal control over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC. If we cannot favorably assess, or our independent registered public accounting firm is unable to provide an unqualified attestation report on, the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

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

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

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

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

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

Exhibit Number	Description
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934 as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934 as amended.
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

* Furnished herewith. This certification is not deemed filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and is not deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.

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 1, 2016

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

Date: August 1, 2016

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

EXHIBIT INDEX

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* Furnished herewith. This certification is not deemed filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and is not deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.

Exhibit 31.1

CERTIFICATION

I, Harold E. Selick, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 1, 2016

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

Exhibit 31.2

CERTIFICATION

I, Joel A. Fernandes, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 1, 2016

/s/ Joel A. Fernandes
Joel A. Fernandes
Vice President, Finance and Controller
(Principal 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, 2016, 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 1, 2016

/s/ Harold E. Selick, Ph.D.
Harold E. Selick, Ph.D.
Chief Executive Officer
(Principal 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, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joel A. Fernandes, Vice President, Finance and Controller of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 1, 2016

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